

# Registers for networked medical research in Germany

## Situation and prospects

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### Keywords

Competence Networks, documentation, register protocol, registers

### Summary

**Background:** Several disease specific registers are operated by members of the 'TMF – Technology, Methods, and Infrastructure for Networked Medical Research', an umbrella organization of research networks in Germany.

**Objective:** To describe the coverage and the current state as well as financial and organizational issues of registers operated by member networks of the TMF, to identify their requirements and needs, and to recommend best practice models.

**Methods:** A survey with a self-completion questionnaire including all 55 TMF member networks was carried out in winter 2007/2008. Interviews focusing on technological issues were conducted and analyzed in summer 2009 with a convenience sample of 10 registers.

**Results:** From 55 TMF member networks, 11 provided information about 14 registers. Six registers address diseases of the circulatory system with more than 150,000 registered patients. The interviews revealed a typical setting of "research registers". Research registers are an important mean to generate hypotheses for clinical research, to identify eligible patients, and to share data with clinical trials. Concerning technical solutions, we found a remarkable heterogeneity. The analysis of the most efficient registers revealed a structure with five levels as best practice model of register management: executive, operations, IT-management, software, hardware.

**Conclusion:** In the last ten years, the TMF member networks established disease specific registers in Germany mainly to support clinical research. The heterogeneity of organizational and technical solutions as well as deficits in register planning motivated the development of respective recommendations. The TMF will continue to assist the registers in quality improvement.

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## 1. Background

According to Dreyer and Garner, “registries are being used to fill important gaps in evidence” and “support timely decisions by regulatory agencies” [1]. Brooke defined a register<sup>a</sup> as “a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose” [2]. A recent Austrian health technology assessment differentiates between epidemiological registers, quality registers, and “risk, disease or intervention oriented registries” [3]. Gladman and Menter list several types of clinical registers [4]: administrative ones, for clinical trials, for longitudinal observational studies, and for genetic studies. We look at registers as a documentation type with four characteristics [5–7]:

- a) answering questions concerning groups of patients (or other observational units),
- b) having a clear target population,
- c) aiming at a complete coverage of the target population or at least a recording of a representative sample,
- d) starting with broad or unspecific research questions.

Whereas several recommendations about register development and operation had been published in the last years [3, 8], reviews about existing registers other than cancer registers are rare. As one exception, Newton and Garner performed an analysis of disease registers in England in 2000 [9]. They recommended the formulation of a national strategy for England, the establishment of respective public observatories, the implementation of at least one national academic center, a differentiated funding approach and a national solution concerning data protection issues.

### 1.1 TMF and registers

Starting in 1999, Competence Networks in Medicine and Clinical Trial Centers were funded by the German Federal Ministry of Education and Research. Located at university hospitals, Clinical Trial Centers are centralized providers of services for researchers. They supply personnel and logistical resources on site for planning, conducting and evaluating clinical trials in compliance with internationally accepted quality standards. Trials are also run under contract for third parties, such as industrial clients. Competence Networks in Medicine are disease oriented research networks which focus on a two pronged approach: They are directed at innovation oriented research and at the transfer and implementation of research results into practical and economically viable solutions.

The networks received an annual budget of about 2.5 million Euro for a broad range of tasks as provision of common services like reference diagnoses of relevant pathogens, multicenter clinical studies, continuing medical education, consultation services for doctors, patients and relatives. As part of their general mission of interdisciplinary cooperation of patient care and clinical and basic research, the Competence Networks built up disease specific registers in Germany. The TMF – Technology, Methods, and Infrastructure for Networked Medical Research supports the Competence Networks and Clinical Trial Centers as well as other structures of joint research in Germany on behalf of the Federal Ministry of Education and Research.

The principal aim of the TMF is to improve the organization and infrastructure for networked medical, i.e. clinical, epidemiological, and translational research. Under the roof of the TMF, expert opinions, studies, concepts, requirement specifications, services, and tools are discussed and created. To support the registers of research networks, the TMF provides for example data protection concepts and their reconciliation with national authorities [10], developed and evaluated IT components like electronic data capture (EDC) solutions, and delivered solutions for quality assurance and quality management [11] (most results available for the public via the TMF, see <http://www.tmf-ev.de/>). In the following, we will present the first analysis about registers in Germany, focusing on registers that are operated by TMF member networks.

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<sup>a</sup> The terms “register“ and „registry“ are more or less conterminously used in the literature. With the exception of citations we use „register“ throughout this paper.

## 2. Objectives

The German Federal Ministry of Education and Research as the main funding organization requested an evaluation concerning the success of research networks in establishing national registers. Therefore, the TMF carried out a survey including all member institutions. This survey should answer questions regarding the expansion (i.e. regional, national, or European) and medical coverage of the registers as well as financial and organizational issues. A second survey was carried out 18 months later focusing on IT service management. The aim was to describe the current state of registers, to identify requirements and needs, and to recommend best practice models.

## 3. Methods

For the first survey, a self-completion questionnaire was developed based on a list of questions provided by the Federal Ministry. A first draft was tested with three competence networks. The final version includes 84 closed and open questions grouped into 11 sections. All TMF member networks were invited to this survey in November 2007. A response was requested solely from member networks that operate at least one register. For each operated register, the questionnaire should be filled out by the member networks themselves in paper or electronic form. "Register" was not further defined. The questionnaire was sent by email as file in Microsoft Word format to the executives of the member networks by the TMF office. A reminder was sent out in December 2007 by email as well. Recruitment stopped in January 2008. Unclear answers were discussed with the contact persons quoted by the member networks.

The second survey was planned as a semi-structured interview of register offices. A field manual with 111 questions was developed based on the results from the first survey. The first module covering organizational issues corresponds to the previous self-completion questionnaire. The second module covers technical issues, the third service management tasks of the register office and the fourth achieved objectives. A convenient sample of ten very active register offices was asked for participation in a computer-assisted personal (CAPI) or telephone interview (CATI): Competence Network Hepatitis, Competence Network Depression, Competence Network HIV/AIDS, Competence Network Community-Acquired Pneumonia, Brain-Net, Competence Network Atrial Fibrillation, Competence Network Dementia, Competence Network Congenital Heart Failure, Competence Network Rheumatology, and Competence Network Parkinson's Disease. During May 2009, the first author conducted four CAPI and five CATI, one response was in written form.

The results of the second survey were compiled by a sub-group of specialists from three member networks (Hepatitis, Congenital Heart Failure, Parkinson's Disease), together with a representative from the field of clinical cancer registries. This group outlined recommendations for the TMF's IT strategy for register research.

## 4. Results

### 4.1. Survey 1 – self-completion questionnaire

Fifty-five TMF member networks were asked for participation including 17 Competence Networks and 10 Clinical Trial Centers. Eleven networks provided information about 14 registers. Participants were eight competence networks (47% of 17 Competence Networks) and three others (8% of other networks). Eight registers are active throughout Germany; six are restricted to specific regions as federal states or smaller areas. The medical coverage in terms of diseases is shown in ► Table 1. The registers cover nine out of 22 chapters of the German modification of the ICD-10 (39%) and 53 out of 1707 categories (3%). Clear focus is on diseases of the circulatory systems with 6 registers and more than 150,000 registered patients. Cancer is missing as the clinical or epidemiological cancer registries in Germany are not members of the TMF yet. ► Table 2 presents further details about the registers.

Services provided by registers might be support of publications, recruitment for clinical trials, analyses accomplished for network members or for the public, redelivery of data to the recruitment centers or forwarding of data to third parties. ▶ Figure 1 shows the services offered by the 14 registers. One register offers all; six registers offer 4 to 6 different services. The analysis of the reporting strategies revealed some specific trends.

- Reimbursement of data recording – for example by a fee for an annual recording of a specific data set for a patient – is rare. Only 4 registers offer a financial compensation.
- Most of the registers receive data spontaneously; only 4 registers use predefined visits.
- Data are pseudonymized and stored centrally. Two registers mention the storage of anonymized data.
- Medical and personal data are separated. Three registers use a trustee for the storage of personal data.

Paper forms as well as EDC-systems are used as reporting channel. Some registers offer both to their recruitment sites. Only three registers import data previously collected for other purposes, e.g. from a hospital information system. Four out of seven registers that receive paper forms perform a double entry. Most of the registers inform their recruitment sites regularly about the data quality. Six registers out of 11 with respective possibilities use source data verification as part of their monitoring strategy. Hospitals and health care professionals are responsible for the provision of data in most of the registers. However, in three registers, patients and relatives participate in data recording.

## 4.2. Survey 2 – interviews

All 10 register offices asked for participation agreed and received the field manual per email before the interview. Seven of the 10 offices belong to member networks that participated in the first survey, three did not. The interviews revealed a specific type of register present in the competence networks. We call that type “research register”. Common characteristic of the ten registers is strong support of clinical research, identified by the achieved goals (cf. ▶ Fig. 2): generation of new research hypotheses (10 registers), recruitment of patients for clinical trials (8), and linkage with clinical trials (6). Consequently, the registers use the same tools and concepts as clinical trials: trial management systems for EDC, case report forms for data structuring and data recording. Only one register uses an electronic patient record system for data entry. All but one offer at least links to bio-banks. Representativity is neither assessed nor aspired.

Concerning technical solutions, we found a remarkable heterogeneity. Three different commercial EDC-systems are used in five registers: one uses MACRO (InferMed), one uses MARVIN (XClinical), and three use secuTrial (interActive Systems). One half uses web-clients for data recording, the other half uses fat-clients. Six registers declared the use of the secure sockets layer (SSL) protocol for a secured communication between clients and servers. The data are mostly stored unencrypted. The design of forms is less supported. Most of the registers use text processing software for design and revision of input forms. The accepted version is then reprogrammed with the EDC-system. Three registers receive support by third parties defined in respective service-level agreements.

## 4.3. Hands-on recommendations for the organization of register management

As mentioned before, the expert group from the second survey compiled hands-on recommendations for the organization of register management. The analysis of the most efficient registers revealed a structure with five levels as best practice model of register management: executive, operations, IT-management, software, hardware. The levels should have clear interfaces to guarantee autonomy, flexibility, scalability, and security. Then, either the tasks could be distributed to different players, one for each level, or the register could be operated one-stop. Players could be companies as well as non-profit organizations on all levels.

The executive board should identify with the register's objectives and the medical field. This helps to represent the register outwards and to set goals inwards. Operations include development and maintenance of user interfaces, user administration, monitoring, data management, training, dunning, archiving, and reporting. Further analysis of the data should be released to statistical institutes, unless that institute is also responsible for register management. A Chief Information Office (CIO) should be responsible for IT-service management, having profound skills in management and operation of computer-based applications in health care. In Germany for example, a certificate of the two scientific associations, the German Association for Medical Informatics, Biometry and Epidemiology and the Association for Informatics, prove this qualification by a certificate in medical informatics. Whether the CIO focuses on contracting or service delivery depends on the organization of the two bottom levels, software and hardware.

Concerning business software, the choice of a special EDC-system is a strategic investment decision. If the register's data management is similar to clinical trials, a commercial trial management system will be preferred. If the data management is oriented to clinical activities, an electronic health record system could be appropriate. At least, two physical servers (production, backup) are needed to implement the register, supplemented by firewall components. In accordance with the generic data protection concepts of the TMF, data access should be divided by separate storage of medical and other organizational data or using trusted third parties for sensitive data. Other reasons for further servers, may be virtual ones, could be the software architecture, or the need for additional test and/or development environments.

## 5. Discussion

In two surveys we analyzed 14 and 10 registers operated in Germany by TMF member networks. Finding an accepted definition for the term "register" for the surveys was a major problem. Especially in the first survey open for all TMF member networks, questions regarding differences between registers, cohort studies, and national cohorts arose. From our point of view, register is a loosely defined type of medical documentation; it is no study type. Consequently, cohort studies for example might use registers for documentation. Then, register research is an umbrella covering different types of studies as cohort studies, observational studies, and studies in health services research. The differentiation to electronic health records comes from the intended usage. The primary usage of electronic health records is to support individual health care, whereas the primary aim of registers is to support the analysis of groups of individuals. Recently, Drolet and Johnson presented a formal approach for a certification of databases as registry called MDR-OK [12]: to have Mergeable data, a standardized Dataset, Rules for data collection, defined inclusion principles, Observations associated over time, and Knowledge of outcomes. The research registers operated by the TMF members fulfill the first four criteria, but not necessarily the remaining two.

The surveys showed a multifaceted scene of registers operated by member institutions of the TMF. On the one hand, the registers mainly support clinical research in various ways, e.g. by identification of eligible patients (cf. ►Fig. 2). Furthermore, the close connection to bio-banks demonstrates the ability of the registers to support translational research [13]. Links to health services research are less visible. Single source concepts [14, 15] were not present at the time of the surveys. Thus, the TMF member networks mainly achieved a linkage of different research groups with the registers ("horizontal linkage"). The linkage from experimental research to health care (from bench to bedside, "vertical linkage") was only partially fulfilled. This corresponds with a limited use of so-called "disease-only registers" claimed by Raftery et al. in a health technology assessment about routine databases [16]. Further criticism against the evidence of register research was formulated by Roovers concerning confounding, data quality, and business interests [17]. Due to the public funding, there are no business interests present in the registers operated by the TMF members. Data quality is an ongoing issue in any type of medical documentation. Concerning registers, elaborated concepts of quality control have been published [11, 18]. Case reports confirm the success of strong quality control procedures [19]. Confounding remains as an issue to be solved.

On the other hand, the organizational and technical implementation of the registers differs considerably. The available literature about registers lacks in respective recommendations [20]. There-

fore, the group of experts involved in the second survey compiled recommendations on their own, being aware of the fact that external performance measures for registers are not applied within this work. At the moment, a project is in preparation to foster the usage of IT service management concepts by the TMF members based on the ISO/IEC 20000 IT Service Management System [21] or on the Information Technology Infrastructure Library (cf. <http://www.itil.org/>). But it will be a long way until these standards are incorporated in the networks that are mainly operated by academic researchers.

The expert group recognized major deficiencies in the planning and design of registers. Only one competence network in the second survey developed standard operating procedures for operating the register, none uses specific software for creating or maintaining its register. In accordance to others [3, 6, 8], the use of a register protocol describing what should be considered or done in which order during the creation of a register is strongly recommended.

Some research questions remain. Some registers follow the view of clinical trials on patients, i.e. having clearly defined visits, others follow the view of electronic health records, i.e. having an activity oriented documentation. It will be interesting to establish models for data recording and data storage that support both views without losing the individual advantages, e.g. simple interpretation on the one hand and timely information on the other hand. Sustainability is an unsolved issue in register research. TMF members are funded for a specific period, but most of them strive for an ongoing recording or at least lifelong follow-up of their patients. It will be worthwhile to think about a central institution responsible for storing register data after termination of the initial project. Due to the strong regulation in the area of data privacy, the expert group did not address specific recommendations.

Within the TMF the first consequences arose from the presented surveys. A project dealing with IT service management in medical research was launched. A yearly update about the IT structure of the TMF member networks is planned. Sustainability of register research is regarded as a topic of high priority and first project outlines are discussed, especially regarding the long-term storage of data after termination of the respective projects.

## 5.1 Study limitations

The total number of the registers operated by TMF member networks is unknown. At least half of the registers from the competence networks were included in the first survey. One might suggest that the responders are the most active networks. However, in the second survey we were able to include three non-responders from the first survey (Brain-Net, Community Acquired Pneumonia, Hepatitis) that present themselves as very successful. Therefore, we interpret the responders of the first survey as a representative sample. In opposite, the results of the second survey are intentionally based on a convenient sample of active member networks in order to develop respective recommendations.

Three experts from survey 2 are involved in three of the analyzed registers. These relationships might introduce bias, e.g. through a trend to positive ratings. However, we regard the overlap as an advantage due to the detailed knowledge of the experts about the topic as well as about the specific registers.

## 6. Conclusions

During the last period of networked medical research in Germany, research registers were generated as a specific type of medical documentation. Ten years after the establishment of the national funding scheme, the analysis shows that the projects reached several of the proposed objectives. Mainly the support of clinical trials could be achieved, even though neither representativity nor sustainability could be fully accomplished. From our point of view, there is a lesson to be learned from this experience. Some of the interviewed registers suffer from the lack of register planning. We highly recommend new networks using a systematic and structured approach of register planning and register operation. In Germany, the compilation of a recommendation concerning register planning is currently an agenda task of health services research. With the presented results from networked



medical research, the TMF wants to support this direction. A periodical update of the surveys will enable a continuous assessment of the improvements achieved in register research.

**Conflict of Interest**

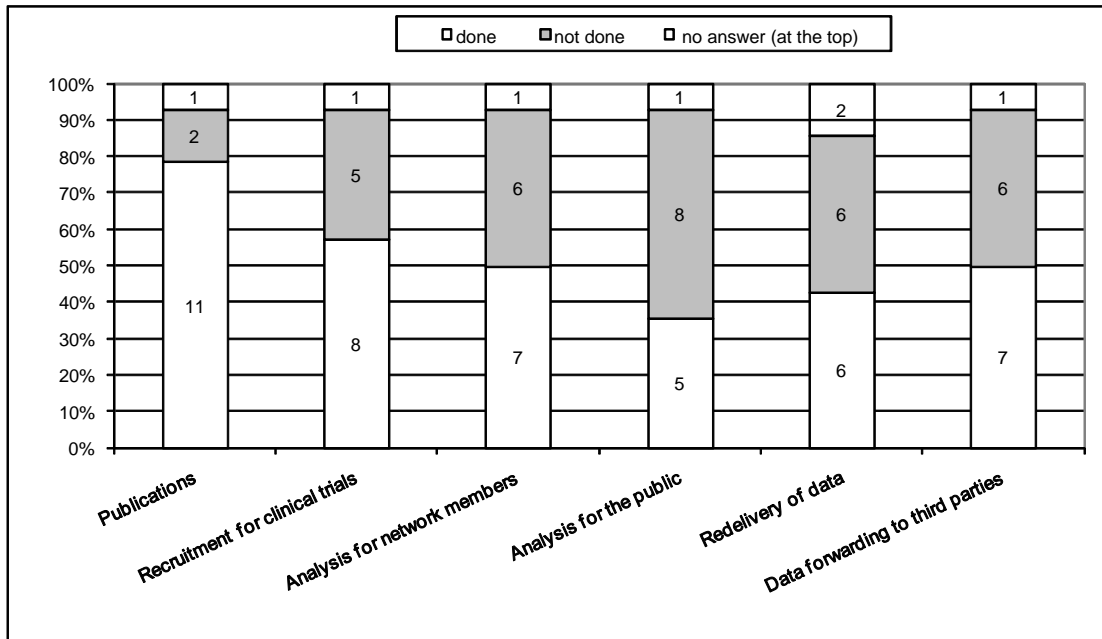
The authors do not declare any conflicts of interest.

**Human Subject Research**

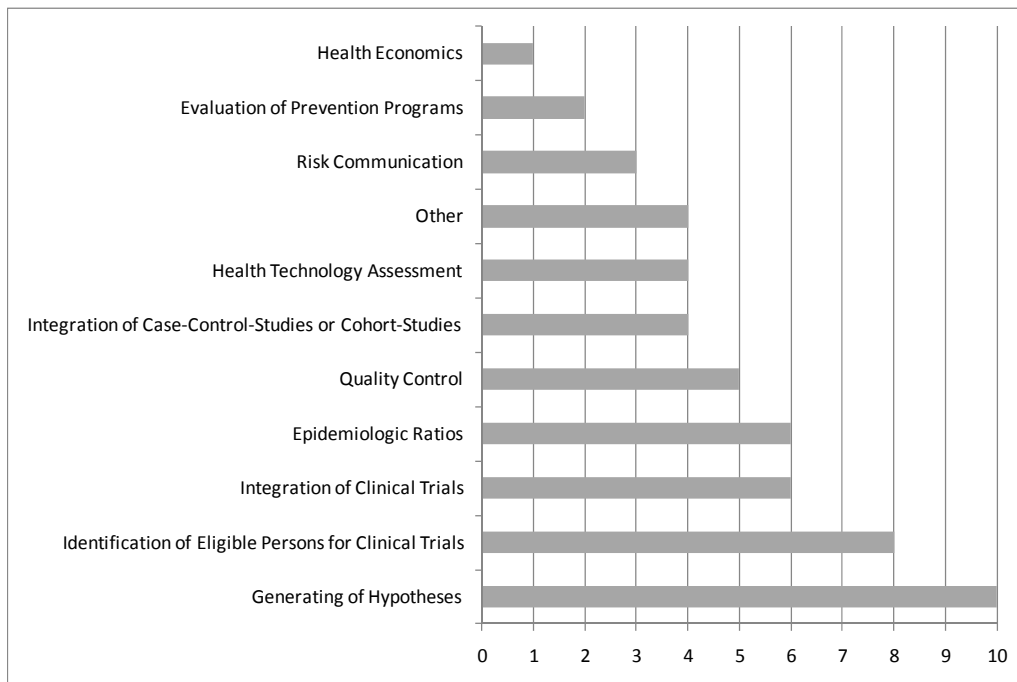
No human subjects were used during this study.

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**Fig. 1** Services offered by 14 registers of TMF member networks from the first survey (multiple answers possible). Publication of peer-reviewed papers based on register data is denoted as "publications". Analysis for network members and analysis for the public comprise additional analyses of register data on request, not covered by the analysis plan of the register.



**Fig. 2** Goals achieved by 10 TMF research registers (multiple answers possible).



**Table 1** Classes of the German modification of the ICD-10 covered by the registers. Multiple parts per register possible.

Chapter		Part covered by the registers	
I	Certain infectious and parasitic diseases	B20-B24	Human immunodeficiency virus [HIV] disease
V	Mental and behavioural disorders	F00.-*	Dementia in Alzheimer's disease
		F01.-	Vascular dementia
		F02.-*	Dementia in other diseases classified elsewhere
		F03	Unspecified dementia
		F32.-	Depressive episode
VI	Diseases of the nervous system	G20.-	Parkinson's disease
		G23.1	Progressive supranuclear ophthalmoplegia [Steele-Richardson-Olszewski]
		G45.-	Transient cerebral ischaemic attacks and related syndromes
		G90.3	Multi-system degeneration
IX	Diseases of the circulatory system	I21.-	Acute myocardial infarction
		I48.1-	Atrial fibrillation
		I61.-	Intracerebral haemorrhage
		I63.-	Cerebral infarction
		I64	Stroke, not specified as haemorrhage or infarction
XIII	Diseases of the musculoskeletal system and connective tissue	M05.-	Seropositive rheumatoid arthritis
		M06.-	Other rheumatoid arthritis
		M34.9	Systemic sclerosis, unspecified
XVII	Congenital malformations, deformations and chromosomal abnormalities	Q20-Q28	Congenital malformations of the circulatory system
XVIII	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	R45.8	Other symptoms and signs involving emotional state [Suicidal ideation (tendencies)]
XXI	Factors influencing health status and contact with health services	Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
XXII	Codes for special purposes	U51.-	Cognitive impairment

**Table 2** Characteristics of the 14 registers of the first survey.

Register			Sample size		Recruitment sites		Follow-up	Basic data set
ID	Start	Population	Planned	Current	N	Type	Period	Item N
1	2003	unknown	complete	26,233		Pat, Aff	life-long	49
2	2003	n. a.	2,000	2,000	13	UC	3 years	800
3	2005	1,320		1,320	8	UC, H	not done	3
4	2004	59,000	8,000	15,500	26	UC, H, Phys	life-long	121
5	2001	200,000 – 250,000	unlimited	5,500	44	UC, H, Phys	life-long	140
6	2001	n. a.	10,000	5,642	200	UC, H, Phys	10 years	>>100
7	2000	700/year	complete	2,300	2	UC	up to 4 years	18
8	2006	600/year	complete	1,139	1	UC, H, Phys, Pat, Aff, Nurs	1 year	14
9	1999	unknown	complete	100,000	110	UC, H	not done	37
10	2004	850,000	10,000	12,500	302	UC, H, Phys, Pat	up to 5 years	207
11	1997	212,157	7,008	4,310	1	n. a.	life-long	>>>1,000
12	2000	5,500	unlimited	3,500	37	UC, H	life-long	5
13	2005	n. a.	n. a.	1,016	16	UC, H	1 year	232
14	2004	n. a.	unlimited	2,090	36	UC	life-long	8

Aff – affiliates, H – hospitals, n. a. – no answer, Nurs – community nurses, Pat – patients, Phys – physician offices, UC – university clinics, N – Number

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