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The German Research Network on Schizophrenia—impact on the management of schizophrenia

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The German Research Network On Schizophrenia (GRNS) is a nationwide network currently comprising 16 psychiatric university departments and 14 state and district hospitals, as well as six local networks of psychiatric practices and general practitioners collaborating on about 25 interrelated, multicenter projects on schizophrenia research. The GRNS aims to intensify collaboration and knowledge exchange between leading research institutions and qualified routine care facilities, both within (horizontal network) and between (vertical network) the two levels of research and care, in order to create the scientific preconditions for optimization of the management of schizophrenia. The concept and the first results of studies aiming at the investigation of (i) strategies for early detection and early intervention in the prodromal stage of psychosis; (ii) treatment in first-episode schizophrenia; (iii) quality management; and (iv) destigmatization, are described as examples of this effort.

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Aims and organization of the network

The German Research Network On Schizophrenia (GRNS) is one of 17 existing medical research networks funded by the German Federal Ministry of Education and Research (BMBF) since 1999 in order to improve care of patients with illnesses characterized by high morbidity and/or mortality. Each of these networks is funded for a maximum of 8 years, with up to 2.5 million Euro per year during the first 5 years and up to 0.5 million Euro per year for the last 3 years. Additional sponsoring (about 5% of the budget) by the industry is provided for research projects or public relations activities of the network. One of the main reasons that the BMBF established such networks originates

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from the fact that new knowledge from research is only insufficiently transferred to practice, and problems in everyday care worth being scientifically investigated are only insufficiently recognized by researchers.

Thus, the structural aim of the GRNS—in a way to be taken as a precondition—consists of the establishment of long-term communication structures between research, services, consumers, and the public. A means for attaining these aims is the creation or expansion, intensified utilization, and routine application of collaboration and knowledge exchange within (horizontal networking) and between (vertical networking) the two levels of research and care. With regard to the funding by the Federal Ministry of Research, the framework for attaining these objectives is that of research projects, which constitute the means for intensified collaboration between institutions and optimized care for patients with schizophrenia. The network comprises about 25 interrelated research studies and projects on health care education with high practice relevance. A current total of 16 psychiatric university departments and 14 state and district hospitals, as well as six local networks of psychiatric practices and general practitioners throughout Germany, participate in these studies.

As regards content, the major objective of the GRNS is to create the scientific preconditions for the implementation of strategies for early detection and early intervention in the prodromal stage of the first episode (“Project Network I”), for the optimization of acute and long-term treatment in first-episode patients and for the rehabilitation in patients with residual symptoms (“Project Network II”). Quality of care in hospitals and practices is evaluated and improved by quality assurance programs implementing the existing guidelines for out- and inpatient treatment. Basic research on structural and functional brain imaging and genetic markers investigates underlying determinants of the manifestation and re-manifestation of the illness as well as the individual response to drug treatment (“Special Network” on molecular and pharmacogenetics). A number of more general projects on fighting stigma and discrimination, health care economy, postgraduate training, quality assurance, and methodology complete the spectrum of network projects (see ref 1 and www.kompetenznetz-schizophrenie.de for more information). Generally, the studies are multicenter studies designed in such a manner that vertical and horizontal networking is forced, essential, or at least supported. In order to create synergy and added

value as important criteria for successful networking, most of the projects are strongly interrelated regarding conceptual background, method, and organization.

The superordinate aim of these studies is to allow for an improvement of the course and the outcome of schizophrenia along with considering cost-benefit aspects. Examples of these studies will be given in subsequent sections. Since some of the studies are long-term studies which finished recruitment only recently, reliable results will only be available later in 2006. Thus, the description will mainly focus on the concept of the studies with regard to the improvement of the management of schizophrenia.

Example I: early intervention in persons at risk of schizophrenia

It is known that the first treatment contact of people suffering from schizophrenia is preceded by a period of manifest psychotic symptoms, on average lasting for 1 year, and a prepsychotic prodromal period of about 5 years with increasing negative and unspecific symptoms and functional impairment.² At the same time, it has been shown that a delayed treatment is associated with significant disadvantages for schizophrenia patients, often resulting in functional and social decline.³⁻⁶ Thus, in order to optimize outcome it seems essential to recognize and treat at-risk persons and schizophrenia patients as early as possible. For this purpose awareness programs are being carried out as a first step in several German cities within the GRNS, in order to improve utilization of newly founded early-recognition centers by at-risk persons. As a second step, two early recognition and intervention studies are carried out; these are also used to prospectively validate a two-step early-recognition inventory (ERI) and a set of cognitive tests developed for early detection of at-risk persons.⁷

For the two early intervention studies, two groups of at-risk persons are selected from the larger group of persons referred to the early-recognition centers, according to their presumed prodromal stage. Based on previous longitudinal observations, an “early initial prodromal stage” is assumed in case subjects report predictive basic symptoms in the ERI⁸ or in case they have a first-degree relative with schizophrenia and show a marked decline in global functioning. “Late initial prodromal stages” are defined by the occurrence of brief limited intermittent psychotic symptoms (BLIPS) or by attenuated positive

symptoms. Persons at risk for psychosis in the early prodromal state are included into an early intervention study examining the effects of a newly developed cognitive-behavioral therapy (CBT) strategy for prodromal persons, which is compared with clinical management within a randomized control design over a 24-month period.^{9,10} Persons in the late prodromal state of psychosis are included into a second early intervention study, which compares the effects of atypical antipsychotic medication with amisulpride in combination with clinical management (supported by crisis intervention or family counseling in case of need, but no regular psychotherapy) to such clinical management alone.¹¹ This is a phase-III study with an open-label, randomized parallel design, with a treatment period of 2 years. Effects of both studies will be evaluated with regard to improvement of prodromal symptoms, prevention of social decline, and suppression, or at least delay, of progression to psychosis. Preliminary results of both studies are encouraging, indicating a benefit for at-risk persons treated with CBT or amisulpride, respectively, compared with the control treatments with regard to these outcome variables. Should these trends be validated in the final analyses, the use of early recognition and early intervention strategies as developed within the GRNS would be an important step in the management of developing psychosis.

Example II: acute and long-term treatment in first-episode schizophrenia

Though a number of studies have shown advantages of “atypical” second-generation antipsychotics compared with conventional antipsychotics in acute treatment (for review see ref 12) as well as in long-term treatment of schizophrenia (for review see ref 13) it is still under debate whether these results may be biased by the high dosages of conventional antipsychotics usually used in these studies.^{14,15} Low-potency neuroleptics even might not induce more extrapyramidal side effects under a low-dose strategy than second-generation drugs¹⁶ and the potential advantage of atypical antipsychotics may be compromised by their side effects, such as weight gain and metabolic effects.¹⁷ Nevertheless, atypical antipsychotics are recommended as first-choice treatment for both first- and multiple-episode schizophrenia¹⁸⁻¹⁹ or for first-episode schizophrenia preferentially.²⁰ However, independent long-term studies in first-episode patients substantiating these recommendations are lacking²¹⁻²² or

are still under way, such as the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) trial in the US²³ and the European First Episode Schizophrenia Trial (EUFEST) study in Europe;²⁴ Beyond this uncertainty regarding the best kind of antipsychotic treatment for the special group of first-episode patients, it is furthermore unclear how long treatment should be continued after cessation of the first acute phase.²⁵⁻²⁶ Published guidelines recommend treatment durations of minimum 1 year;²⁷⁻²⁸ the appropriate duration of further treatment in case of symptom remission, however, has not been adequately specified.

In order to contribute to these open questions, a comprehensive acute and long-term treatment study in patients with first-episode schizophrenia is currently being conducted in up to 13 German university hospitals within the GRNS.²⁹ The study comprises a prospective double-blind, randomized, parallel-group comparison of risperidone as a new-generation antipsychotic with haloperidol as a conventional antipsychotic. Both drugs are administered in rather low daily dosages of 2 to 8 mg per day during the 8 weeks of acute treatment, and thereafter in a reduced dosage—where possible—of 2 to 4 mg per day during a 2-year long-term treatment period. To investigate the necessary duration of long-term treatment in first-episode patients, patients completing the first treatment year without relapse are randomly allocated to either maintenance treatment or stepwise drug discontinuation in the second treatment year. In case of impending re-exacerbations, prodrome-based early intervention, either by means of resumption or augmentation of neuroleptic treatment (depending on the basic treatment strategy of discontinuation or maintenance treatment) or by means of treatment/additional treatment with the benzodiazepine lorazepam is applied in the second treatment year to prevent relapses. This randomized, double-blind comparison shall contribute to the open question of whether prodromes are unspecific consequences of stress experience, treatable with benzodiazepines, or have to be regarded as more specific, prepsychotic symptoms requiring neuroleptic treatment.³⁰ Preliminary findings so far suggest that the treatment with low dosages of antipsychotics is feasible and effective, and leads to a significant improvement in positive, negative, and prodromal symptoms in first-episode schizophrenia patients. None of the patients has fulfilled the criteria for relapse within the first year of treatment. Because the medication is only about to be unblinded,

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comparison of differential treatment or side effects between both drugs is not yet available.

Example III: remediation of social cognitive impairments

Schizophrenia patients often exhibit impairments in facial affect recognition (see ref 31 for review), which is already present in first-episode patients,³² and even in unaffected siblings of schizophrenia patients.³³ Such impairments are strongly associated with more global social dysfunctions characteristic of schizophrenia³⁴⁻³⁵ and may have adverse effects on psychosocial functioning independent of the presence and severity of positive and negative symptoms and cognitive deficits.³⁶ Thus, these impairments represent a core feature of the disorder and are of high relevance for the psychosocial functioning of the patients. The traditional drug and psychological treatment usually administered to schizophrenia patients seem to be ineffective in this regard, as indicated by the stability of the impairment across different stages of the disorder despite treatment.³⁷ Against this background, a new training program for the remediation of such impairments has been developed within the GRNS. The effects of this “Training of Affect Recognition” (TAR)³⁸ have been compared with a cognitive remediation program (CRT) primarily aiming at improving attention, memory, and executive functioning, and with treatment as usual (TAU) without participation in a specific remediation program within a randomized three-group pre-post design.³⁹ Results indicated that patients on TAR significantly improved in facial affect recognition, with recognition performance after training approaching the level of healthy controls from former studies. Patients on CRT and those without special training (TAU) did not improve in affect recognition, though patients on CRT improved in verbal memory functions. According to these results, remediation of disturbed facial affect recognition in schizophrenia patients is possible, but not achievable with a traditional cognitive rehabilitation program such as the CRT. Instead, functional specialized remediation programs such as the newly developed TAR are a more suitable option. Whether these promising training effects of the TAR endure across time and pervade into everyday social functioning has to be investigated by future studies. If these effects can be validated, such training programs could become an important module of psychosocial rehabilitation programs in future.

Example IV: quality management in routine care facilities

Optimizing treatment of schizophrenia through implementation of guidelines is essential for early and acute as well as long-term and chronic phases of schizophrenia. Such measures of quality assurance shall guarantee optimal care in accordance with the state-of-the-art knowledge under consideration of available resources. At present it is estimated that only 40% to 50% of schizophrenia patients are treated according to scientific standards and treatment guidelines.⁴⁰⁻⁴¹ Although several treatment guidelines for schizophrenia have been published in recent years, it has been supposed that only a case-focused implementation of these guidelines will lead to an improvement in outcome quality measures.⁴²

Therefore, two projects targeting quality assurance, either in inpatient care or in outpatient care, have been performed within the GRNS. The first of these projects targeted the systematic development, implementation, and evaluation of specific measures of quality management in inpatient treatment of 597 schizophrenia patients at seven psychiatric hospitals, mostly district hospitals.⁴³ Using an experimental control group design with pre- and post-assessments, quality-orientated interventions according to the concept of Total Quality Management (TQM) and with reference to the German treatment guidelines²⁸ were compared in four experimental hospitals with documentation of structural parameters (hospital and patient characteristics), of treatment, and of outcome in three control hospitals. Experimental hospitals received feedback by means of comparative benchmarking, and were guided in implementing quality circles for specific problem areas identified from the benchmarking process. Results indicated that poorer average clinical outcome was associated with lower guideline conformity in a variety of treatment domains. After case-mix adjustment, benchmarking proved to be an opportunity to improve quality of treatment and promote guideline conformity.

The second project followed a similar approach for optimizing outpatient treatment of schizophrenia. The main focus was to implement guidelines, but also other elements of internal (documentation system, monitoring) and external (benchmarking) quality management in four hospital-associated networks of private psychiatric practices in three different German cities (Düsseldorf, Freiburg, and Munich). One of the three experimental

groups used a computer-based documentation system with implemented treatment guidelines and decision-support, and received comparative benchmarking.⁴⁴ This computerized documentation system draws the attention of the physician to the treatment guidelines by means of a pop-up window showing the relevant guideline algorithm whenever the entered data indicate critical changes in the patient's clinical status. Two further experimental groups used either the computer-based documentation system without implemented guidelines and benchmarking, or paper-and-pencil documentation with additional organization in quality circles. A control group used paper-and-pencil documentation without additional organization in quality circles.

Results in 583 patients with schizophrenia treated by 55 psychiatrists for at least 16 months demonstrated a significantly better outcome in patients in the experimental practices, either using the decision support system or working with quality circles, as compared with those practices merely documenting their treatment, either computer-based or with paper and pencil, but without further measures of quality assurance.

Example V: reduction of stigmatization of people with schizophrenia

The stigma associated with mental illness and psychiatric treatment, and the discrimination toward people with mental illnesses that frequently results from this, are the main obstacles preventing early and successful treatment. To reduce such stigma and discrimination, especially towards people with schizophrenia, the World Psychiatric Association's (WPA) global anti-stigma program "Fighting Stigma and Discrimination because of Schizophrenia - Open the Doors"⁴⁵ is currently being implemented in 27 countries. Since August 1999, the campaign has also been carried out in seven cities in Germany, partly within, and with funding of, the GRNS.⁴⁶ A survey of attitudes towards people with mental illness was conducted at the beginning of this campaign in 7246 persons in six German cities by telephone using a standardized questionnaire.⁴⁷ The respondents were asked about their knowledge with regard to schizophrenia, their social distance from people with schizophrenia, and estimations of the social stigmatization of mental patients in general. Thereafter public information programs and educative measures aimed at selected target groups were performed, and the opportunity for personal contact with

mentally ill people was promoted in two of the cities in order to improve the public's knowledge regarding symptomatology, causes, and treatment options for schizophrenia. The first results of a recently executed second survey of the same persons indicate that such improvement could indeed be partly obtained in these two cities, whereas no comparable changes occurred in the cities not participating in the antistigma campaign. The next step to be performed is to investigate whether improved knowledge in turn also contributes to abolishing prejudice and negative perceptions and facilitates the social reintegration of those suffering from mental illness.

Perspectives

The GRNS has now been funded for about 6 years. During this period, significant structural improvements regarding intensified collaboration between and within the research and care levels have already been achieved. Moreover, significant contributions to improved management of schizophrenia have already been obtained, for instance in the area of quality assurance in inpatient and outpatient treatment. Several studies regarding early detection and early intervention, as well as treatment of first-episode schizophrenia, were initially designed as long-term studies lasting up to 5 years, which only recently reached the phase of analysis. Due to the comprehensive design of these carefully coordinated studies targeting a number of important and open questions in schizophrenia, significant results and surplus effects can be expected for the coming months. The next essential task will be to transfer these results into health care. Based on a successful midterm evaluation, further funding has recently been granted by the BMBF until mid-2008 in order to promote this transfer process. Thus, development and implementation of measures for early recognition and intervention, for treatment of first-episode schizophrenia, for quality management, and for destigmatization will be in the focus of this last funding period before the GRNS has to finance itself by other resources. These measures will comprise development of manuals and brochures, and continued medical education measures, as well as the setting up of special competence centers for each of these topics. Nevertheless, an ongoing aim of the GRNS will still be to offer a research platform, particularly for clinical studies, in order to continue successful horizontal networking between the institutes of research. Maintenance and extension of the exist-

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ing DNA and clinical data banks will be an important part of this effort. The complexity of psychiatric disorders on the one hand, and the progressive specialization in research, especially when using complex biological methods, on the other hand, results in an increasing necessity for inter- and intradisciplinary collaboration organized into larger networks like the GRNS. Primarily, such a

strategy seems promising to find answers to the urgent and complex questions regarding schizophrenia that are still unresolved. □

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La red de investigación alemana sobre la esquizofrenia y su repercusión en el tratamiento

La Red de Investigación Alemana sobre la Esquizofrenia (GRNS), de ámbito nacional, abarca en este momento 16 servicios universitarios de psiquiatría y 14 hospitales estatales y de distrito, así como seis redes locales de consultas de psiquiatría y medicina general que colaboran en cerca de 25 proyectos multicéntricos interrelacionados sobre el estudio de la esquizofrenia. La GRNS pretende intensificar la colaboración y el intercambio de conocimientos entre instituciones científicas de primer orden y establecimientos cualificados de atención sanitaria, tanto dentro (red horizontal) como entre (red vertical) los dos niveles de investigación y asistencia, a fin de crear las condiciones científicas previas para optimar el tratamiento de la esquizofrenia. Como ejemplos de esta iniciativa se describen el concepto y los resultados preliminares de los estudios para la investigación de (i) estrategias para la detección e intervención precoz en el estadio prodrómico de la psicosis; (ii) tratamiento del primer episodio de esquizofrenia; (iii) gestión de la calidad; e (iv) eliminación de los estigmas.

Le réseau de recherche allemand concernant l'impact de la schizophrénie sur sa prise en charge

Le réseau de recherche allemand sur la schizophrénie (GRAS) est un réseau international comprenant actuellement 16 services universitaires de psychiatrie et 14 hôpitaux régionaux et d'états, ainsi que six réseaux locaux de psychiatres et de médecins généralistes travaillant ensemble sur environ 25 projets multicentriques et corrélés concernant la recherche sur la schizophrénie. Le but du GRAS est d'intensifier les échanges de connaissance et de collaboration entre les établissements de recherche de premier plan et les structures qualifiées de soins courants, à la fois à l'intérieur (réseau horizontal) et entre (réseau vertical) les deux niveaux de recherche et de soins, dans le but de créer les conditions scientifiques initiales pour optimiser la prise en charge de la schizophrénie. Voici comme exemples de cet effort le concept et les premiers résultats visant la recherche 1) de stratégies pour une détection et une intervention précoces au stade des prodromes de la psychose ; 2) un traitement du premier épisode de la schizophrénie ; 3) une prise en charge de qualité ; et 4) une déstigmatisation.

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