

REVIEW

The NAFKAM International Registry of Exceptional Courses of Disease Related to the Use of Complementary and Alternative Medicine

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The increasing use of complementary and alternative medicine (CAM) represents a continuing demand for treatment approaches in parallel with, or as an alternative to, conventional healthcare delivery.^{1,2} Some patients report considerable health improvements related to their use of CAM,³⁻⁶ and others report no effect or possibly harm.⁷ Limited efforts have been made so far to systematically collect patients' personal experiences with various CAM therapies. Methods to collect "best cases" after the use of CAM in cancer patients have been initiated in the United States and Germany.^{5,8,9} The focus of these projects has been to assess treatment response on outcomes measured independently of the patients' awareness of, experience with, and reflections on things such as tumor size or survival.⁶ They have either concentrated on one condition or have constituted a one-time limited research project. The National Research Center in Complementary and Alternative Medicine (NAFKAM) in Norway believes it is important to monitor positive as well as negative patient experiences after the use of CAM, and in 2002, the first international registry for long-term collection of exceptional "best" and "worst" cases was established. In the beginning, only severe and chronic diseases such as cancer, multiple sclerosis (MS), asthma and allergy, migraine, and chronic fatigue syndrome were included, but the registry has since been expanded to include all health conditions. The Registry of Exceptional Courses of Disease (hereafter referred to as "the Registry") serves as a basis for research on questionnaire data, medical assessments, and interview data from "exceptional" patients' experiences and reflections.^{3,6}

GOALS

The purposes of the Registry are to (1) collect patient-reported experiences from courses of illness/disease that have followed a different course than expected; (2) make these patient experiences accessible to researchers in a searchable format; and (3) monitor the collected experiences and refer series of similar experiences to researchers and health authorities.

INFRASTRUCTURE

The Registry is located at NAFKAM's offices in Tromsø, Norway. NAFKAM is part of the Department of Community Medicine at the Faculty of Health Sciences, University of Tromsø. A steering committee has been established (2 researchers from NAFKAM and

a representative from a national patient organization), and a 50% administrative position has been allocated to the day-to-day running of the Registry. The Registry is 100% funded by NAFKAM, which in turn is funded by the Norwegian Ministry of Health and Care Services.

Information about the Registry is available through the websites of NAFKAM and the Norwegian Information Center on Complementary and Alternative Medicine as well as the websites of a number of cooperating patient organizations throughout Scandinavia. Doctors, alternative practitioners, and the media also provide patients with information about the Registry. So far, no paid advertising has been used.

Data to be included in the Registry can only be submitted by the patient him- or herself or by close family (if the patient is a child or has passed away). The data are collected through a self-administered questionnaire (on paper) with both open and closed questions. Topics include demographic information, history of diseases, CAM and conventional treatments used, and reasons for the "exceptional" classification of the disease course. A request is made for informed consent for the use of the collected data for research purposes and consent for access to medical records from hospitals, general practitioners, and CAM providers. Some patients have attached letters, notes, books, etc.

Core information from the questionnaire is entered into a database at NAFKAM, and the whole questionnaire and the informed consent form are physically stored, along with medical records collected for some cases, in fireproof, locked filing cabinets at NAFKAM. The documents are also stored in portable document format for future retrieval. The database is placed as a part of EUTRO (an information technology solution designed to protect and manage biologic material, metadata, data, and projects for major health surveys) at the Department of Community Medicine. An overview of all available Registry variables can be found online (http://www2.uit.no/ikbViewer/page/ansatte/organisasjon/hjem?p_dimension_id=88112&p_menu=42374&p_lang=1).

Eligible Patients

To be included in the Registry, a patient must have (1) had a disease/health problem, (2) experienced unexpected improvement or worsening of the course of disease, and (3) related this improvement or worsening to the use of CAM. In the Registry, "exceptional courses

of disease” refers to both best and worst courses related to the use of CAM. In best courses of disease, patients report disease remission, cure, symptom relief, or improved survival. In worst courses of disease, patients report severe adverse reactions. In best courses of disease, the patients do not define improvement of their courses of disease related to the use of CAM as miracles or spontaneous remissions, although their exceptional courses of disease can include spiritual or religious experiences or practices.³

Medical Assessments

Some reported exceptional courses of disease are medically assessed by physicians at NAFKAM and external specialists according to a predefined procedure. The assessment is performed on the basis of patient records that we have collected with the patient’s consent from hospitals and primary care. The purpose of this assessment is to determine whether a reported course of disease is likely to happen in a similar patient undergoing conventional treatment alone. These assessments are currently limited to conditions where a patient-independent evaluation is possible. A patient-independent evaluation is an evaluation where there is no need for verbal or nonverbal input from the patient to achieve a disease status description. The only condition in the Registry fulfilling this requirement at the present time is cancer. The Registry is, however, also piloting whether a similar assessment procedure can be followed for patients with MS.

The medical assessment makes a conclusion at 3 possible levels.

1. Not medically exceptional: a physician would most likely see this course of disease in at least 10% of similar patients.
2. Possibly medically exceptional: a physician would most likely see this course of disease in less than 10% but more than 1% of similar patients.
3. Medically exceptional: a physician would most likely see this course of disease in 1% or less of similar patients.

Research Opportunities

Research based on data from the Registry can be initiated in 2 ways.

1. Researcher-initiated research:

Information about the collected data is available on the website of the Registry (http://www2.uit.no/ikbViewer/page/ansatte/organisasjon/hjem?p_dimension_id=88112&p_menu=42374&p_lang=1). Any researcher can apply to the Registry steering group for access to the data. If the necessary formalities (ethics, etc) are in place, a data set will be submitted to the researcher. After ethics approval, a researcher is also allowed to contact the patient(s), initially via NAFKAM, for further information collection by interview, questionnaire, etc.

2. Registry-initiated research:

When the Registry has received 5 positive courses of similar chronic disease and the same treatment, a pseudonymous report of these 5 cases will be transferred to the NAFKAM researchers for possible efficacy/effectiveness research. The same is done after 3 courses of serious/life-threatening diseases.

Safety Warnings

When the Registry has received 3 negative courses of similar chronic disease and same treatment, a pseudonymous report of these 3 cases will be sent to the Directorate of Health in Norway as a warning of a potentially harmful treatment. The same is done after one negative course of serious/life-threatening disease.

Results So Far

The Registry has received and registered a total number of 322 patient-reported exceptional courses of disease (by December 31, 2011), 317 positive and 5 negative. Of the cancer and MS courses that have been medically assessed, one has been classified as medically exceptional and 14 have been classified as possibly exceptional.

The most common conditions the patients have been suffering from are cancer, MS, asthma/allergies, chronic fatigue syndrome/myalgic encephalomyelitis, conditions patients ascribe to dental-filling materials, migraine, ulcerous colitis, diabetes, and rheumatic conditions. The most commonly used CAM treatments have been massage, acupuncture, reflexology, dietary supplements, healing, and homeopathy.

Published Research

Four scientific articles based on data from the Registry have been published to date.^{3,6,10,11} The first and second publications are a general description of the Registry and a comparative study of the procedures used internationally to register and assess exceptional courses of disease. Findings from the other 2 publications are as follows:

1. MS patients change from passive recipients of care to active explorers of healthcare independently of treatment systems. CAM facilitates the patients’ own efforts that are needed for improved health and well-being in their lives with MS.
2. Patients reporting their disease courses as exceptionally positive most often also take responsibility for developing the condition in the first place. This creates a basis for handling their disease now and in the future, often involving major changes in lifestyle and attitude toward the conventional healthcare system.

Four additional scientific manuscripts based on data from the Registry are under review for publication, and one doctoral thesis will be completed in 2012.

DISCUSSION

Internationally, NAFKAM is, as far as we know, the first research institution to establish a registry for patients having experienced exceptional courses of disease related to CAM treatment(s). Previously, somewhat similar approaches have been limited to positive (best) cases after cancer patients' use of CAM and were initiated in the United States and in Germany.^{5,6,8,9,12} Characteristics of the NAFKAM Registry that differentiate it from previous efforts/projects are as follows:

1. It is a long-term, ongoing registry.
2. Both positive and negative courses of disease are collected.
3. Disease courses are always patient-reported and patient-defined.
4. Medical assessments are based solely on patients' medical records.

The exceptional courses of disease submitted to the Registry constitute a self-selected sample of patients from Scandinavia. It is therefore important to emphasize that based on the Registry, it is impossible to establish incidence or prevalence of being an exceptional patient. It may, however, be possible to identify some common patterns among patients reporting their disease courses as exceptional.

The Registry is not intended to be a collection of miracles and spontaneous remissions. The term *miracle* implies a relationship to the divine and thereby to issues of faith.^{13,14} *Spontaneous* means something that occurs naturally and not as a consequence of an intervention. Thus, spontaneous remissions are defined as recoveries without reason or cause¹⁵ and are recognized in many health disorders.¹⁶ Spontaneous events could also be seen as events without "known" cause, and miracles as events where the cause is thought to be "divine." In that understanding, both events could be interesting for the Registry. Based consistently on patient reports, the Registry has the unique opportunity of being an important basis for research on the patients' body of knowledge. This body of knowledge can include numerous aspects of understanding that are normally not included in medical records. This body of knowledge has already resulted in valuable insight into perspectives that are important for patients to understand their diseases and change their behavior. These research results are fundamental in building an understanding of the context of patients' CAM use, the first step in the NAFKAM research strategy.¹⁷

With medical assessments available for patients with cancer and MS, the Registry also can provide insight into patient-experienced exceptional disease courses from a strictly conventional medicine perspective. The medical and patient perspectives can be perceived as complementary perspectives underpinning different aspects of a chronic disease and living with a chronic disease. Our experience so far has shown that some of the discrepancies in these 2 perspectives are

caused partly by a misunderstanding on the patient's part with regard to his or her exact diagnosis. There also seems to be an interesting discrepancy between "objectively" measured symptoms and signs of disease on the one hand and reported symptom load on the other hand. Patients report feeling better even though the "measured" symptoms and signs may remain unchanged. This knowledge can become an important foundation for research based on the patients' experiences.

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