



ICODIMS



ICODIMS PLATFORM PRESENTATION SCHEDULE

Friday, May 30, 2003

9:30 am - 9:35 am	Introduction
9:35 am - 10:00 am	NARCOMS Database
10:00 am - 10:20 am	Update on the Australian MS Longitudinal Study
10:20 am - 10:40 am	Positive Symptom Complexes in Multiple Sclerosis
10:40 am - 10:50 am	Break
10:50 am - 11:10 am	Costs and Quality of Life of Patients with Relapsing Remitting Multiple Sclerosis Currently on Immunomodulatory Therapy in the United States
11:10 am - 11:30 am	MSBase: The First International Online Registry Dedicated To Evaluating Outcomes Data In Multiple Sclerosis
11:30 am - 11:50 pm	Designing An MS Database In New Zealand
11:50 pm - 12:10 pm	The Perfect Database: The Journey From Dream To Reality
12:10 pm - 12:30 pm	Discussion

ICODIMS POSTER PRESENTATION

- Effectiveness and Cost-Effectiveness of New Drugs in Slowing MS Disability Progression: An Observation Study Using Nova Scotia Data From 1980 – 2004
- Validation of Patient-Reported Disease Descriptors in the NARCOMS Patient Registry
- Expanding Nursing Support to Patients with Multiple Sclerosis – the B.E.T.A. Nurse Program

UPDATE ON THE AUSTRALIAN MS LONGITUDINAL STUDY

The Australian MS Longitudinal Study (AMSLS) is a nation-wide, multi-disciplinary database owned by the MS Society of Australia. It is designed to facilitate both basic and applied research on MS. As a starting cohort, we targeted 2,000 randomly chosen people with MS, and by February 2003 more than 1,500 had been enrolled, with expectations of meeting target by May 2003. In addition, all Australians diagnosed with MS after June 30, 2002 are eligible to join the study.

Partial data analysis to date indicates that, according to their neurologist or treating physician, 95.8% of participants have Definite MS, and a further 3.1% have Possible MS (McDonald 2001 criteria). For disease course (Lublin and Reingold 1996 criteria) Relapsing Remitting MS = 55.6%, Secondary Progressive = 28.4%; Primary Progressive = 11.8% and Progressive Relapsing 4.0%. The female: male ratio on the database is 3:1. Fifty-three percent of participants were on some kind of immunomodulatory therapy. In the last 12 months, 33% of participants had relapsed at least once. In the same period, only 34% of respondents had clinical progression. Analysis by Disease Steps (Hohol et al. 1995) indicated a bimodal distribution of disability, with a nadir at Step 5 (late cane). Fatigue was the most common clinical symptom (73.8%). Cognitive impairment was noted in 22.0%, and sexual dysfunction in 22.9%. By self-report, 88% could complete their own questionnaires, the rest needed assistance. In this sample, 56% of Australians with MS had access to a computer and the Internet, while 29% would like help with Internet connection and/or instruction. The first major research project using the AMSLS database is a national study of the economic impact of MS on people, their families and the wider community. Planning for this study is well advanced and it will commence about June, 2003 on a sample of over 2,000 people.

Study supported by the MS Awareness Group of Rotary International in Australia, and by untied donation to MS Australia for the AMSLS by Schering Pty Ltd Australia, Biogen Australia, and Aventis Pharmacy

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 The Spectrum of Multiple Sclerosis Care
 

POSITIVE SYMPTOM COMPLEXES IN MULTIPLE SCLEROSIS A NARCOMS STUDY

Positive symptoms complicating multiple sclerosis occur in about over 80% of patients [shown preliminarily in Ni et al. 2001]. In a recent survey of the NARCOMS (North American Research Committee on MS) Patient Registry, we assessed the prevalence of various pain and uncomfortable sensations (Positive Symptoms Complexes or PSCs). Patients listed all the body locations where they experience pain or uncomfortable sensations, and described the types of discomfort and intensity associated with each location, such as intermittent leg spasms. In addition, patients indicated the treatments used, treatment satisfaction and the type of providers who prescribed them. Of 10,176 MS patients surveyed, 77% reported PSCs (34% constantly and 66% intermittently) and 70% reported a duration of greater than one year. The most frequently reported sites of PSCs were legs (22%), back (14%), feet (12%), arm (11%), headache (10%), and neck (8%).

Each patient endorsed up to three adjective descriptors for each PCS site. The most common syndromes suffered by MS patients were: aching (31%) and spasms (15%) in the back; spasms (21%), aching (19%) and tingling/crawling in the legs (14%); burning (18%) and tingling/crawling (18%) in the feet; aching in the arms (20%) and neck (29%); tingling in the face (17%); and throbbing (23%) in the head.

Focusing on the leg symptoms, for example, PSCs reported were: burning (9.7%), electric-like shocks (5.6%), velvety numbness (7.3%), sharp/stabbing (6.0%), throbbing (6.2%), sensitive/painful to touch (4.4%), and squeezing or pressure (3.4%). Most commonly prescribed medications for leg symptoms include ibuprofen (22%), acetaminophen (14%), baclofen (12%), gabapentin (9%), tizanidine (7%), clonazepam (3%), amitriptyline or nortriptyline (3%). Details of other syndromes will be described at the meeting.

Women, African-American or Hispanic patients, those actively relapsing and with greater MS-related disability were more likely to report severe PSCs than the rest of the patients. Age or duration of disease did not correlate with the reporting of positive symptoms.

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**COSTS AND QUALITY OF LIFE OF PATIENTS WITH RELAPSING REMITTING
MULTIPLE SCLEROSIS CURRENTLY ON IMMUNOMODULATORY THERAPY IN THE UNITED STATES**

A number of studies have highlighted the direct, indirect and intangible cost of multiple sclerosis (MS). However, little is known about how costs have changed with the introduction of immunomodulatory therapies. The objective of this study was to estimate costs and quality of life for persons treated with FDA-approved therapies for relapsing-remitting MS in the US at the beginning of 2002. In addition, differences in resource consumption and quality of life at different levels of functional disability, and in remission or relapse were investigated. Members of the MSWatch® database with treated RRMS were invited to complete a cross-sectional electronic survey. The structured survey included questions about their disease and their resource consumption in the past year, a generic quality of life (utility) instrument (EQ-5D) and a validated work impairment measure (WPAI). A total of 711 completed the survey; 191 were treated with interferon-beta-1b, 221 with interferon-beta-1a and 299 with glatiramer acetate. Mean total costs amounted to US\$25,921 for the sample, of which US\$21,740 were direct costs. Compared to earlier studies, the proportion of costs represented by drug treatment was higher, but it appears that inpatient and outpatient care, as well as informal care costs decreased. Sixty-seven percent of respondents reported having a relapse during the past year, and those currently in a relapse had significantly higher costs than those in remission (+US\$3276 or 16%) and a significantly lower utility (-0.15 on a scale between 0=death and 1=full health). Direct costs, work impairment and utility were significantly correlated with functional disability measured with a self-reported disability scale. Our data confirm findings from earlier international studies, but represent the first estimate of the burden of RRMS since the introduction of immunomodulating therapy. Although to compare to earlier studies, it appears that some of the burden of MS is reduced with treatment.

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MSBASE: THE FIRST INTERNATIONAL ONLINE REGISTRY DEDICATED TO EVALUATING OUTCOMES DATA IN MULTIPLE SCLEROSIS

Objective

To describe the design and implementation strategy for MSBase, the first web-based, online international database dedicated to multiple sclerosis.

Background

Long-term, prospective data-basing of large patient cohorts has provided an understanding of the natural history of multiple sclerosis. Data-basing provides the only opportunity to perform outcome comparisons for all the various therapies and compare treated and untreated patient cohorts prospectively. Currently, several regional databases dedicated to the acquisition of these data exist, but their usefulness is limited by patient numbers. MSBase has been developed in order to provide the first truly international, online platform for collaborative data-basing.

Design

MSBase is an online disease registry freely available to neurologists, worldwide. Participating clinicians contribute data on diagnosis, relapse frequency, neurological status, treatment and clinical management of their MS patients. Participation mandates ethics approval, quality assurance by on-line certification of Expanded Disability Status Scale proficiency, a commitment to annual reassessment, and the requirement for transmission of a minimal data set for each patient. MSBase uses the iMed electronic patient record system, and is compatible with EDMUS. After anonymisation, patient information is transmitted online to the MSBase web portal (www.msbase.org). All participating neurologists have access to the aggregate data. MSBase allows the on-line creation of local, national or international data-bases. An international scientific advisory board governs the database.

Results

The web portal has been created, in conjunction with the appropriate data-basing software. MSBase is in its pilot enrollment phase and will be launched in April 2003.

Conclusion

Substantial variations exist in the management of MS world-wide. Whether current treatment strategies improve long-term outcomes remains uncertain. MSBase is an international, web-based MS registry that allows the creation of international cohort comparisons and local, national and international sub-studies.

Study supported by an unrestricted educational grant from Serono Symposia International SA (Geneva, Switzerland), a non-profit education provider.

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 DESIGNING AN MS DATABASE IN NEW ZEALAND

The need for multidisciplinary research in the field of MS is highlighted by the fact that this remains a disease with no cause and no cure. As a relatively rare disease, case-control studies are best suited to investigating possible exposures and risk factors associated with MS. However, the cost of identifying representative groups of patients prohibits most epidemiological research from being conducted. We are proposing that New Zealand accumulate data on MS patients in a systematic way, making data available to a diverse group of researchers and end-users.

There is no national strategy for collecting information on MS patients in New Zealand, currently. With an estimated 3,500 patients in New Zealand, it is both feasible and statistically desirable to collect information on as many willing participants as possible. This will be best accomplished by conducting a national prevalence survey with internationally relevant diagnostic information. Data collection methods were discussed in an international multidisciplinary meeting in Wellington in January 2003.

Relevant scientific inquiries in New Zealand:

- Accurate estimates of disease prevalence for planning of health services
- Equitable access to treatments across the country and monitoring of the success/failure of those treatments.
- Latitudinal variation in MS prevalence in New Zealand
- Differences in MS prevalence based on ethnicity, place of childhood residence, gender, and rural lifestyle
- Comparisons between New Zealand, Australia, Canada, Europe, the US and Australia in terms of MS prevalence and the natural history of MS
- Suitable methods for measuring cognitive function and disability status

A pilot study is planned to develop methods for a national prevalence survey. Depression, cognitive function, disability assessment, occupational opportunities for patients and access to healthcare services are addressed in this pilot.

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THE PERFECT DATABASE: THE JOURNEY FROM DREAM TO REALITY

Background:

A comprehensive database combining clinical and research data enhances clinical care and resource management, while facilitating population-based epidemiological and basic science research.

Methods: The existing clinical databases from Calgary and Montréal MS Clinics were used as a framework for developing a combined clinical-research database: MSdb. The National Population Health Survey and MS literature were used to identify relevant socio-demographic and disease-specific questions, respectively. Validated scales were also used. This approach will allow comparing our data to Census and published MS data. Database fields were designed to capture existing and prospective data for the purpose of measuring potential MS predictors and outcomes. Assigning users different access levels preserves patient confidentiality.

Results: Questionnaires have been developed and an operating version of the database is piloted in Calgary. MSdb stores data collected from clinic visits, telephone encounters, and patient questionnaires. It offers immediate patient information to nurses providing telehealth services while concurrently capturing the encounters. Based on stored data, MSdb generates patient and administrative reports for direct clinical care and queries for research purposes. MSdb supports tracking the storage of serum, cell, tissue, and DNA-banking as well as imaging data. Updated contact information supports communication with patients to provide project updates and MS information to interested patients. Due to its well-structured design, MSdb can differentiate clinical from self-report data, while its flexibility allows on-demand adaptations to unforeseen requirements of future projects. During this journey we learned that (1) constant review of data fields is essential, (2) development is time consuming and costly, (3) data management methods must be standardized and documented; and (4) the paper trail must be maintained initially.

Conclusions: The competent design of MSdb makes it compatible in other healthcare and disease settings. It is possible to build a comprehensive database to benefit patients, clinicians, and researchers.

Development and maintenance of this database is funded by the Canadian Institute of Health Research as part of an Interdisciplinary Health Research Team grant to study matrix metalloproteinases in MS.

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EFFECTIVENESS AND COST-EFFECTIVENESS OF NEW DRUGS IN SLOWING MS DISABILITY PROGRESSION: AN OBSERVATION STUDY USING NOVA SCOTIA DATA FROM 1980 – 2004

Introduction

Effectiveness of new therapies in slowing multiple sclerosis disability (EDSS) progression is measured by increased time to disability endpoints or reduced probability of progression. Evidence on effectiveness (E) and cost-effectiveness (C/E) of new therapies for chronic disease, derived from post-marketing 'real world' observational studies, complements efficacy and cost-efficacy evidence derived from short-term clinical trials.

Objectives

Measure the effectiveness and cost-effectiveness of new MS drugs in slowing MS disability progression.

Nova Scotia Observational Data

Includes 23 years of retrospective data and 24 months of prospective data, to April/04. Person-level linkable data include: clinical data (1980 – Apr/04); MS drug therapy clinical data (Aug/98 – Apr/04); MS drug prescriptions and costs (Aug/98 – Apr/04); health services utilization data (medical, hospital, Seniors pharmacare, Community Services pharmacare) from universal publicly funded healthcare programs (Apr1989 – Apr/03)

Methods

Effectiveness in slowing EDSS progression is measured using Kaplan-Meier and Cox proportional hazard multivariate methods, applied to contemporary and historical control groups. Net treatment cost (C), given slower progression, is measured using utilization data. Cost-effectiveness is expressed as either cost per disability-adjusted-life-year avoided (C/DALY) or cost per health-related quality-adjusted-life-year gained (C/QALY). Two complementary methods are used: 1) regression models using person-level data and 2) a simulation model that incorporates summary measures of EDSS natural history, treatment effectiveness, health outcomes and net treatment costs (public, private, societal).

Variables Modeled

Include EDSS-weighted DALY; QALY; % Disease Burden Avoided (DBA); MS (EDSS) natural history by MS class; age at onset; years since onset (YSO); sex; effectiveness size; treatment eligibility/termination criteria; compliance; treatment start by YSO; treatment duration; post-treatment regression; gross and net costs; discount rate.

Discussion

Measures of the effectiveness and cost-effectiveness of new drugs in slowing MS disability, derived from Nova Scotia observational data, will inform ongoing debates regarding appropriate treatment strategies and public policy for these drug therapies.

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VALIDATION OF PATIENT-REPORTED DISEASE DESCRIPTORS IN THE NARCOMS PATIENT REGISTRY

Background:

The NARCOMS (North American Research Committee on MS) Patient Registry with over 20,000 participants, collects data on MS including information on seven key questions related to the onset of the disease, frequency of relapses within the previous years, and overall changes in MS symptoms over time. This information is used to stratify patients into disease categories.

Objectives:

This is a validation study on the agreement between patient and physician reported data on the type of MS and disease activity.

Methods:

Patients coming for clinic appointments to the Yale Center for MS Treatment and Research at Yale University were asked to fill out a section of the Registry questionnaire. During the visit, treating physicians were also asked to complete the same questionnaire on behalf of the patient and to determine the patient's clinical type of MS (relapsing remitting, secondary progressive, primary progressive, and unsure of type).

Results:

There are 44 patients in this preliminary dataset. The treating physician characterized 37.5% as Relapsing Remitting, 37.5% as Secondary Progressive, and 17.5% as Primary Progressive. For 7.5% of patients the type was not clear. Overall agreement between patients' and doctors' responses on whether the patient had a diagnosis of MS was 100%. There was 87% agreement on the year (+/- 2 years) of first diagnosis with MS; 67% agreement on the year of first symptoms (+/- 2 years), (and up to 77% agreement within four years). Agreement on experiencing a relapse within the last two years was 57%.

The study is ongoing and the data will be validated on a larger dataset.

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EXPANDING NURSING SUPPORT TO PATIENTS WITH MULTIPLE SCLEROSIS
THE B.E.T.A. NURSE PROGRAM

Nurses play a critical and important role in the ongoing care of people living with multiple sclerosis (MS). Nurse involvement complements the physician - patient relationship. This involvement has been reported to have a positive affect on long - term adherence to MS therapy.

Recognizing the value of nurses, Berlex has developed the B.E.T.A. (Betaseron® Education, Training and Assistance) Nurse program by establishing B.E.T.A. Nurses throughout the U.S. The program aims to provide MS specialized nurses to people touched by MS, particularly those taking Betaseron®.

The B.E.T.A. Nurse program is designed to provide training, assistance and education on the administration of Betaseron®. Training also focuses on ways to adjust to therapy and regular contact is provided at least 18 months. During this time, the B.E.T.A. nurse offers educational and wellness programs focusing on disease management and ways to live with MS. The training and educational approach has resulted in a 90% adherence to therapy for patients participating in the B.E.T.A. Nurse program for one year.

Data on frequency of contact, adherence to therapy and patient satisfaction will be presented in the outcomes of this program.

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