

MS As A Disease, Copaxone® As a Treatment and MS Patient Care

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THE EARLIEST CASES

- Described for many centuries
- First Case – Lidwina Van Schiedam
Noted in 1421
- Became more well documented in the 1800s
- Well described by Charcot in the late 1800s –
Correlated clinical science and pathology –
opened the door for others to build on his work.

THE TREATMENT -THEN

- Early treatment centered on the current therapies that apply to any illness

Early etiologic theories:

- Worry and overwork
 - Spirochete
 - Toxins – heavy metal poisons
 - Infections
-

EARLY INTERVENTION

- Manage relapse
- Symptom Management
- Physical therapy for rehabilitation

Origin of MS

- Geographic distribution suggests environmental factor
- Viral hypothesis
- Native Americans, Eskimos, Lapps and Hungarian gypsies genetically protected.

Demographics of MS

- Age of onset 15 to 45 years¹
- Gender 70% women²
- Geography incidence increases with distance from equator³
- Incidence 8,500 to 10,000 new cases per year²
- Prevalence 350,000 in U.S.²

1. Anderson DW et al. *Ann Neurol*. 1992;31:333-336.

2. Jacobsen DL et al. *Clin Immunol Immunopathol*. 1997;84:223-243.

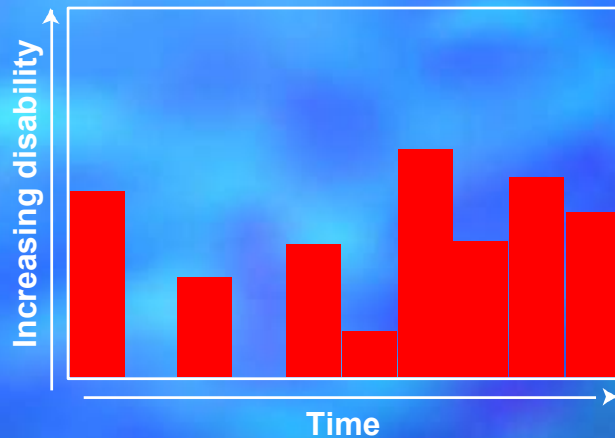
3. Hauser SL. *Harrison's Principles of Internal Medicine*. 1994.

Genetic Prevalence of MS

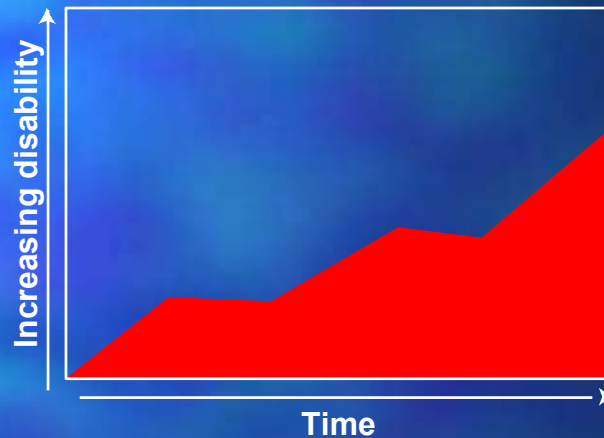
- 10 X increase for MS if direct relative affected.
- Higher prevalence in identical twins.
- Variability in severity of disease in twins and affected relatives.

Course of disease in MS

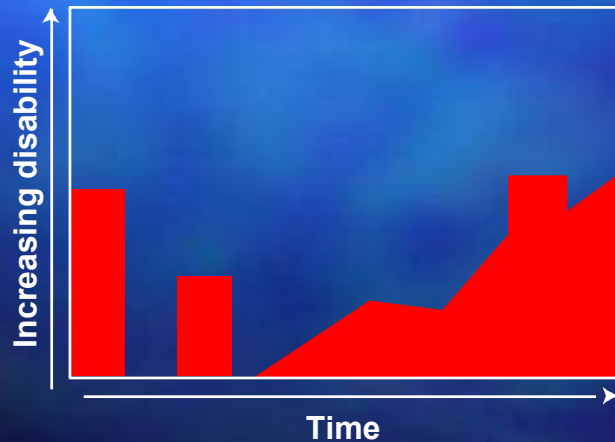
1. Relapsing-remitting



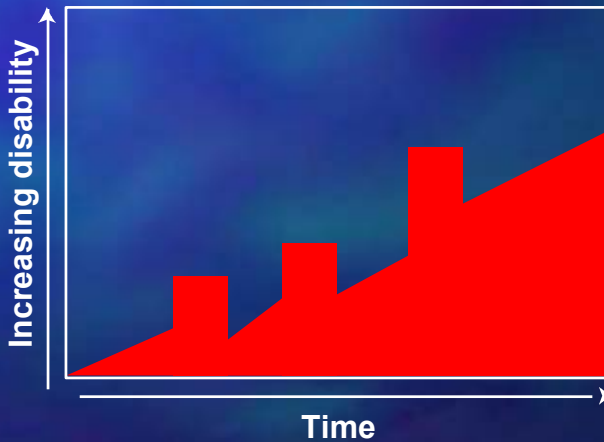
2. Primary-progressive



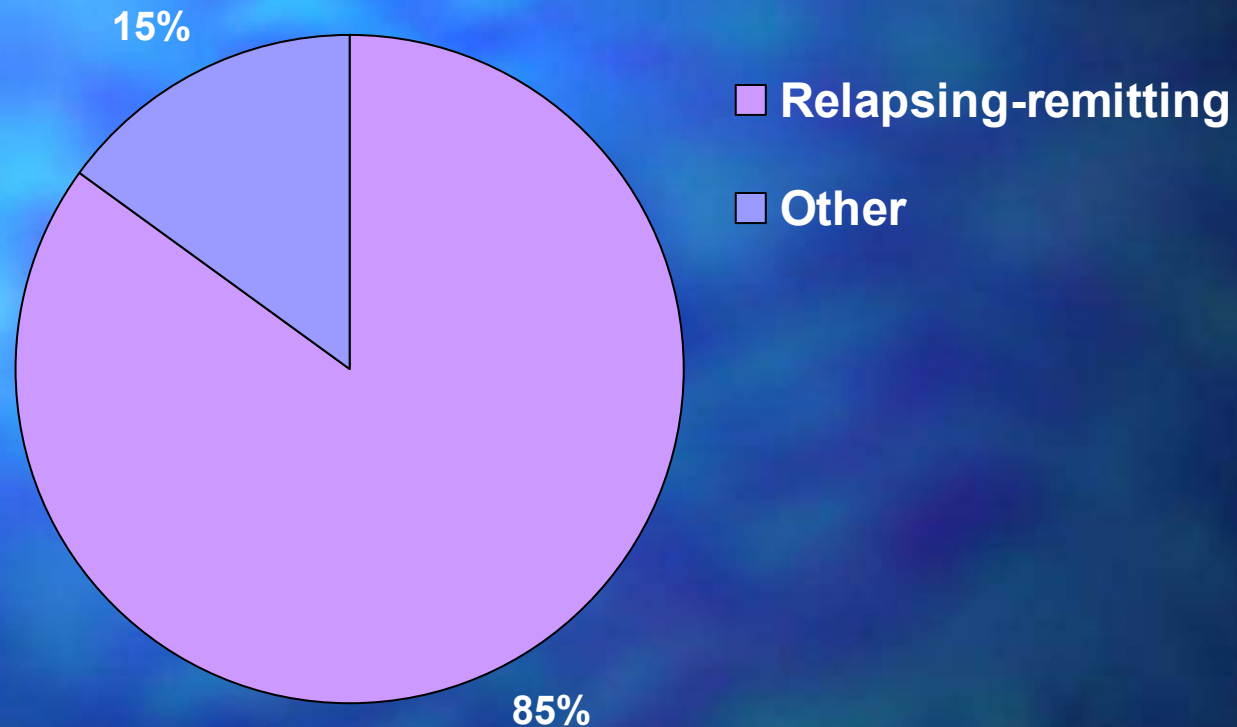
3. Secondary-progressive



4. Progressive-relapsing



Percent of patients presenting with relapsing-remitting MS



- 50% of patients require walking aids within 15 years of diagnosis

Adapted from: Weinshenker BG et al. *Brain*. 1989;112(1):133-146.

Direct costs of MS

- Care provided professionally or by family
- Home alterations, special equipment, transportation, disease-specific medical costs, etc.
 - Total annual cost
 - \$9.7 billion for health care system in 1994 dollars
 - average \$35,000 per patient per year
 - \$50,000 for primary-progressive
 - \$30,500 for relapsing-remitting

Indirect costs of MS—lost days

- Patients still working lose no more days than peers
- Restricted activity
 - 23% are restricted 1-7 days/2 weeks
 - 16% are restricted 8-14 days/2 weeks
- Confined to bed
 - 27% confined to bed ≥ 1 day/2 weeks
 - 10% totally confined to bed

Clinical Presentation of MS

- Primary Symptoms

- Visual complaints, gait problems, pain, spasticity, weakness, speech difficulty, bladder/bowel dysfunction

- Secondary Symptoms

- UTIs, urinary calculi, muscle contractures, URI, poor nutrition

- Tertiary Symptoms

- financial, social, emotional, vocational problems

Diagnosis:

- **Neurological examination**
 - (dissemination in time and space)
- **Magnetic Resonance Imaging**
- **Cerebro-spinal fluid**
 - (Oligoclonal bands, intrathecal IgG)
- **Evoked potential VEP**

Principles of management

- Treat relapses
- Manage symptoms
- Modify/reduce relapses
- Delay progression to disability
- Facilitate an acceptable quality of life

Principles of management

■ Manage symptoms

- fatigue
- spasticity
- pain
- bowel, bladder
- memory loss and affective disorders
- swallowing problems

- tremors
- visual changes
- sexual problems
- speech disorders
- balance and mobility dysfunction

■ Psychological and emotional support

Treatments

1/ Acute exacerbation: i.v. steroids

2/ Long term immunomodulation:

a. interferons

b. GA - selective immunomodulation

3/ Symptomatic relief

4/ Management of treatments' side effects

MS Immunotherapy

- Currently four immunomodulatory drugs are available for use in the treatment of Multiple Sclerosis
 - AvonexTM: Interferon β 1a
 - Betaseron[®]: Interferon β 1b
 - Copaxone[®]: Glatiramer Acetate
 - Rebif[®]: Interferon β 1a

Factors that influence treatment decisions

- Stage of disease and amount of recent disease activity
- Magnetic resonance imaging (MRI) lesion burden
- Safety and tolerability profiles of immunomodulating agents
- Patient preferences, expectations, capabilities, and lifestyle issues

Adherence to Therapeutic Regimens

- Considerable barrier to health care regimens
 - 30-70% nonadherence, average 50%
- Adherence as opposed to compliance
 - incongruent to nurse-patient relationship
 - compliance “the extent to which a person’s behavior coincides with medical or health advice”
 - adherence “active, voluntary and collaborative involvement of the patient in a mutually acceptable course of behavior that leads to therapeutic outcomes”

Barriers to Adherence in MS

- Communication problems
- Knowledge deficits
- Physical impairments
- Social and cultural variables
- Financial concerns
- Emotional distress
- Psychiatric disorders
- Cognitive deficits

lifestyle issues

- Maintain balance between side effects and efficacy (risk/benefit ratio)
- Factor individual patient circumstances into equation (e.g., employment, schedule, family responsibilities, capabilities, physical assessment)

Indications and Usage

- Copaxone is indicated for reduction of the frequency of relapses in patients with RRMS

Copaxone[®] Safety Data

- Placebo Controlled Trials in R - R patients
- (269 GA : 271 Placebo)
- Open label trials 3,736 patients
- Post marketing safety data (active surveillance)
(> 40,000 patients)

COPAXONE®

- Five studies, 181 investigators, 706 patients all point to one common conclusion- COPAXONE® effectively reduces relapse rates, has favorable effects on both disability, and virtually all MRI parameters.
- It has been shown to have a sustained effect for over a 8 year period

Customer Support Resources

- Shared Solutions – Call Center
 - Enrollment Process
 - Home Health
 - Benefits Investigation
 - Autoject
 - Patient Support / Education
 - Literature / Materials
 - Adherence & Compliance
- MS Watch
- Patient Assistance

Who We Serve

External:

Patients

Caregivers

Physicians

Internal:

Sales Associates

Marketing

Medical

Current State

- A. Transition Completed 9/30/02
- B. Shared Solutions® Members: 84,315
 - On COPAXONE®: 54,063
- A. Average Enrollments per Month: 1,835
- B. Staffing 24 Nurses 19 CSRs
- C. Siebel CRM System
- D. Avaya Computer Integrated Telephony
- E. Coverage 7:00am – 10:00pm CST M-F

Call Center Activity

- Inbound Call Volume 2002 – 18,500/month
 - 4th Quarter – 10,500/month
- Outbound Compliance Call Volume approx. 9,000/month
 - Compliance Call Schedule

Compliance/Adherence Opportunities

- Script to First Injection Elapsed Time 21 days
- Decreased 90 Day Drop Rate 37%
- Decreased 360++ Day Drop Rate 37%

Shared Opportunity

- New Enrollees
- Increased Level of Support for Physician Offices
- Expedited Time to Product
- Increased Compliance & Adherence
- Optimize Business Results

Sales Force + Shared Solutions =
Win Win
Patients TNS



CSR

- Triage calls
- Return voicemail
- Enroll callers in SS
- Obtain orders from physicians
- Provide information

Nurse

- Educate
- Support
- Set realistic expectations
- File reports
- Outbound calls to patients

Patient Assistance Programs

- **NORD**

Program for uninsured/underinsured patients to obtain COPAXONE®

- **PSI**

Assistance with co-payments/co-insurances

NORD has served MS Patients since.

- **1994 to 1996** – COPAXONE® Early Access Program
- **1996 to present** - COPAXONE® Patient Assistance Program
- **6,000+** referrals to NORD since 1996

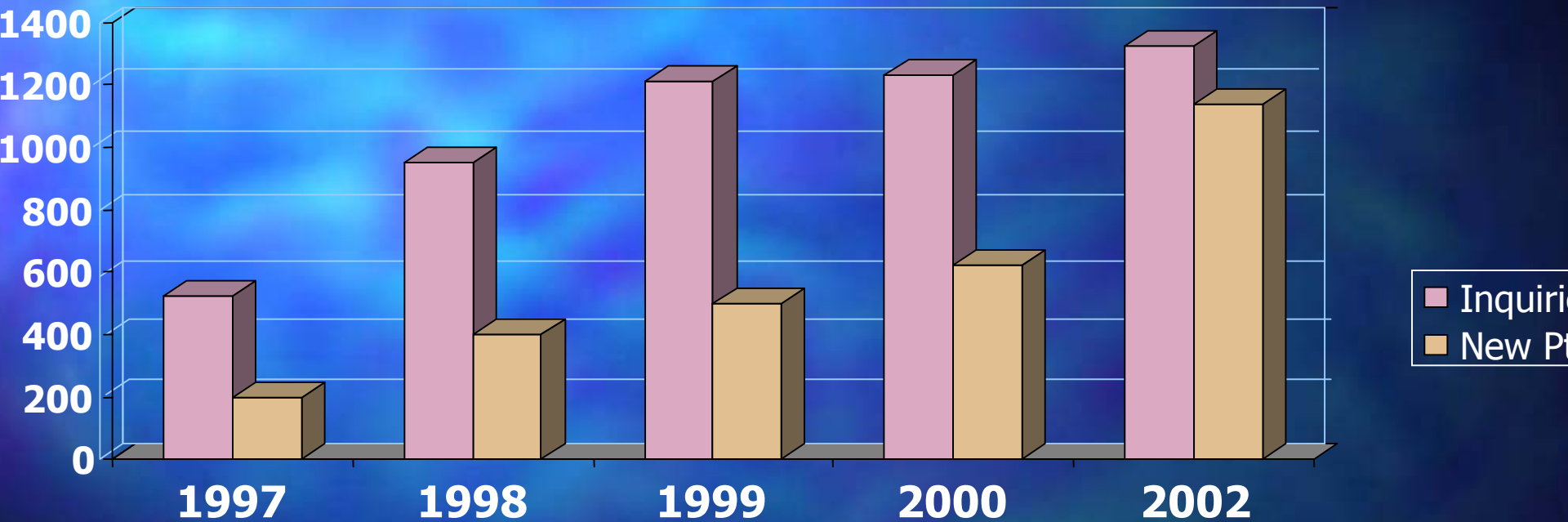
Who is eligible for COPAXONE® Assistance?

- Individuals diagnosed with RR-MS
- The uninsured
- Health insurance does not include Rx coverage
- Income is too high for Medicaid but too low to pay out-of-pocket for COPAXONE®

COPAXONE® Demographics...

- Out of 1,800+ active patients in the COPAXONE® Patient Assistance Program:
 - 74% Female
 - 26% Male

COPAXONE® - NORD ACTIVITY



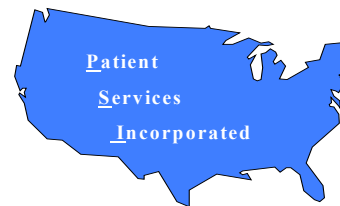
Patient Assistance Programs

- **PSI**

Assistance with co-payments/co-insurances

GAPS in Most Corporate PAP'S

- **Can not pay health insurance premiums**
- **Can not pay co-payment and deductible**



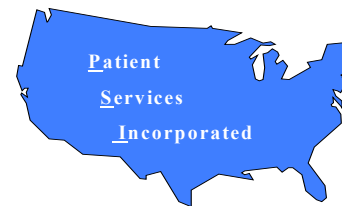
PSI Provides These Services

■ Premium Assistance Program

- Cobra Payments
- High-risk Payments
- Open-enrollment Payments
- Full Assistance or Share-of-Cost

■ Co-payment Assistance Program

- Full Assistance or Share-of-Cost

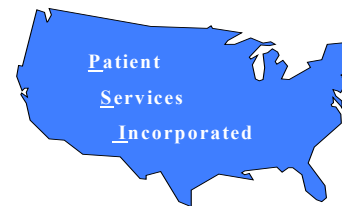




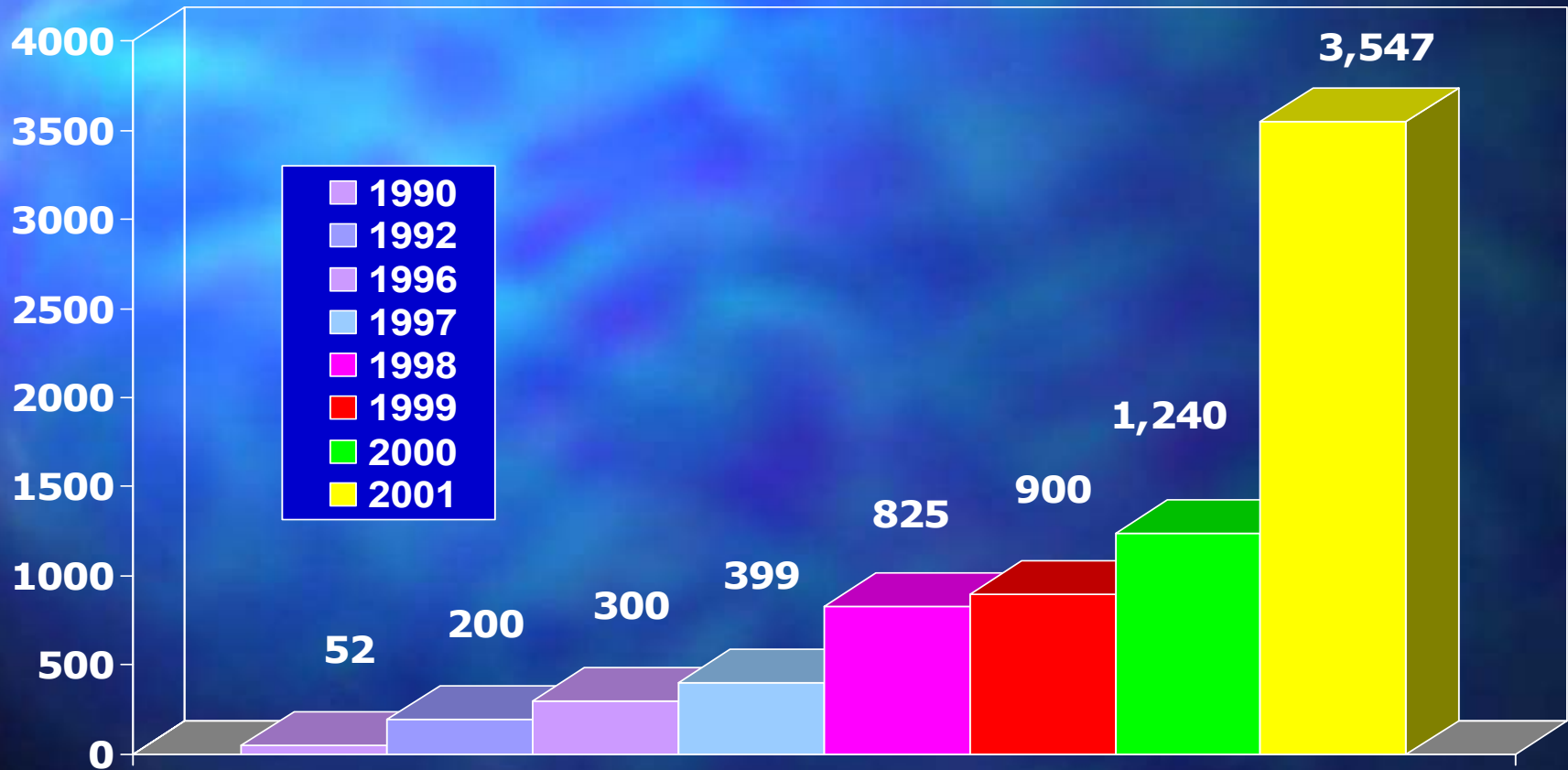
COST SHARING

based on PSI criteria

- **General Living Expenses**
 - To Include:
 - Rent/Mortgage
 - Food
 - Utilities
 - Clothing, etc.
- **Number of Dependents**
- **State where family resides**



GROWTH OF PSI CASELOAD (ALL MS THERAPIES)



COPAXONE Assisted Patients Through PSI

- Number of patients served 600
- Number of patients by year end 1,000