# THE TOTAL ASSESSMENT OF RHEUMATOID ARTHRITIS BY PHYSIOTHERAPISTS: A RANDOMIZED CONTROLLED TRIAL.

# THE TOTAL ASSESSMENT OF RHEUMATOID ARTHRITIS BY PHYSIOTHERAPISTS: A RANDOMIZED CONTROLLED TRIAL

BY

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ABSTRACT

Are the outcomes of rheumatoid arthritis patients improved when their family physicians are provided with information gathered by specially trained physiotherapists?

Two physiotherapists were selected and trained in detailed objective techniques of evaluation and problem identification, leading to a clear and succinct report designed to assist the family physician in treatment decisions. From June 1974 to January 1977, a randomized controlled trial was conducted to assess the effect of these reports on the outcomes of women with rheumatoid arthritis treated in the community by their family physicians.

On admission to the trial, patients were randomly allocated to two groups: one experimental group which was assessed according to modern quantitative techniques of evaluation and, following communication of results to family physicians, were treated at home by the trained physiotherapists; and a control group which was assessed according to traditional techniques of evaluation and, following communication of results to family physicians were treated at home by traditional physiotherapists. All subjects were interviewed initially, at four, and at 12 months by independent assessors who used a standardized

prestructured questionnaire designed to measure the level of joint inflammation, functional capacity, compliance and mood.

In association with this trial, a pooled index was developed converting five separate outcome measures into a single prespecified variable, to measure treatment differences.

The author's unique contribution to this trial related to: development, formulation and execution of the experimental design, and more specifically, the use of independent assessors in rheumatology, allocation strategies, processing of intakes, supervision and control of data gathering procedures and the introduction of modifications in the design following the pretest and during the experimental period that made this trial feasible.

This is a "compound" thesis, focussing on the present state of knowledge and rationale for the research, the original design and modifications introduced following the pretest and during the experimental period. The rationale and effects of these modifications will be discussed in detail.

ACKNOWLEDGEMENTS

Words alone do not express my sincere appreciation to all those who gave their assistance and counsel in the preparation of this thesis.

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Professor H.A. Smythe (University of Toronto) who first proposed the research had a major impact on my career aspirations, both as collaborator and friend. Similarly Professor C.H. Goldsmith who joined the team in 1973, completed the triangle. I hope that my association with them is only a prelude for better things to come.

Special mention also goes to Gerald Chan who assisted in the statistical analysis, the staff of the Field Survey Unit for their

excellent service and to Christine Brabant who struggled valiantly with this text.

Last, but not least, I would like to thank my dear wife for extending her ultimatum, without which this work would never have been completed.

# 1 - INTRODUCTION

Preceeding the design and execution of experimental trials, investigators must explore to what extent a basic research question is likely to shed a new light on a problem and, therefore, contribute to the present state of knowledge.

The outcome of patients with rheumatoid arthritis (RA) receiving primary care is a basic health and societal issue and to date, it has received very little attention from investigators in the field. This will be revealed by a total absence of documentation in the current literature and any information that is available tends to be anecdotal.

To justify the relevance of this research, the author will expound in this section on the magnitude of the challenge facing society in dealing with RA, by first describing the disease, its prevalence, incidence, natural history and cost of resultant disability. Second, the types of available therapy and sources of care will be discussed and finally the author will provide justification for conducting this research and describe briefly the design and his unique contributions.

## 1.1 Rheumatoid Arthritis: Brief Description and Disease Manifestations

Rheumatoid arthritis (RA) is a chronic illness of unknown etiology, in which non-suppurative inflammation of synovial joints is frequently combined with a variety of extra-articular manifestations. The disease process within the joints begins as an inflammation of the synovium, in most cases leading to an increase in the amount of synovial fluid, distention of soft tissues at the joint site a swollen appearance and acute pain. This may be the first clue to the disease, and in many instances, these symptoms may clear completely or remain confined to a few joints causing little or no impairment in joint function. Commonly, however, there is a tendency toward relapse or continued inflammation leading to a thickening of the synovium, marked destruction of articular cartilage and permanent joint disability.

Although RA is chiefly an affliction of joints, patients with severe disease often exhibit symptoms of "systemic" or "malignant rheumatoid disease", terms used to designate this broad clinical picture. It is believed that vascular lesions play an important role in the development of joint lesions and subcutaneous nodules, and it has become increasingly apparent that an underlying vasculitis is responsible for many of the systemic manifestations of the disease. For convenience these features are divided into four categories: subcutaneous and subperiosteal nodules; organ involvement such as the heart and lungs;

systemic complications such as anemia and osteoporosis; and features associated with vasculitis such as digital arteritis, Raynaud's phenomenon and chronic leg ulcers.

The variable clinical course of RA summarized in Table I[1] which, if sustained or continuing to progress, may result in serious consequences to the individual.

In terms of remissions and exacerbations the clinical course of RA has been shown to follow three cyclic patterns[2] (Fig. 1), with 65% progressing to American Rheumatism Association (ARA) stages of disease II (moderate), III (severe) or IV (terminal),[3] so that the likelihood of a complete remission of any duration is extremely slight after three years of sustained disease.

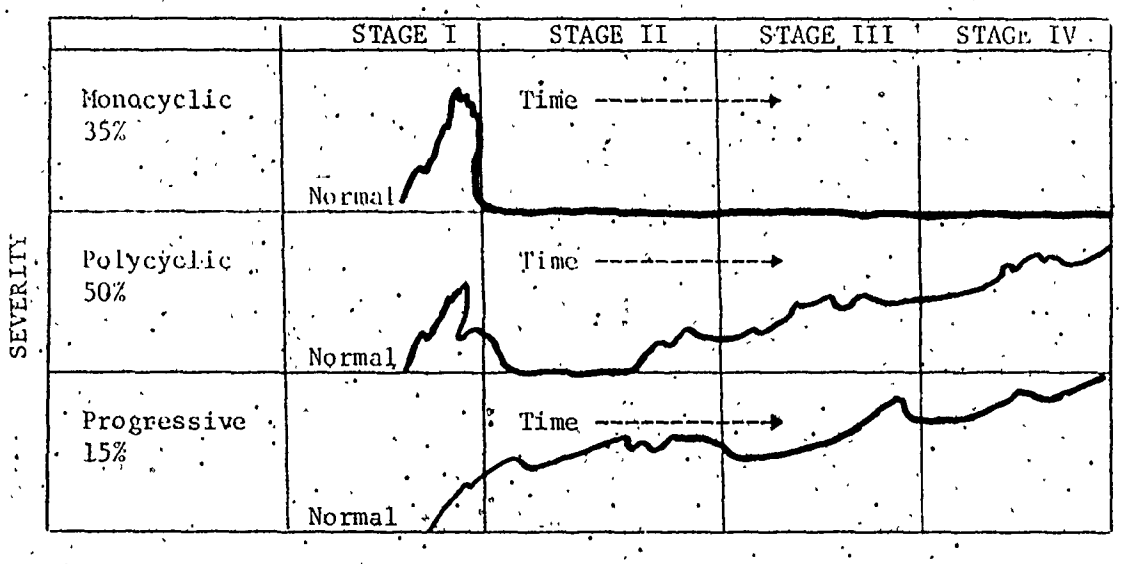
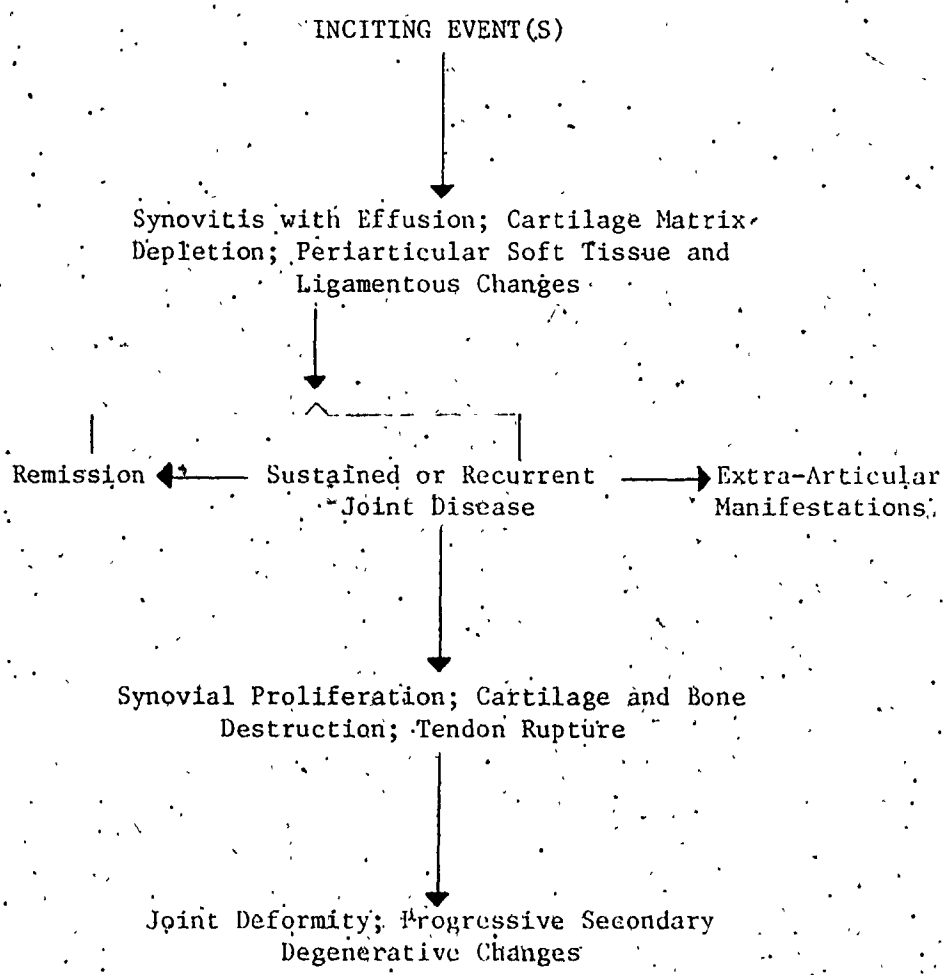



Fig. 1 - The clinical course of RA in three hypothetical cases.[2]

TABLE 1

Variable Clinical Course of RA[1]



The course of the disease in any particular person is unpredictable, however, continuous joint symptoms before the age of 30 accompanied by extra-articular features such as nodules and vasculitis, and a high rheumatoid factor titre, often lead to a poor prognosis.

## 1.2 The Epidemiology of RA

The challenge facing society in dealing with RA can be explained from the perspective of its prevalance, incidence and the effect of long-term disability and its economic cost.

Prevalence - The National Centre for Health Statistics in the United States (U.S.) has collected and processed data relating to RA, through the National Health Interview and Examination Surveys (N.H.I.E.S.) on the civilian non-institutional population. The information gathered was based upon a medical history, physical examination of the joints, bentonite floculation test (for rheumatoid factor) and roentgenograms of the hands and feet.[4, 6] The findings of that survey (Table 2)[7] were applied to the ARA criteria for a diagnosis of RA,[8] demonstrating a prevalence rate of 3.2% of the population examined. Of these, 30% met ARA criteria for "definite" or "classical" RA and "probable" for the remainder. The prevalence rates for women were 4.6% and for men 1.7%, a ratio of nearly three to one, with rates for both sexes increasing with age. While these findings must be accepted within the limits of

TABLE 2

Percentage of Men and Women With Specified Findings and Relative Prevalence by Sex: United States 1960-62[7]

| Findings | Men % | Women % | Women / Men Relative Prevalence |
|---|---|---|---|
| Symmetrical joint swelling | 0.9 | 3.1 | 3.3 |
| Tenderness | 9.4 | 17.5 | 1.9 |
| Pain on motion | 1.9 | 3.4 | 1.8 |
| Swelling one joint | 1.7 | 1.8 | 1.1 |
| Positive bentonite fluctuation test | 3.4 | 3.5 | 1.0 |
| Swelling, two joints | 1.0 | 0.6 | 0.7 |
| Morning stiffness | 22.1 | 32.2 | 1.5 |
| Positive x-ray | 1.0 | 0.6 | 0.7 |

survey design, prevalence rates gathered during the past 20 years from many different parts of the world (Table 3)[5] demonstrate no consistent geographic, climatic or cultural trends; the similarities were far more striking than the disparities.[9] The most consistent findings are that prevalence increases with age up to the 60's and that women are generally afflicted two to three times more frequently than men.

The rates for Canada are believed to be comparable. With an adult population 15 years and over of approximately 15 million, and assuming a 1% prevalence rate for "definite" RA, 150,000 adult Canadians are expected to suffer from this disease at any point in time.

Of special interest to health planners and economists is RA's high prevalence amongst the highly productive middle-age groups and its relationship to a number of other socio-economic factors. Wolfe's report[5] on the U.S., N.H.I.E.S. findings pertaining to RA reveal the following:

a). No difference in RA prevalance amongst white and negro adults of either sex,

b) RA is more prevalent than expected in adults of either sex with less than five years of education. In males the rate decreases with increasing years of education. This is less evident in females,

TABLE 3

The Prevalence Rates of RA[5]

| Place - Investigator | Year | Age | Number | Per Cent Examined | RA Prevalence Rate Male % | RA Prevalence Rate Female % | "Definite" Total % |
|---|---|---|---|---|---|---|---|
| National Health Examination | 1960-62 | 18-79 | 7,710 | 87 | - | - | 0.96 |
| Pittsburgh - Cobb | 1953-54 | 15+ | 798 | 60 | 0.4 | 1.0 | 0.7 |
| Wensleydale - Lawrence | 1961 | 15+ | 1,025 | 87 | 0.4 | 1.4 | 1.1 |
| Leigh - Lawrence | 1961 | 15+ | 1,565 | 86 | - | - | - |
| The Netherlands - de Graff | 1954-59 | 15-64 | 141,845 | - | 0.4* | 1.0* | - |
| Tecumseh - Mikkelsen | 1959-60 | 6+ | 8,000 | 90 | 0.20 | 0.57 | 0.39 |
| Blackfeet Indians - Burch | 1963 | 30+ | 1,281 | 86 | 1.4 | 1.3 | 1.4 |
| Pima Indians - Burch | 1963 | 30+ | 1,126 | 86 | 0.6 | 2.5 | 1.5 |
| Haida Indians - Gofton | 1964 | 15+ | 492 | 88.6 | 0.42 | 1.01 | 0.69 |
| Guaynabo - Mendez-Bryan | 1961-63 | 18+ | 3,885 | 25.5 | 0.16 | 0.40 | 0.33 |
| Hiroshima-Nagasaki - Wood | 1966 | 15+ | 18,559 | 87.7 | 0.19 | 0.45 | 0.35 |
| Coastal Islands - Valkenburg | 1964 | 15+ | 1,146 | 95.2 | 0.6 | 3.5 | 2.1* |
| Sofia, Bulgaria - Tzonchev | 1966 | 15+ | 4,318 | 100 | 0.24 | 1.21 | 0.86 |
| Jamaica - Lawrence | 1966 | 35-64 | 600 | 89 | 1.90 | 2.24 | 2.08 |

* Definite and Probable

c) observed rates for females by family income levels do not differ from expected rates. Amongst males, however, where family income is less than $2,000/year the rate is twice than expected. It would seem, therefore, that the relationship of income to RA is a reflection of the effect of disease on the income potential of the patient, rather than a clue to etiology,

d) women who have never married and widowed men have less RA than expected,

e) the rates for women with four or more children do not differ from rates in women with one to three children.

Incidence - data on incidence are very scarce, as this will depend on the ability of diagnostic criteria to identify correctly new cases within a specific time interval. Since RA is characterized by remissions and exacerbations the task becomes even more difficult. A study of an urban population of 25,000 in Rotterdam,[10] where all patients were seen at least once a year at the Rheumatism Centre for clinical, radiological and serological examination, revealed an annual incidence rate of 0.86%.

In another study in Sudbury, Massachusetts,[11] which dealt with selecting and re-examining an age-stratified sample of the population,

revealed an annual incidence rate of 0.29%. The difference in these findings were due to the methods used to determine an RA diagnosis. In Rotterdam the ARA criteria were used; in Sudbury, ARA criteria yielded a disproportionately high incidence rate, this was modified so that a diagnosis was based on the physician's clinical impression and the agreed upon rate was estimated at 0.29%.

Disability - there are no accurate figures regarding the rate of disability resulting from RA, or its economic costs. A number of longitudinal studies and joint prevalence surveys provide some information on the subject.

In a group of 239 patients followed over a 25 year period (Table 4)[12] in various arthritis clinics, 49% were in the "improved" or "stationery" categories after 10 years of treatment by simple medical and orthopaedic measures. Thereafter, more patients begin to appear in the "worst" category.

As joint function depends on the integrity of its articular cartilage, damage of this structure will inevitably result in disability. A measure of progression of articular damage is the appearance of new or enlarged erosions on serial roentgenograms of the joints. Based on the cause of RA in 154[13] cases, it was shown

TABLE 4

Natural History of RA (1930-1954)[12]

| Patients | 1937 | 1947 | 1954 |
|---|---|---|---|
| Number | 239 | 225 | 174 |
| Clinical Status(%) | | | |
| Remission | 17 | 17 | 13 |
| Improved | 37 | 38 | 22 |
| Stationary | 27 | 11 | 2 |
| Worse | 19 | 34 | 63 |

that articular damage is directly proportional to the duration and intensity of the active disease. In another study of 57 RA patients[14] observed over a period ranging from 11 to 40 months, 20 of 45 cases with ARA stage III (severe) and IV (terminal) disease, developed moderate to severe progressions in erosions, in spite of comprehensive management. Others have noted new or enlarged erosions in the hands, whether or not Gold,[15] low dose corticosteriods[16] or conservative therapy was used.[17]

Based on this evidence, we may presume that the rate of disability in those affected tends to be high, and that it is directly proportional to disease duration and severity.

Economic costs - information regarding the social and economic costs directly attributable to RA is scarce. These may only be determined by the high rate of disability in those affected than by numbers alone. According to a 1962 bulletin released by the U.S., Department of Health Education and Welfare, nearly one-half the patients in the 50 to 60 years of age group, and one-third of those between 25 and 50 are disabled.[18] The economic toll is further aggrevated by a substantial prevalence of RA in the young and middle-aged, when productive capacity and earning potential would normally be at their greatest.

The costs of arthritis as a whole to the U.S. economy has been calculated in some detail,[19] and was estimated at over $3.5 billion/year in 1966 (Table 5). The direct medical costs of $1 billion in Table 5 do not include: costs of prescription drugs, certain services in physicians offices, physical therapy costs and private insurance benefits. Nonetheless these amounts are staggering.

By extrapolation, the potential earnings lost to the Canadian economy from arthritis in 1966 would amount to $237 million. With an annual inflationary rate of 10%, in today's dollars (1977) this amount would be $474 million. To what extent disability resulting from RA contributes to these costs is not known. However, in view of its high prevalence, and the high proportion of patients with a disability, it would be safe to assume that RA is responsible for a major share of these costs.

## 1.3 The Management of RA

The challenge of RA is not only confined to the individual and his family, but to an equal degree the burden is shared by the providers of care. According to Engleman: "Choice of treatment for rheumatoid arthritis is a particular challenge to the physician. The unknown etiology of the disease and the multiplicity of its manifestations, have given rise to modes of therapy as numerous and diverse as the

TABLE 5

The Cost of Arthritis To The United States Economy (1966)[19]

| LOST WORK PRODUCTIVITY: | MILLIONS |
|---|---|
| For those unable to work | $1,500 |
| Lost time from work | 200 |
| Lost homemaker's services | 600 |
| Earnings lost by premature death | 49 |
| SUBTOTAL: POTENTIAL EARNINGS LOST TO THE ECONOMY | 2,369 |
| OTHER: | |
| Direct medical costs (at least)* | 1,000 |
| Quackery | 250 |
| Existing programs for arthritis** | 26 |
| TOTAL | $3,645 |

* Excludes costs of drugs, devices, physiotherapy, certain services in physicians' offices, care in private homes and private insurance benefits.

**Cost of Public Health Programs, Veteran's Administration, The Arthritis Foundation, vocational rehabilitation and state grants.

concepts of its pathogenesis. The disease is characterized by spontaneous remissions and exacerbations, making evaluation of treatment extremely difficult. So called specific agents may be effective in reducing the symptoms and signs of RA, sometimes to a dramatic and deceiving degree. Unfortunately, the risks are often great and the eventual course of the disease probably unaltered by their use. All evidence to date indicates that conservative management offers a long-term prognosis at least no worse, than that of more spectacular measures!"[20]

This assessment made over 10 years ago is still true today. Controlled trial of therapy for RA have failed to demonstrate long-range benefits that offer a more favourable prognosis for patients with severe disease.[15, 16, 17]

The primary objective of RA therapy is the control of inflammation as it affects synovial joints and other organs. The therapy of choice for any patient will depend on the natural history of his disease in terms of duration and severity; the number of actively inflammed joints and the presence of extra-articular manifestations at a point in time. These considerations have led to the development of problem oriented management plans, that focus on quantitative measures of joint inflammation, destruction and dysfunction, which permit subsequent therapeutic decisions to be made on the basis of a sound quantitative

evaluation of progress.[21] These schemes depicted in Table 6 were developed from four separate measures of disease activity proposed by the Co-operating Clinics Committee of the American Rheumatism Association following their seven day variability study of 500 RA patients with unchanged therapy.[22] The findings were divided into 10 grades of relative severity (see Table 7). While variation of any one measure into adjacent grades was common (about 30%) change of more than two grades or more occurred uncommonly (about 5% of cases). Thus, if major changes were observed, these likely reflect real changes in the patient's condition and not chance variation.[21]

In scores of clinical trials the most sensitive measures of the effect of anti-inflammatory drugs have been the number of tender joints, grip strength and duration of morning stiffness.[23] The erythrocyte sedimentation rate (ESR), in itself a more objective measure, often has proved disappointingly insensitive to drug effects in older patients.[21] Grip strength is one of the most repeatable and sensitive measures, but may be affected markedly by age and established deformities.[21]

As a result the relative severity indicated by any one of the above four measures rarely agreed exactly with the other three.[23] The search to reduce multiple measures to a single number, led us to develop a "pooled index",[24] resulting in major gains in sensitivity and reliability as shown by data analysis of 33 hospitalized RA patients, each evaluated an admission and 10 days later by four groups of observers.

TABLE 6

UNIVERSITY OF TORONTO RHEUMATIC DISEASE UNIT

RHEUMATOID DISEASE ASSESSMENT Date_____

Patient's Name Mr. Mrs. Miss_____ Age_____

Address_____ Tel:_____

Rheumatic Diagnosis_____ Duration_____

INFLAMMATORY ACTIVITY

Duration of morning stiffness, hours_____

Grip strength, mm. of Hg. Right_____/20

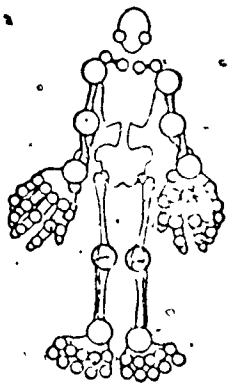
Left _____/20

Number of active joints _____

Sedimentation rate _____

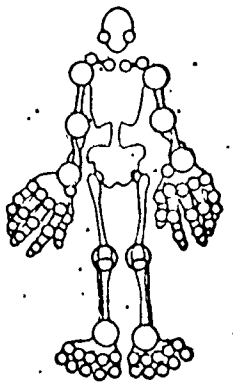
ACTIVE JOINTS

(Mark if effusions, tenderness)



LIMITATION OF RANGE

Mark if more than 20% loss of flexion, extension, or total movement. Note range.



DESTRUCTION AND DEFORMITY

Mark lax collaterals, subluxation, malalignment, metatarsal prolapse, hammer toes, bone-on-bone crepitus (excluding osteoarthritis).

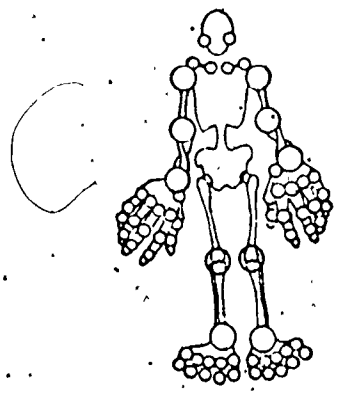


TABLE 7

Ten Day Variability Study of 500 RA Patients[22]

| | Percentile Grade Limits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 |
| Morning stiffness (minutes) | 5 | 30 | 60 | 75 | 90 | 120 | 160 | 220 | 300 |
| | Males | | | | | | | | |
| Grip strength (mm mercury) | 250 | 190 | 160 | 140 | 125 | 105 | 90 | 75 | 55 |
| | Females | | | | | | | | |
| | 190 | 150 | 130 | 110 | 100 | 85 | 75 | 60 | 50 |
| Number of active joints | 4 | 6 | 9 | 12 | 15 | 20 | 25 | 30 | 36 |
| Sedimentation rate (Westergren mm/hr) | 10 | 20 | 28 | 35 | 40 | 50 | 60 | 70 | 90 |

While the major application of the "pooled index" will be in the evaluation of experimental manoeuvres, it lends itself well to clinical evaluations of individual patients, so that each plan of management becomes a miniature therapeutic trial.

Of all the therapies available, the most important is control of joint inflammation through judicious drug management. Smythe's quote in this regard is very apt: "When the fire is raging, the most urgent task is to bring it under control."[25] The protocol for drug management he describes in Table 8, was applied to patients in the validation study, and its efficacy was strikingly demonstrated under the ideal conditions of a Rheumatic Disease Unit[24] (RDU).

Complimenting this protocol, other therapies provide a wider dimension of care, based on a model comprehensive pyramidal plane of management (Table 9).[2] How comprehensive management can favourably affect the functional outcome of patients with RA was aptly demonstrated in a series of longitudinal studies in Edinburgh.[26] Of 307 hospitalized patients who were followed over a period of two years, improvement was most noticable on discharge from hospital, was somehow maintained at two years and due to unrelenting disease, declined at nine years from levels previously achieved (Table 10).

TABLE 6

Expectable Results with Drug Therapy for Rheumatoid Inflammation[25]

| Problem | Treatment | % Responding | Comments |
|---|---|---|---|
| First presentation, active polyarthritis | Enteric-coated aspirin to serum level of 20 mg% | About 30% | Typical dose 50-60 grains/day; scale initial dose according to size and age, starting slightly low |
| Complaints, uncontrolled disease, side effects, or secondary relapse | Re-education to maintain anti-inflammatory levels of aspirin continuously | About 20% | Patients often prejudiced against or fearful of aspirin, or equate analgesia with anti-inflammation; keeping diary improves compliance, patients should be told salicylate levels |
| Polyarthritis, uncontrolled or relapsed | 1. Hospitalize (see comments)<br>2. Initiate disease-suppressive therapy (gold or chloroquine) | 1. Improvement, 75% in 10 days; adequate control, 50% in 10 days<br>2. Improvement, 50% in 3 months; adequate control, 35% | 1. Hospitalization faster, probably cost-effective; identifies non-responders early for advanced therapy |
| One or two stubborn joints | 1. Local steroid<br>2. Radiation synovectomy or surgery (see comments) | 50% - 70% | 2. Radiation best when no instability, malalignment, or bone-bone crepitation; surgeon can correct mechanics as well as remove synovium |
| Erosive resistant disease | Advanced disease-suppressive therapy (see comments) | Adequate control in 50% | Gold or chloroquine, if not previously tried; azathioprine, penicillamine, or other cytotoxic agent for non-responders |
| Failing function | Systemic steroids | Adequate function in about 50% | Indicated for no more than about 10% but prescribed for up to about 50% of patients with RA |

TABLE 9

A Comprehensive Pyramidal Plan For RA Management[2]

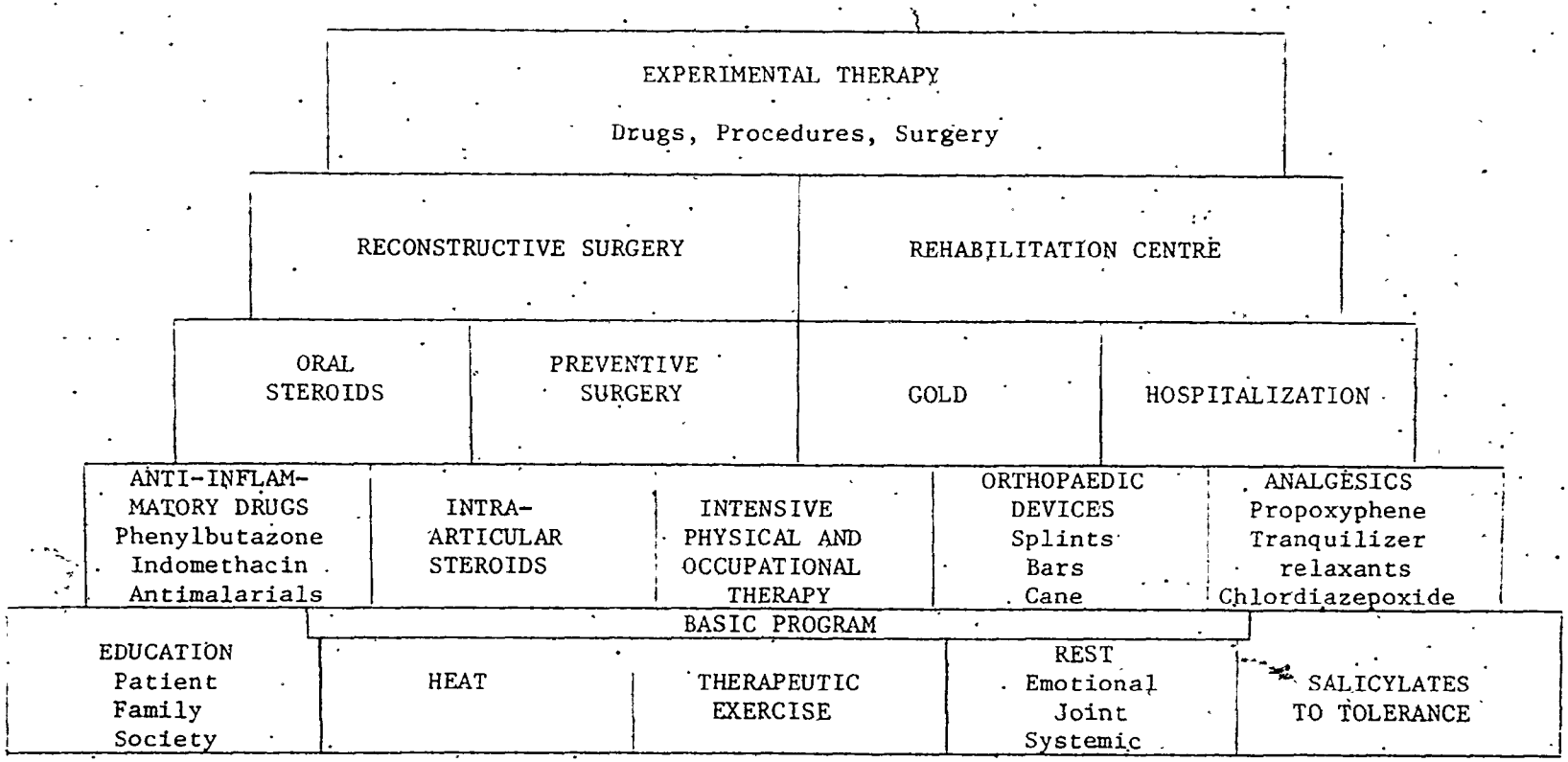


TABLE 10

Nine Year Follow-up of 307 Hospitalized Patients with RA - Edinburgh[2,3]

| Category | On Admission | On Discharge | At 2 Yrs. | At 9 Yrs. |
|---|---|---|---|---|
| Severely handicapped | 200(65)* | 77(25) | 86(28) | 120(39) |
| Fit for light work | 107(35) | 196(64) | 135(44) | 126(41) |
| Normal activities | 0 (0) | 34(11) | 86(28) | 61(20) |

(%)*

A more recent randomized controlled trial[27] of RA patients, demonstrated that comprehensive management using an inter-disciplinary team approach is superior to standard management in an arthritis clinic. Changes in five indices of disease activity over seven to 10 month periods resulted in improvement in both groups, however, the improvement in the comprehensive management group was superior in all indices though not statistically significant. The data suggest a trend in a favourable direction for the comprehensive group when compared over time, with the control group.

Although there is no evidence in the literature that the natural progression of the disease is altered by any of the available types of therapies, much can be done to control joint inflammation and thus improve function in patients exposed to intensive and comprehensive management.

1.4 Sources of Care

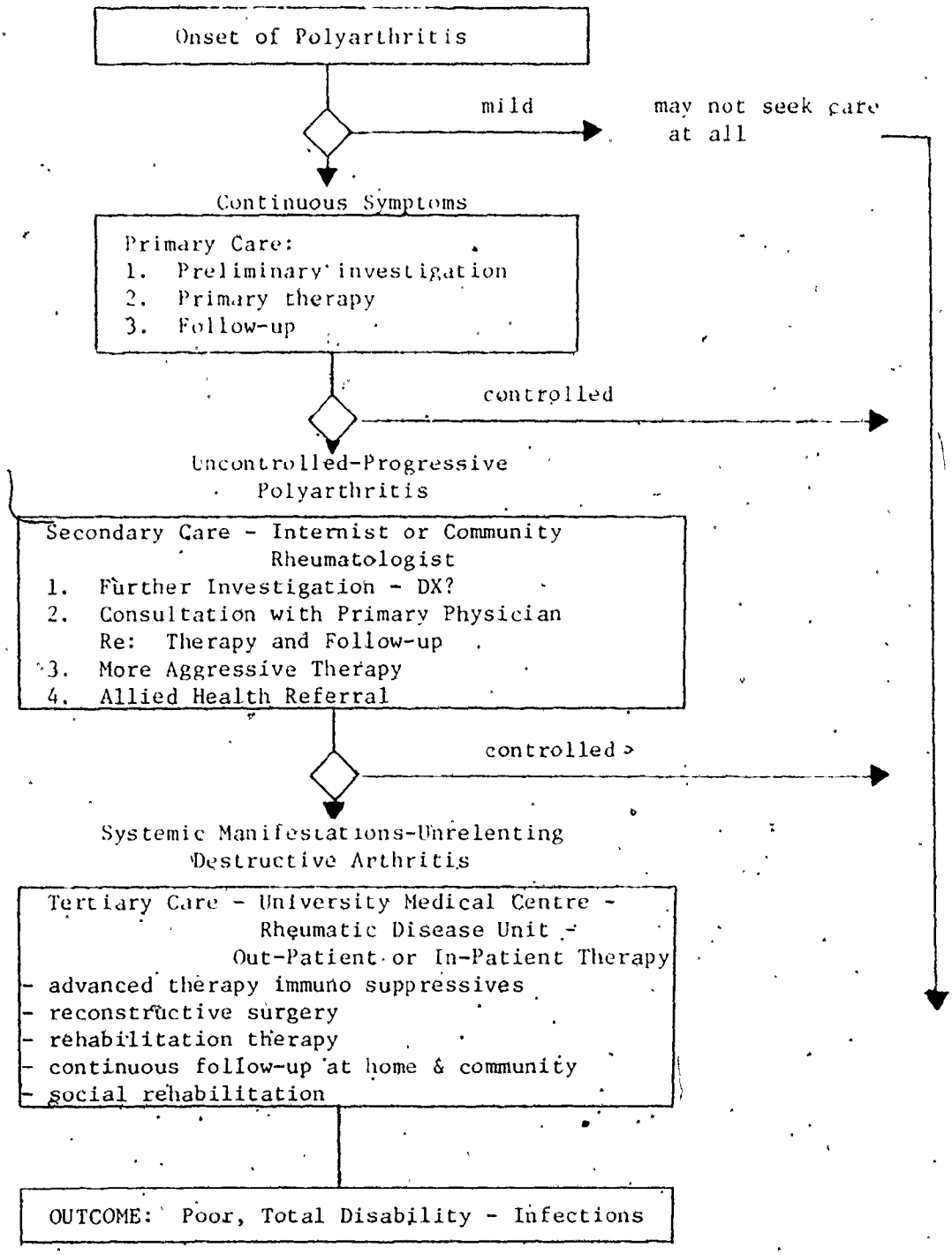
Where and how an RA patient is best to be treated at any point in time depends upon his disease severity and prognosis and the availability of professional skills and institutional resources within his community.

Table 11 provides a schematic presentation of the processes of care available to the typical patient with RA in Southern Ontario. The unpredictable nature of RA, its varying levels of disability and complexity of management from the perspective of family physicians often conspire against the patient receiving appropriate care even when specialists and specialized services are readily available. Patterns and frequencies of referrals from primary to secondary or tertiary levels have not been investigated to date. Some patients seek primary medical care after the characteristic deformities have been established, others are referred for consultation to specialists too late or not at all, and still others are referred to surgeons (rather than internists) who may embark on expensive and often ineffective preventive and reconstructive surgery. An unknown number never seek medical care for their RA, falling early victims to quacks and quasi health cures. Others may resort to quackery after medical therapy has failed them.

According to the New Haven Survey of Joint Diseases[28] and surveys in England and Wales,[29] only 15.3% of arthritis patients aged 35 to 64, and 22.5% of those aged 65 and over, seek medical care for their arthritis. A recent study of arthritic and rheumatic complaints in Southern Ontario,[30] revealed that only 25% of those with complaints sought medical care. The higher rates amongst those who sought care in Southern Ontario is probably due to universal health insurance.

TABLE 11

SOURCES OF CARE FOR RA PATIENTS IN SOUTHERN ONTARIO



Amongst those who do not seek care an unknown number are probably victims of quacks or their cures. According to a U.S. survey, arthritics in one year spent $250 million on quackery, compared to $117 million on prescribed medications[19] (Table 5, page 14). This probably stems from the folksy attitude of society, at large, towards arthritis, or according to Acheson[28] is probably due to an attitude of resignation to what patients with progressive joint disease consider to be the inevitable; it takes many years for the inevitable to happen.

Institutional care for arthritics in Canada is available within the mainstream of other health services. A sudden onset of symptoms or an exacerbation of disease may result in hospitalization or hospitalization may be prompted by the need for reconstructive surgery and finally, institutional chronic care may be necessary for those who can no longer fend for themselves. Therefore, the institutional care setting may be in an acute community hospital, a university medical centre, or an extended care facility. Before and following hospitalization care is available in the various communities on an out-patient basis, or in the home through the mobile services of home care programs and The Arthritis Society.

In Canada, hospital care at the tertiary level (university medical centres) in a specialized Rheumatic Disease Unit (RDU) setting was pioneered in the early 1960's with the first such Unit in North

America opening its doors in 1962. Today RDUs are affiliated with all Canadian medical school teaching programs, providing an essential resource for the training of specialists in the field, and basic undergraduate training for medical and allied health students. In addition, the RDUs act as a focal centre for research in the field of arthritis. Fig. 2 provides a schematic presentation of the RDU concept as envisaged by Ogryzlo et al.[31] The effects of the RDU program on treatment outcomes have never been evaluated in an experimental trial. Most recently, in a study of 33 patients, evaluated on admission to an RDU and 10 days later it was shown that patients achieved approximately 40% improvement in five separate measures of inflammation compiled into a pooled index[24] (Table 18). As a follow-up to that research, the authors are presently investigating in an experimental trial the relative cost effectiveness of in-patient therapy in an RDU, compared with intensive out-patient therapy.

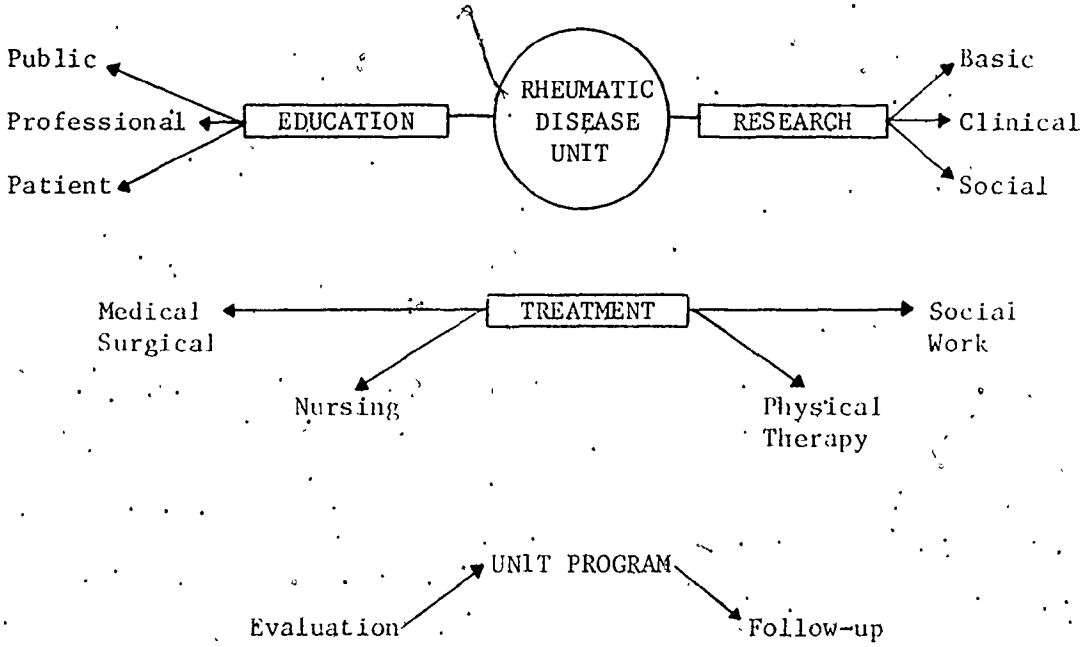



Fig. 2 The Rheumatic Disease Unit Concept[31]

The RDU program had a major effect on the development of rheumatology manpower and resources in Canada. These may be measured in terms of:

a) An increase in the number of rheumatologists from two in 1948 to 89 in 1974,

b) an increase in RDU beds from 30 in 1962 to 338 in 1975,

c) a decrease in average patient stay from two months in 1964 to 18 days at present.[32] Table 12 provides a list of RDUs by location, number of beds and patient productivity.

TABLE 12

RDU - Selected Statistics
for the 12 months ended June 30, 1975[32]

| University | No. Beds | No. Discharges | No. Out-Patient Visits |
|---|---|---|---|
| Memorial | 17 | 169 | 1,695 |
| Dalhousie | 18 | 243 | 2,023 |
| McGill | 4 | 852 | 5,725 |
| Montreal | 12 | 376 | 1,754 |
| Sherbrooke | 20 | 218 | 3,081 |
| Ottawa | - | 18 | 2,025 |
| Queen's | 16 | 273 | 2,859 |
| Toronto | 102 | 1,573 | 6,636 |
| McMaster | 45 | 461 | 3,972 |
| Western Ontario | 18 | 265 | 1,313 |
| Manitoba | 20 | 205 | 3,969 |
| Saskatoon | 12 | - | 4,812 |
| Alberta | 20 | 210 | 5,744 |
| Calgary | 12 | 307 | 1,271 |
| British Columbia | 22 | 159 | 537 |
| Totals | 338 | 5,329 | 47,016 |

The constraints on expansion of health services and the development of new programs imposed by federal and provincial governments in Canada are expected to reduce the rate of growth in RDU programs. At present not more than 2% of patients requiring active treatment for RA are admitted to an RDU in any one year, and in view of these constraints, it is unlikely that this proportion would increase appreciably in the next 10 years. Furthermore, a substantial increase in rheumatology manpower is not likely as most graduate training programs are imposing quotas on the total number of trainees in the various subspecialities of medicine. In Ontario, rheumatology was given second priority behind such subspecialties as dermatology, respirology and immunology. With these limits on growth, the RDUs can act only as tertiary referral centres for a small number of patients with complex problems, the majority receiving care from other specialists, primary care physicians and a large proportion not receiving care at all.

From the perspective of specialists in the field, the low usage rates for medical services amongst arthritics probably stems from an attitude of pessimism, imparted on the patients by providers of primary care, who are incapable of duplicating results achieved in specialized centres such as RDUs. Ogryzlo in an editorial on rheumatology manpower, expounds further on this issue: "The great variety and complexity of many of these diseases make it apparent that no family practitioner can ever hope to acquire an adequate working knowledge in rheumatology,

and at the same time remain proficient in all of the other diseases that afflict mankind. This is even more true when one considers that the vast majority of physicians practicing today, received no formal education or instruction in the rheumatic diseases, during their undergraduate training and little or no exposure to patients suffering from arthritis during their internship in hospitals."[33]

These views are further confirmed by a survey of undergraduate medical training in Canada, based on information obtained from Directors of RDUs (Table 13),[32] where it was shown that not all medical graduates are exposed to rheumatology, and when training is provided it does not equip the physician with the skills necessary to provide effective care. It is extremely unlikely that existing training programs and manpower resources can provide adequate training for all undergraduates in the next decade.

The needs of the practising physician are even more urgent. Existing consultation services, travelling clinics and refresher courses cannot hope to fill the educational or service gap. The time available to the average family physician to acquire and keep up-to-date on modern treatment skills in the rheumatic diseases is probably not cost effective as on the average he may be caring for no more than two or three RA patients at a given time. It is estimated that fewer than 5%[33] of those affected are likely to receive the benefit of a con-

TABLE 13

Rheumatological Education of Undergraduates

In Canada 1975[32]

| Graduating Classes (all schools) # | Didactic Instruction | | | Clinical Experience: Bedside Demonstration Clinics or Equivalent | | |
|---|---|---|---|---|---|---|
| | Less than 10 hrs. % | 10 to 20 hrs. % | More than 20 hrs. % | Less than 5 hrs. % | 5 to 15 hrs. % | More than 15 hrs. % |
| 1541 | 29 | 51 | 20 | 28 | 43 | 29 |

sultation to a rheumatologist in any given year, so that the remainder are cared for in the mainstream of medicine, by quacks or do not seek care at all.

It is evident from the foregoing that certain realistic and achievable alternatives for care are needed to provide expert assistance to physicians and patients at the primary care level.

## 1.5 Special Training For Arthritis Society Physiotherapists: A Randomized Controlled Trial

Since its inception in 1948, The Arthritis Society in Canada recognized the need to provide home service for patients with complex rheumatic problems. The first such programs began in the early 1950's in both British Columbia and Ontario and remain the only services of that type provided to arthritis patients in these provinces. At present the Society's program in Ontario consists of home physiotherapy only, delivered by a staff of 27 full-time physiotherapists (PTs) deployed in Southern Ontario.

In constrast to family physicians physiotherapists are full-time professionals in the field of musculoskeletal diseases. The Society's therapists working specifically with rheumatological disorders, provide treatment services and assess changes in the level of function at the physician's request. At present, they are not asked to probe more deeply

in the causes of failing function, leaving these "diagnostic" responsibilities to the physician.

Standardized and quantifiable techniques for evaluating RA have been developed and are regularly in use at RDUs.[21, 23, 25] These methods lend themselves well to communication with specialists and non-specialists. The success achieved in RA treatment outcomes in an RDU has been attributed to the use of these techniques.[25] Their direct affect on outcome at all three levels of care have never been tested in an experimental trial.

It is plausible that physiotherapists, specially trained in their use, could vastly improve their own effectiveness and more importantly by specially prepared reports, also increase the effectiveness of primary care physicians in the control of joint inflammation.

Such assistance is likely to have effects on the community parallel to the effects of an intensive inter-disciplinary program in an RDU and will result in a more intensive goal-directed treatment program, a reduction in inflammatory activity and, therefore, an increase in the level of function, and a financial saving to the community due to a decrease in medical follow-ups, consultations and hospitalization.

This potential for patient benefit led to the formulation of the following research question: Are the outcomes of RA patients improved

when their family physicians are provided with information gathered by specially trained physiotherapists?

To answer this question, a randomized controlled trial design was selected as the most powerful strategy to determine efficacy. The prespecified experimental manoeuvre was the modern quantitative techniques of evaluation of women with RA provided to family physicians by physiotherapists specially trained in their use. The prespecified comparison manoeuvre was the traditional evaluation of women with RA provided family physicians by physiotherapists without any training in the specialized techniques. RA women referred to The Arthritis Society home service by their family physicians, and who met prespecified selection criteria were randomly allocated to two groups evaluated and treated at home by specially trained or traditional physiotherapists. On admission to the trial at four and at 12 months, patients in both groups were evaluated at home by an independent assessor, a non-medical person trained to gather information using a structured questionnaire.

This skeleton design was developed into a detailed proposal which was submitted to the Ontario Health Resources Development Plan, and was subsequently approved for funding in the spring of 1973.

To summarize: arthritis is a major health problem in the province, whether measured in terms of time lost from work, cause of

disability, or resulting human suffering. An effective arthritis control program must be based on four foundations:

a) Removal of financial barriers,

b) a leadership organization with a plan,

c) special treatment training centres,

d) community delivery systems.

The Arthritis Control Program in Canada is among the very best in the world,[31] with respect to the first three factors, but major problems still exist in delivering care to patients in their own community. This new program is designed to help close that gap by providing the community physician with information and skills not presently available to him.

## 1.6 The Author's Unique Contribution

The author of this thesis was engaged from the outset with a medical colleague and a biostatistician as co-investigators, and in that capacity made a unique contribution to the trial in the following areas:

a) Development of the experimental design in preparation for submission for funding. Specifically, the formulation of research questions, hypothesis and design; the introduction of the independent assessor to the field of rheumatology as a measure of outcome in RA trials,

b) following approval of the submission, was engaged in the following activities during the preparatory period: selection and hiring of independent assessors and trained physiotherapists; implementing the necessary strategies to prevent contamination of the experimental manoeuvre; designing all the necessary forms and instructions to be used for and by research subjects,

c) execution of the design during the pretest and experimental period. More specifically: overall supervision of the activities and performance of physiotherapists, independent assessors and research assistants; supervision of intakes, allocation strategies and quality of data provided by the assessors; based on pretest experience, modifying intake strategies, experimental manoeuvre, sample size and outcome strategies,

d) preparation and submission of annual reports and budgets to the agency funding the trial,

e) assisted his co-investigators in the design, execution and super-

vision of a validation study that preceeded the experimental trial, which was conducted to determine the effectiveness of the assessment techniques used in detecting treatment differences.

This is a "compound" thesis, focussing on the design and execution of a randomized controlled trial. A number of modifications were introduced to the design following the pretest and validation study, and others during the experimental period. These briefly related to criteria for selection and training of physiotherapists and assessors, the experimental manoeuvre, prognostic stratification, allocation strategies, slow intakes, sample size and the prespecified outcome measures. Section II, Methods: design, will focus on the original design at the time of submission for funding. Section III, Methods: execution, will focus on the modifications introduced following submission, and includes justification of these changes and a discussion of their effects on trial design.

## 2. METHODS: DESIGN

### 2.1 Introduction

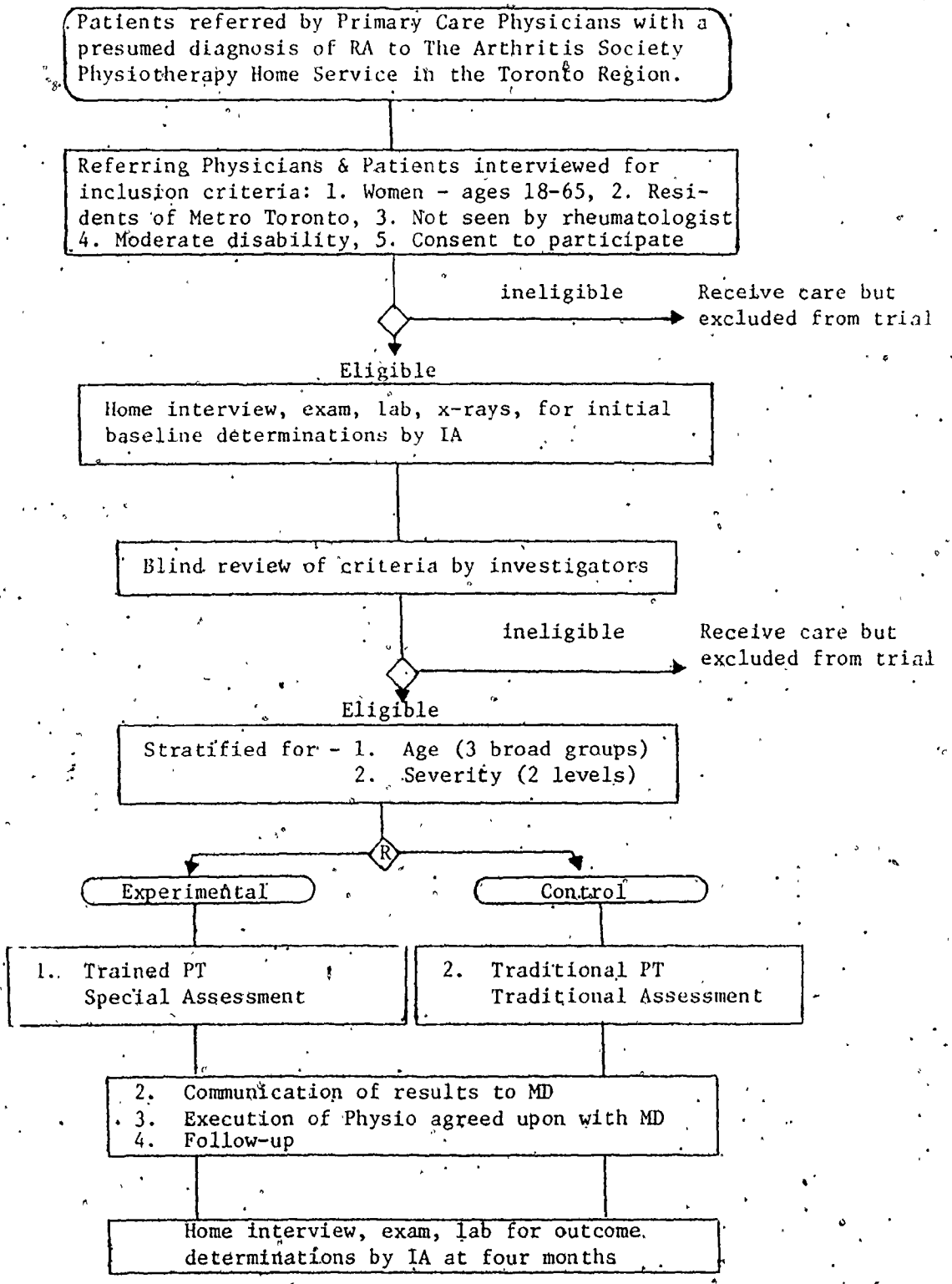
In order to determine if the outcomes of patients with RA could be improved by providing the family physician with detailed information on the patients clinical state by specially trained PTs, a randomized controlled trial design was chosen. Fig. 3 provides a flow chart of the experimental design as it was envisaged at the time the protocol was submitted for funding. The chart describes the source of intakes, criteria for inclusion, stratification methods for eligible candidates, patient allocation into groups, baseline determination and blind review of criteria. This is followed by the application of the experimental and control manoeuvres, the provision of services and follow-up care, and finally, outcome determinations at four months.

The material in this section will describe the design in detail, elaborating on strategies developed for patient selection and allocation, the evaluation of outcomes to be developed, the experimental manoeuvre, ethical consideration and the criteria for favourable results.

### 2.2 The Trial Site

The region of Metropolitan Toronto, Ontario was selected as the

FIG. 3. SCHEMATIC PRESENTATION OF TRIAL DESIGN AS ORIGINALLY ENVISAGED



trial site, as the resources of the University of Toronto and The Arthritis Society needed to conduct the research are readily available, and due to the regions' population density. The University maintains the largest and best equipped RDU in Canada and a professional staff with experience in research and medical education. The Arthritis Society in Canada maintains its national headquarters in Toronto from where the clinical, administrative and professional resources, of the region are co-ordinated. In view of that this centre lended itself well to the day-to-day co-ordination of the trial.

In addition, the Society maintains a smaller but geographically separate office for its five staff physiotherapists including a Senior PT, all of whom provided home services for patients in the region. The two separate offices and large staff of PTs make it possible to select randomly experimental and control PTs, and thereafter separate them by office location to avoid contamination of the experimental manoeuvre. Finally, the larger population in the area was to yield a larger proportion of subjects suitable for research than smaller centres would. All these factors combined made this site the preferred choice.

## 2.3 Referrals to The Arthritis Society Physiotherapy Home Service

All medical referrals for home service are received at The Arthritis Society's Toronto Service Centre (60 Overlea Blvd.). These are screened

and processed by the Senior PT and then assigned to staff PTs according to geographic location.

For the purposes of this trial, the mechanism of processing referrals was to continue along these lines. However, if upon receipt of a referral, the Senior PT discovered that a patient met all trial admission criteria, the patient was to be tentatively admitted.

## 2.4 Criteria For Patients Admitted to the Trial

Patients were to be admitted to the trial by the Senior PT if they met the following criteria:

a) Women age 18-65, residents of the Metro Toronto region, (all Boroughs of Metropolitan Toronto and the City of Mississauga),

b) referred to The Arthritis Society home physiotherapy by a family physician,

c) with a presumed diagnosis of RA as indicated by the referral and confirmed with the physician,

d) encountering difficulties in self-management at home sufficient to warrant grading in ARA functional class II and III (see Appendix I)

as determined by the physician,

e) had not at any time sought consultation with a rheumatologist or specialist in internal medicine for their RA,

f). that after proper explanation, they sign a consent form.

If subsequent to admission to the trial it was discovered that a patient did not meet these criteria, she was to be withdrawn from the project; however, services would still be provided on a regular basis by the attending PT.

It was recognized that certain personality factors amongst RA patients, such as the "complaining" type and "paradoxical responders" reported by Moldofsky et al,[34, 35] may contribute to the patients decision to seek medical help, and to the physician's decision to request the Society's services. Therefore, assessment of the patient's personality factors, and patient and physician compliance are essential, as these may have a confounding effect on the results of the trial. If it were to become apparent that only psycho-social factors, rather than active polyarthritis were to be the chief determinant for the referral, the patient was to be excluded from the randomized trial.

2.5 Ethical Considerations.

As in all current experimental trials involving human subjects, four ethical issues were considered:

a) Informed consent,

b) freedom to refuse or withdraw without loss of care,

c) freedom from assault,

d) confidentiality.

No patient was to be admitted without the informed consent of both patient and attending physician. On identifying a patient suitable for the research, the Senior PT was to seek phoned consent from the family physician and patient. If after proper explanation both agree to participate, the physician was to be mailed a consent form for his signature (Appendix II), and the patient's signed consent (Appendix III) was to be obtained on the first interview by the Independent Assessor (IA). The consent forms explained to the patient and physician, the objective of the trial and the responsibilities of the IA in obtaining essential clinical information; the withdrawing of blood and arranging for x-rays of the hands. Patient co-operation was to be sought, but they were to be reassured that they were free to withdraw at any time without com-

promising their regular treatment program. They were also to be reassured about the confidentiality of that information.

If a patient refused or failed to sign the consent form, the IAs were to terminate the interview. Simple failure by the physician to return the signed consent form would not have disqualified the patient from participation in the trial but would serve as an important measure of physician compliance.

## 2.6 Independent Before-After Measurement

Patients who met initial admission criteria were to be evaluated by an Independent Assessor (IA) before the application of the experimental manoeuvre and then at four months as an outcome measure, using a standardized prestructured questionnaire.

It was envisaged that the IA would be a female non-medical person, who met prespecified eligibility criteria (Appendix IV) and was trained in interview techniques and the use of a prestructured interview questionnaire, to be developed and validated (Appendix V and VI) in association with this research.

The primary objective of the assessments was to provide a blind and unbiased measure of change in the inflammatory activity of the patient's

RA, the level of physical function, adequacy of previous therapy, patient's personality assessment and patient-doctor interaction. Specifically these measures were to include the following:

a) Inflammatory activity measures to be used were: grip strength using a modified manometer, reflecting level of inflammation in the joints of the hands and wrists; stated duration of morning stiffness measured in minutes; the number of inflammed joints by guiding the patient through a self-examination for tenderness on pressure or stress pain on 32 joints; and the erythrocyte sedimentation rate (ESR) the blood sample withdrawn and tested by the IA at home. (For details see Appendix V, p. 135-138),

b) physical function: by means of structured questions that assess specific activities of daily living (ADL) and major changes in function, each were to be pretested and then numerically weighted and scored, (Appendix V, p. 120-134),

c) data on adequacy of previous therapy was to be obtained by the patient's statement of drugs prescribed and dosage levels, checked against labels on prescription bottles and blood salicylate levels (Appendix V, p. 106-118). Judgment on adequacy of therapy according to a prespecified scoring schedule using a peer review method,

d) the patient's personality assessment was to be based on Cattell's 16 personality factors test (Appendix VII),

e) data on patient-doctor interaction was to be based on patients' stated understanding of the disease process, side effects of medications and actions to be taken in that regard, satisfaction and benefit derived from their medical care. An "interaction" score was to be developed as judged by the peer review method.

The secondary objective of the assessments was to obtain data on the characteristics of the population sampled relating to the diagnosis, prognosis, socioeconomic and demographic factors. That information was to be reviewed by the investigators as baseline determination in terms of diagnosis and prognosis, disease severity and duration as these pertain to inclusion or exclusion criteria (Appendix VIII).

The second assessment at four months was to be designed to measure changes in items a), b), c) and e). In addition, the physician was to be asked to outline treatment prescribed to detect gaps between prescribed, understood (as revealed by questionnaire) and achieved therapeutic program. Referrals from GPs to other medical specialists were also to be recorded.

The IAs were to be trained also to withdraw blood and arrange for samples to be mailed or delivered for analysis of uric acid levels, latex fixation litres and serum salicylate levels. They also were to arrange for x-rays of the hands to be taken. These laboratory data were to be incorporated in the trained PTs report on the experimental patients, but were to be sent directly to physicians of control patients.

## 2.7 Final Selection, Stratification and Randomization

Data derived from the independent assessment was to be transferred to a special selection form (Appendix VIII) for blind review of criteria by the investigators. Following this review patients were to be stratified by three broad age groups and disease severity, then randomly allocated to an experimental group who were to be evaluated and treated by specially trained PTs and a control group, who were to be evaluated and treated by traditional PTs.

## 2.8 The Experimental Manoeuvre

Two PTs were to be selected randomly from a group of six employed by The Arthritis Society, all equally familar with the rheumatic disease field and home services. The two selected were to be trained for a six week period at the University of Toronto RDU, Wellesley Hospital, in detailed assessments of patients with RA, based on techniques[21] currently

in use at that RDU. The PTs, following their training, were to act as the agents who would execute the experimental manoeuvre. Specifically the experimental manoeuvre was to be the detailed assessments performed by trained PTs on patients with RA, reported to family physicians in a readily communicable form by using a summary sheet to be adopted from that shown in Table 6 (see page 17), accompanied by a covering letter which was to provide further interpretation of these clinical findings and, if necessary, recommendations for action.

In contrast, the traditional PTs were to report according to traditional assessment methods employed by Arthritis Society PTs. These were to be reported also in writing to referring GPs and include information on range of movement, muscle power and level of function.

It was suggested that the trained PTs, by obtaining more objective, standardized and quantifiable information on the patients state, would enhance their own effectiveness as therapists and would improve physician and patient compliance and patient outcomes in comparison to the results of traditional PTs.

## 2.9 Compliance

A patient may fail to improve because prescribed treatment was not carried out. Information relating to patient and physician com-

pliance was to be obtained from the Independent Assessor's questionnaire. If the doctor failed to prescribe the recommended treatment measures as judged by peer review, then the doctor was to be scored "non-compliant" (even though the fault may lie in the PTs report). If the patient failed to follow prescribed measures, then the patient was to be scored "non-compliant". As salicylates are the accepted basic therapy in the management of RA, serum salicylate levels were to be taken as these provide objective evidence of non-compliance on the part of patient and physician.

## 2.10 Sample Size and Rate of Intakes

According to Arthritis Society records for 1971, it was predicted that in the two year period of the study, over 280 patients would meet the criteria with 140 in each treatment group. Previous experience predicts that about 30% of patients will improve one functional class or more during this period of treatment; and an increased rate of clinically significant improvement of about 15% ($\alpha = 0.05, \beta = 0.05$) could be detected with groups of this size.

## 2.11 Criteria For Favourable Results and For The Project

Changes in the following variables were to be the chief basis for evaluation of therapeutic success: activities of daily living, count of

active joints, grip strength and erythrocyte sedimentation rate. The finding of superior treatment success within the group of "trained" PTs was not to be essential to the success of the trial. Assuming adequate methodology, a negative result could be extremely important, cancelling or modifying plans for further extensive (and expensive) development of the physiotherapist as total evaluator of the rheumatological state, rather than continuing in the traditional fashion.

## 2.12 Financial Considerations

The trial budget included provisions for the salaries of the two experimental physiotherapists, their automobile expenses for the period in which they were to be mobile, and their secretarial services. It included a fee per service rate for the Independent Assessors; the cost of services of a medical statistician who will act as a consultant on the project; and expenses for travel of guest faculty and Independent Assessors. Office space, administrative services, statistical services, and project supervision and co-ordination were to be supplied by The Arthritis Society and the Wellesley Hospital RDU without reimbursement.

## 3. METHODS: EXECUTION

### 3.1 Introduction

Depending on the state of knowledge in a particular field and the skills and experience of the investigators, the design of randomized controlled trials can be a relatively simple matter, or if new ground is broken, a rather complex activity. Execution of the design is nearly always a complex activity, the trial described in this thesis was no exception. This section will focus on execution of the basic design, including the pretest, experience during the pretest that led to certain modifications of the original design, and changes introduced for the experimental period. The author will describe the difficulties that arose under the appropriate section, providing in each case justification for the changes and discussing the effects they may have on the results.

The study protocol was submitted to the Ontario Health Resources Development Plan (OHRDP) in November 1972, and was approved for funding as a demonstration project in April 1973. The objectives of the research were also discussed and subsequently approved by the Ontario Medical Association, the College of Family Practice, the College of Physicians and Surgeons of Ontario, and the Canadian Physiotherapy Association. It was also approved by the University of Toronto Committee on human experimentation. Total projected duration of the trial, on submission,

was 32 months; May 1, 1973 to Dec. 31, 1975. The Schedule of Time and Events on Submission (see Table 15) was not adhered to, as a number of design problems arose, which led to an extention of that Schedule by approximately 15 months (see Table 16). Changes in the design were justified in full in the respective annual submissions to the OHRDP, which were subsequently approved by the Ministry's reviewers. The effect of these modifications and delays on the total cost of the study will be discussed in a separate section.

## 3.2 Selection of PTs for Special Training

It was envisaged that two physiotherapists were to be randomily selected from a pool of therapists consisting of four employed by the Society in the Toronto region and others employed outside Toronto who are interested and prepared to move to the trial site. Those selected were to be replaced by two others as traditional PTs.

As no therapists from outside the Toronto region were available for deployment, to proceed with random selection of two from a pool of four therapists in the Toronto area, meant that the two selected will be replaced by two new recruits joining the ranks of traditional PTs, with no, or limited experience, in the field of arthritis and home therapy, resulting in bias in favour of specially trained PTs.

TABLE 14

Schedule of Time and Events on Submission

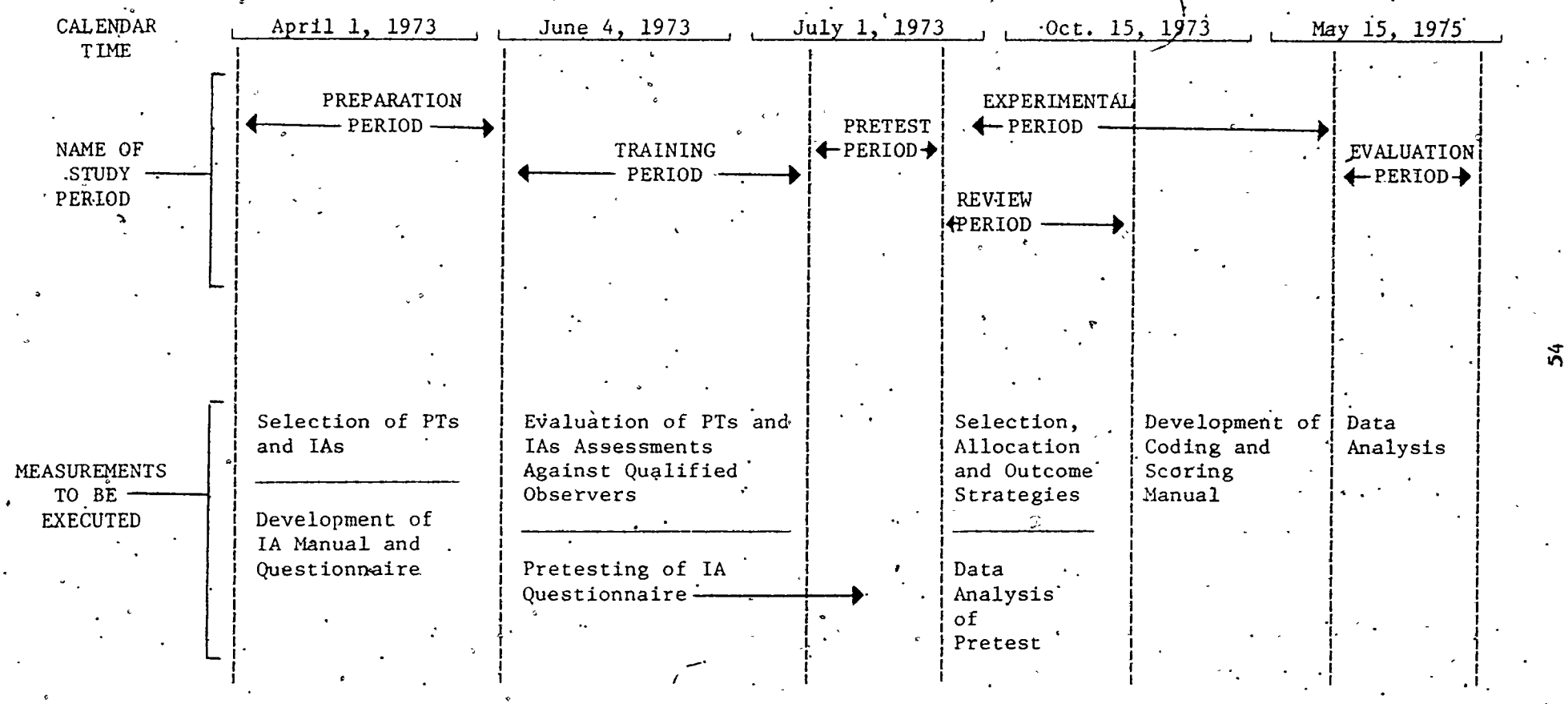
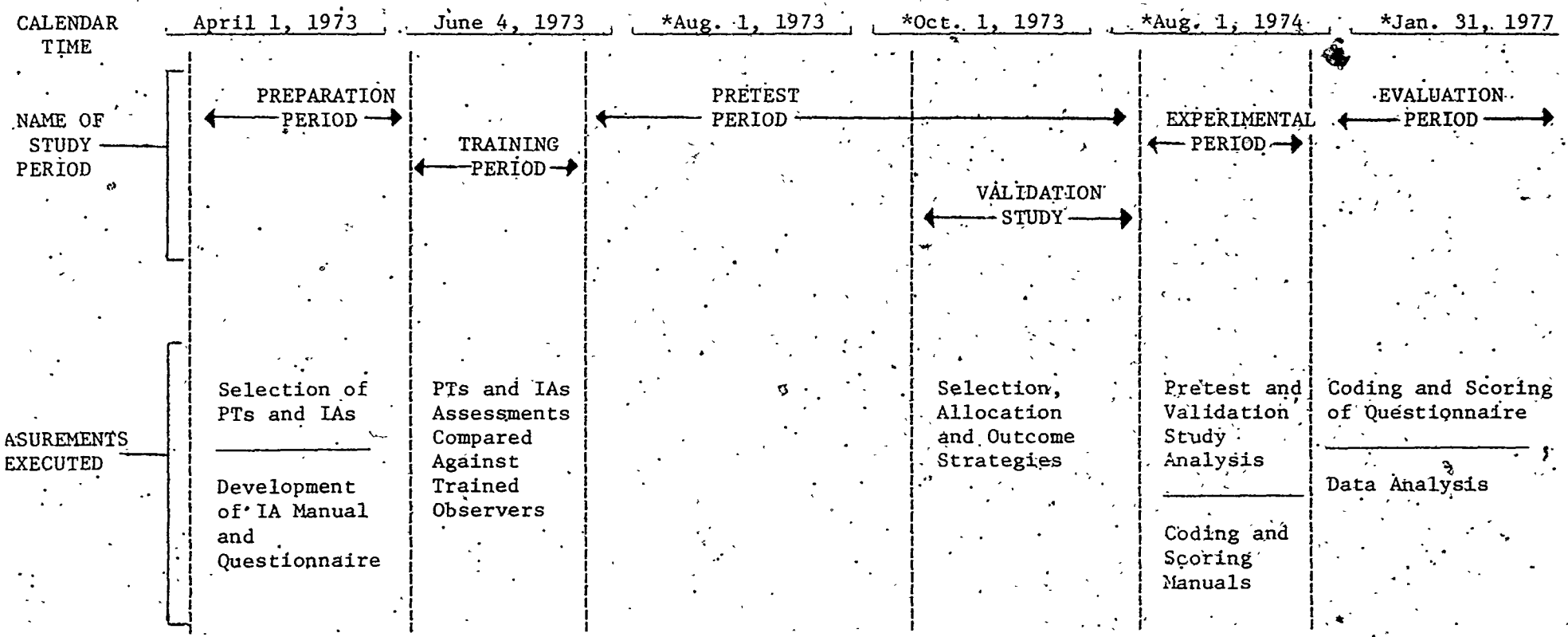


TABLE 15

Schedule of Time and Events on Execution




idicating changes in Time Schedule on Execution.

The two PTs that were finally assigned for special training were selected according to the following criteria:

a) Ability to provide a minimum of a two year commitment to the study,

b) possessing a keen interest in the study and the assessment techniques, and likely to contribute to the future development of these methods on termination.

One candidate was selected from the group of four PTs employed by The Arthritis Society in Toronto, the other was recruited from the outside. A new therapist was hired as a replacement to the PT assigned to the study, restoring the total number of traditional PTs to four with one new recruit, vis a vis two experimental PTs, one of whom was a new recruit. This revised method of selection was more balanced as the pool of available therapists who were able to participate was limited to the four in the Toronto area.

## 3.3 The PT Training Program

The two PTs selected for special training underwent, initially, a four week intensive training program at the Wellesley Hospital Rheumatic Disease Unit in Toronto. The teaching methods consisted primarily of didactic sessions, preceded by assigned reading of core material; plus

bedside demonstrations, case workups and case reviews with assigned faculty. The basis of the curriculum was a standardized system covering:

a) Inflammation,

b) damage and deformity,

c) function,

d) motivation, with a reporting scheme develped from controlled clinical trials conducted at the Wellesley Hospital RDU.[21, 34, 35]

The curriculum also included discussions in sociology, psychology, drug pharmacology and other factors likely to influence results. During that phase and the period that followed, the assessments and reporting schemes of the trained PTs was compared from time to time:

a) Against each other,

b) against an experienced rheumatologist, and

c) against a physician in general practice with no special interest in arthritis.

The intensive training program was followed by a pretest of study methods. During that time, the trained PTs applied their new skills in the field duplicating what was perceived to be true experimental conditions. As an extention to their basic training, the PTs met for one hour each week with an assigned faculty member, to discuss their findings and develop the reporting strategies that are most likely to produce favourable outcomes. The reporting methods, developed during the pretest, served as the experimental manoeuvre, in contrast to the traditional reporting methods of the traditional PTs which served as the control manoeuvre.

## 3.4 Application of the Experimental Manoeuvre

Overly long and complex evaluation schemes are easily developed; simple ones containing essential information expressed in readily communicable form are much more difficult. Measures of inflammation and destruction shown in Table 6 were included in a summary data sheet (Table 16) to which was added:

a) Summary information regarding periarticular and systemic features of the disease,

b) the ARA functional class, extended to one decimal place to indicate position in class, and

TABLE 16

## SUMMARY OF CLINICAL AND LAB FINDINGS IN POLYARTHRITIS

Patient's Name Mr Mrs Miss . . . . . Age . . . . Assessment Date . . . .

Primary Diagnosis . . . . . Onset of Disease . . . .

Secondary Diagnoses

1 Duration of Continuous Symptoms . . . . Yrs . . . . Mths

2 Number of Active Joints
(Definite localized tenderness, stress pain, effusions, not just pain during arc of movement)

3 Number of Damaged Joints
(Including lax collaterals, subluxation, bone on bone crepitus, malalignment, loss of more than 20% passive ROM Excluding Heberden's nodes)

4 Relevant Periarticular Findings

5 Significant Systemic Features

6 Duration of Morning Stiffness . . . . Hrs. . . . . Mins
(normal value < 15 minutes)

7 Grip Strength . . . . R . . . . L
(normal value > 250)

8 Functional Class (see below)
(Complete items 9 11 when data is available)

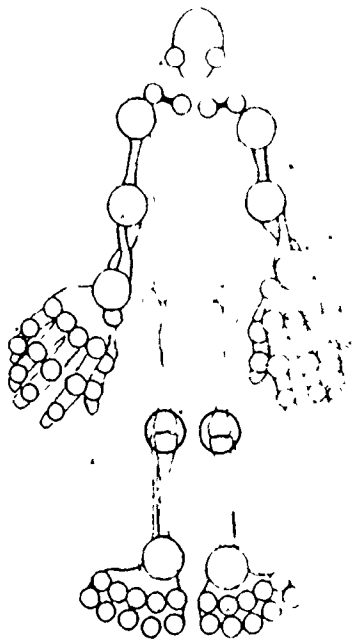
9 Latex Fixation
(abnormal > 1 160)

10 E S R

11 Salicylate Level
(Therapeutic level 15 25 mg.)

12 Major Problems

ACTIVE JOINTS



c) laboratory findings related to the ESR (inflammatory) latex fixation (diagnostic) and serum salicylate levels (efficacy and compliance).

The reporting strategy developed was as follows: the PTs upon initial referral, were to visit the patient at home and perform a complete medical history, evaluate the patient's state according to measures listed in the summary sheet and then compose a brief report in letter form, addressed to the referring family physician. The letter which accompanied the clinical summary, emphasized to the physician the significance of these findings, and based on that evidence suggestions were made, as to desirable courses of action to control inflammation. In addition, the therapist outlined the PT treatment plans and provided information on the patient's life style, social and family interaction and any socioeconomic problems that might have an effect on outcomes of therapy. To improve physician response, the standard response form used by the Society's therapists (Appendix IX) accompanied the correspondence. Patients were maintained on treatment until such time when the physician and PT decided jointly that the therapeutic goals have been achieved.

During the pretest the trained PTs gained experience in the application of the experimental manoeuvre by reporting to referring physicians on patients randomly assigned to them during the pretest

(five in all) and scores of others with polyarthritis who did not meet all study criteria. Pretest experience demonstrated that on patients where medical intervention was indicated, physicians, on receiving the trained PTs reports, responded intially in three different ways:

a) The concerned positively responding physician who was appreciative of the information and initiated or modified the therapeutic regimen,

b) the indifferent physician who took no action at all, and

c) the resentful negatively responding physician who regarded the report as an unnecessary intrusion on the "practice of medicine" and the "doctor-patient relationship".

While these initial reactions were mostly the result of verbal communications between the PTs and physicians concerned and are therefore anecdotal, it became evident that certain modifications in the reporting strategy were required in order to increase the PTs credibility. Furthermore, in discussions with the PTs, it was found that certain positively responding physicians took steps on behalf of their patients that the investigators considered either ineffective or undesirable (e.g. systemic steroids) further revealing a serious educational gap amongst these physicians.

The physicians consent form (Appendix II) which summarized the objectives of the study was obviously inadequate as a tool to gain their co-operativeness.

It was therefore necessary to reinforce the reporting strategy by having the PTs establish initial rapport (with physicians not familiar with the PTs assessments or the implications of the study to their patients) by telephone contact first, at which time the patient's problems were outlined, and if necessary, a course of action suggested. This was followed by the written report and summary. That approach permitted the therapists to gauge more effectively physician response. As physician compliance with the PTs findings was a central issue to the experiment, pretest experience reinforced the need to measure physician compliance and strategies were developed to obtain that information in the before-after evaluation of outcome performed by the IAs (Appendices V and VI).

3.5 Selection and Training of the IAs

In response to a newspaper advertisement, 20 prospective applicants were interviewed, of whom two who met predetermined selection criteria (Appendix IV) were assigned to the study. Both were housewives age 39 and 44 respectively, with grown up families, who in the past were engaged as volunteers by various social agencies

and were highly recommended.

The IAs training curriculum consisted of three elements:

a) Training in the general principles of interviewing techniques by means of pre-structured questionnaires, and specifically the applications of the questionnaire specially designed for this study (Appendices V and VI). This was provided by the staff of the Field Survey Unit of the McMaster University Medical Centre in Hamilton, Ontario and with faculty approval was completed in one week rather than two as envisaged,

b) specific training in physical measures of inflammation and functional capacity as it pertains to RA. This was principally bedside training by the rheumatologist investigator and the author and was conducted during the following week at the University of Toronto RDU, Wellesley Hospital in Toronto, Ontario,

c) training in cubital fossa blood withdrawal as it related to RA patients, by the staff of the clinical investigation unit; and the application of the "macro method" for estimation of the erythrocyte sedimentation rate by the staff of the Haematology Laboratory, of the Wellesley Hospital.

In addition, the IAs were provided with an instruction manual, explaining briefly the purposes of the various evaluation tools used, the procedures taken before, during and following their encounter with patients at home, and the disposition of the questionnaires and blood samples (Appendix X). The basic training program, envisaged to last six weeks, was accomplished in three, a total of 60 hours.

## 3.6 Pretesting and Validation of the Independent Assessment

The IA technique was not previously used in RA trials, their introduction in this study was innovative. It was, therefore, important to establish the IAs credibility during their period of training by comparing their assessments against that of expert observers; by providing them with field experience on patients admitted to the pretest, thus subjecting their assessments to an ongoing process of evaluation by the investigators; and last, but not least, by conducting a full-scale validation study, thereby providing scientific documentation of that experience for possible use and application in future trials of patients with RA.

The IAs performance during their period of training and the pretest was not documented, but on close scrutiny by the investigators, created a favourable impression. This was reinforced by the IAs ability to detect a treatment difference amongst hospitalized patients they

assessed during their basic training and following that on patients admitted to the pretest.

In order to evaluate the IAs performance in a scientific manner, the investigators decided to conduct a full-scale validation study to run concurrently with the pretest which was unavoidably delayed by slow intakes. The other two primary objectives of the study was to validate the trained PTs assessments and develop a pooled index as a statistical device that combines five separate measures of inflammation into a single outcome measure.

The study[24] which involved 33 RA patients, each assessed by four trained observers and the IA before and after 10 days of hospital therapy, has shown that the IAs total assessment provided 84% of the information available in the pooled index, and was more sensitive and reliable than any other single clinical measure. As such these results increased the credibility of this method as a measure of therapeutic outcome in RA.

## 3.7 Separation of PTs and IAs and Patient Records

To minimize contamination of the experimental manoeuvre, the trained PTs were totally separated from traditional PTs by providing separate office facilities and clerical support services at The Arthritis

Society headquarters, remote from the office base of their counterparts. This separation was extended to include all work related activities, such as staff meetings, staff development programs and social functions. Compliance with that manoeuvre was complete for the duration of the trial.

The separation of PTs by office location, meant also that patient records had to be separated. Prior to the trial, all records were kept at the traditional PTs office base. When the pretest was launched, it was decreed that all records on new patients assigned to the trained PTs were to be kept at that office location, and access to these records was denied to the traditional PTs. Similarly records of former patients who were assigned to the trained PTs were transferred and were, thereafter, inaccessible to the other group. Also data gathered by the IAs was kept in separate research files and access denied to both groups of PTs. The trained PTs, however, were provided with initial lab values obtained by the IA (hand x-rays, ESR, latex fixation, salicylate and uric acid levels) to avoid duplication of tests required for their reports to family physicians. Compliance with these manoeuvres on the part of PTs and the file clerk was closely scrutinized by the investigators and was complete.

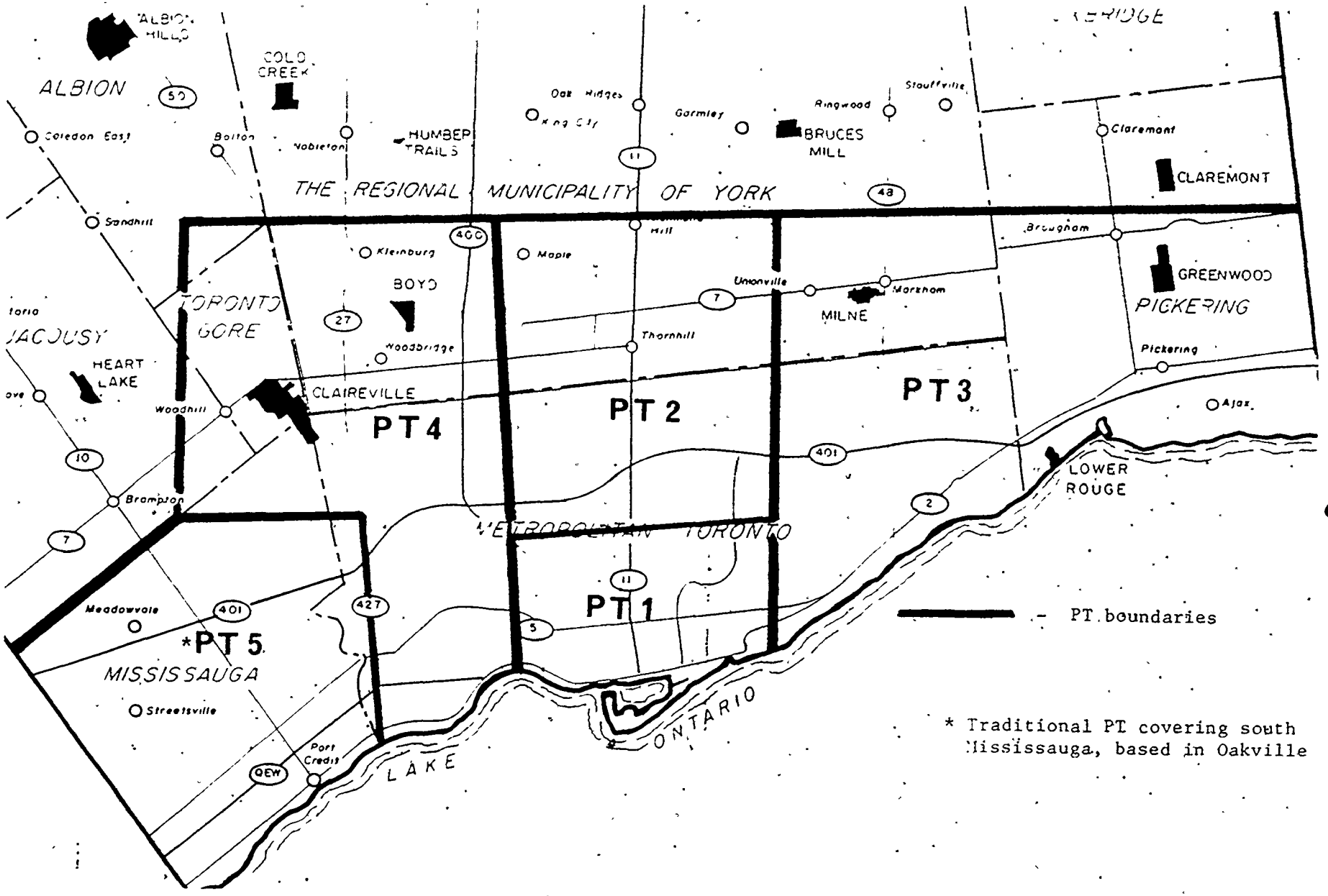
The IAs operated from their homes, and remained unknown to the two groups of PTs. Their assessments were forwarded by mail directly

to the research assistant who maintained and was responsible for the research files.

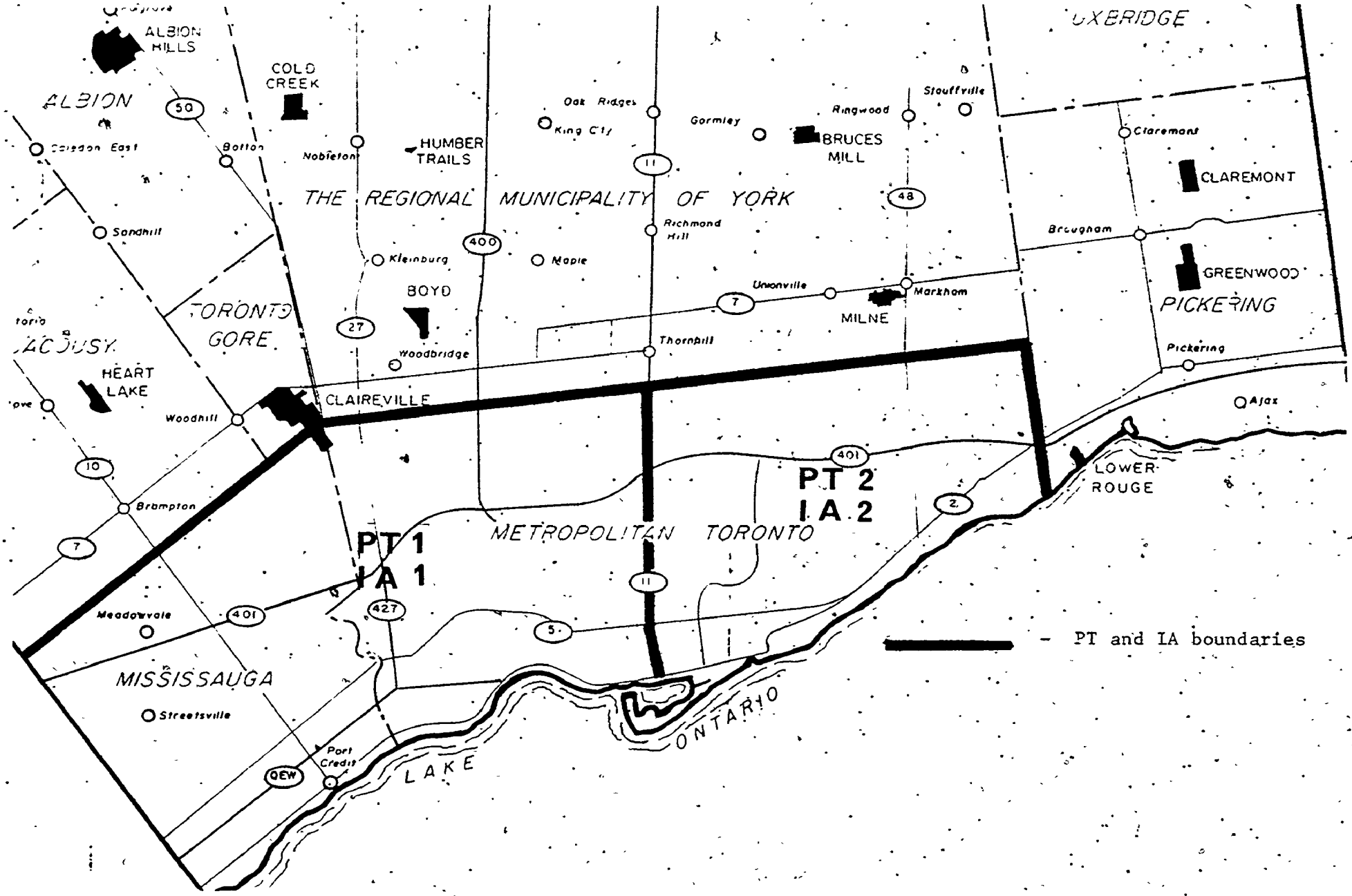
## 3.8 Geographic Assignment of PTs and IAs

The deployment of the four traditional PTs remained unchanged, and included the trial site (all the Boroughs of Metropolitan Toronto and the City of Mississauga), and points east (Durham Region) north (York County) and northwest (North Peel and southern parts of Dufferin Counties). Each was assigned a specific geographic location (Fig. 4). In contrast the trained PTs and IAs were deployed within the trial site only (Fig. 5) each assigned a specific geographic location. The assignment of PTs and IAs to their respective areas was based on their areas of residence in Metro Toronto rather than any other factor, as the Society's records have repeatedly demonstrated that travel time alone accounted for 25% of the PTs total paid hours. The larger overall geographic area of traditional PTs was estimated to be equal in terms of travel time to the smaller geographical area of trained PTs when each PTs geographic area was considered.

Throughout the experimental period, the PTs kept records (as required by the Society) on transportation and patient time, on total patients seen and on total home visits. An analysis will be conducted to determine if differences exist for these factors by group and by PTs


ALBION HILLS
COLD CREEK
ALBION
Oak Ridges
Stouffville
Ringwood
Gormley
BRUCES MILL
Claremont
CLAREMONT
Coledon East
Bolton
Nobleton
HUMBER TRAILS
THE REGIONAL MUNICIPALITY OF YORK
Sandhill
Kleinburg
Maple
Brougham
GREENWOOD
Unionville
Markham
MILNE
PICKERING
TORONTO GORE
BOYD
Woodbridge
Thornhill
Pickering
HEART LAKE
CLAIREVILLE
Woodhill
PT 4
PT 2
PT 3
Ajax
LOWER ROUGE
Brampton
METROPOLITAN TORONTO
PT 1
Meadowvale
*PT 5
MISSISSAUGA
Streetsville
Port Credit
LAKE ONTARIO
PT boundaries
* Traditional PT covering south Mississauga, based in Oakville

GEOGRAPHIC ASSIGNMENT OF TRAINED PT's, IAs AND TRIAL SITE



within each group.

Consideration was given to rotating either the PTs or IAs in terms of geographic assignment in order to minimize biases that are likely to result from differing attitudes amongst them in terms of the patient's socioeconomic factors or those resulting from IAs evaluating patients of the same PTs for the duration of the trial. The resignation of one of the trained PTs and one IA two months before the experimental period began had a similar effect to the projected rotation in the east half of the trial site. Half way through the experimental period the IA assigned to the west half resigned, again affecting a rotation by attrition. Two traditional PTs, one during the pretest, the other during the experimental period also resigned resulting in a rotation for that group.

## 3.9 Attrition Amongst PTs and IAs

Slow intakes during the pretest contributed to a delay for that period from three months as previously projected to almost one year (see Table 14 and 15). For one of the original two IAs (assigned to the east half) this meant a considerably lower volume of work than expected, and she decided to withdraw after one year on the study. Her dissatisfaction was not due to lower renumeration, but solely the need to be engaged in a more uniform type of work. The second IA (assigned

to the west half) resigned later for personal reasons.

The PT who was recruited from another agency also withdrew from the trial after nine months. She anticipated trial extention by one year or more, and could not, therefore, commit herself for the duration. Furthermore, not being familiar with the rheumatic field and home services in general, she found the work exacting and the response of family physicians to her assessments personally disappointing.

Fortuitously, replacements were found and training provided for each prior to the initiation of the experimental period. The new trained PT was recruited from the ranks of the Society's PTs in Toronto, who was replaced by a new recruit assigned to the traditional PTs.

It is not known what effect this attrition rate is likely to have on trial results, however, the ability of the investigators to recruit and train suitable replacements with no time loss (the resignations and appointments overlapped by one month in each case) is reassuring.

## 3.10. Pretest Experience and Modifications in Trial Design

The pretest began in August 1973. The intention was to expose all aspects of the design conceived on submission, to conditions in the field for a period of three months. A number of problems arose during

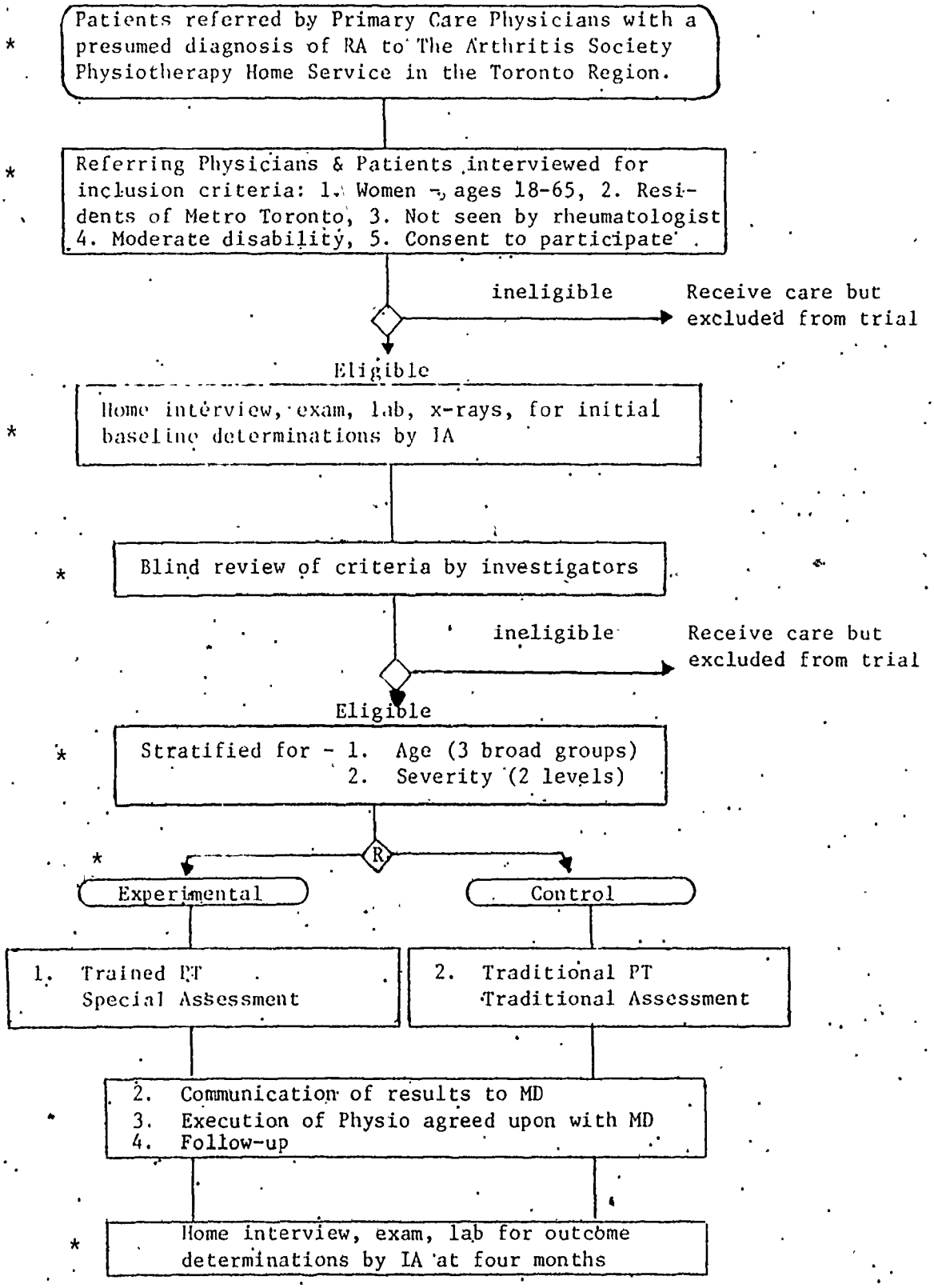
the pretest, important amongst these were: a slow rate of intakes, delays in the processing of intakes and the need to develop an efficient statistical device to determine treatment efficacy.

Each of these issues contributed to significant changes in design strategy as it related to source of intakes, selection criteria, stratification and randomization, sample size, the independent assessment, and the development of a pooled index. The following material describes each of these issues in detail and provides justification for changes in the experimental design. The design on submission is depicted in Fig. 6, with each element that led to difficulties marked by an asterisk. The design of the experiment which began in August 1974 is depicted in Fig. 7, each element that was modified also marked by an asterisk.

## 3.11 Intake Rates During the Pretest

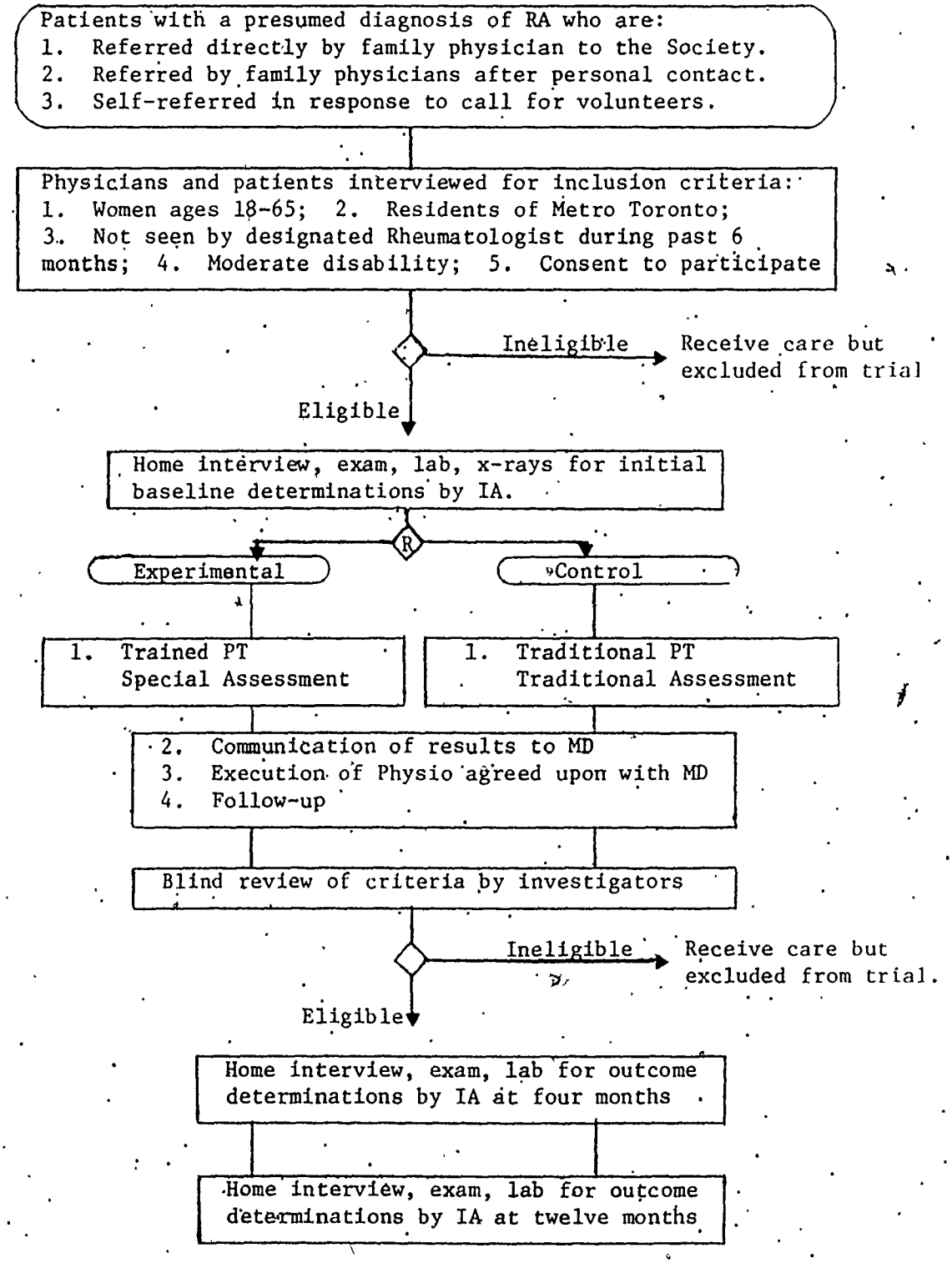
Based on a 1971 analysis of referrals by family physicians to the Society's home service in Toronto, it was predicted that the rate of intakes for the three months of pretest would be approximately 30 patients. That analysis failed to take into account the number of patients who might have been seen by a rheumatologist, the male/female ratio, factors related to accuracy of RA diagnosis, and levels of disease severity. Criteria for patient selection and the list of

FIG. 6 SCHEMATIC PRESENTATION OF TRIAL DESIGN AS ORIGINALLY ENVISAGED




* DESIGN ASPECTS MODIFIED

Fig. 7 SCHEMATIC PRESENTATION OF TRIAL DESIGN EMPLOYED IN THE EXPERIMENTAL PERIOD




* Modifications introduced following pretest experience.

exclusions were further refined and finalized prior to submission in the Fall of 1972, and since data on referrals for that year were not yet available, it was assumed that these refinements would have very little effect on rates of intakes.

When the selection criteria and list of exclusions was applied during the pretest, the expected rate of intakes diminished appreciably. This reduced rate contributed to a delay of the pretest by nine months, during which time only 11 patients completed the study.

An analysis of patients referred to the service during the pretest, demonstrated that the majority of potential subjects were excluded due to an encounter with a designated rheumatologist. Specifically, 65% were referred by rheumatologists and of the remaining 35% a high proportion were seen on consultation by one at a point in time. This may be attributed to a major increase in Toronto in the number of rheumatologists available for consultation; from 12 in 1971, to 22 in 1973, and for the same period an increase in the number of RDU beds from 82 to 132, and a two-fold increase in the productivity of out-patient arthritis clinics.

## 3.12 Changes in Source of Intakes and Selection Criteria

The implications of these developments were that the family physician had more specialists and specialized services at his disposal

and, therefore, did not require the assistance of a specially trained PT. Following consultation with colleagues, it was decided that the basic research question still applies, but in a more global context.

First, the implications of this research cannot be confined to the boundaries of Metro Toronto, but would still apply to other regions of the province and Canada where specialized services remain scarce. Second, the Metro region with a population of three million and a 1% - 3% prevalence rate for RA, of whom 30% may require specialized assistance, would yield a potential RA population of 10,000 - 30,000. For that population the available rheumatologists are capable of handling no more than 3,500 in any given year, the remainder of patients with RA receiving continuous care by family physicians, other specialists, chiropractors, or no care at all.

Under any circumstances, a sample of patients derived from either physicians that traditionally refer, or those that do not, would not be representative, due to the inherent limitations of the referral process. It was, therefore, decided that the design could be considerably improved by drawing on a more representative sample derived from family physicians who traditionally refer to the service, the larger pool of family physicians who do not refer, and directly from the even larger pool of patients who are not obtaining continuous care for their RA. As well, patients within these populations, who

were not seen by a designated rheumatologist within six months should be included if their RA is active, as the majority are seen on consultation only, and their continuous care by family physicians is not likely to contribute to their treatment outcomes during periods of exacerbations.

To effect these changes, sources of intakes and selection criteria were modified to include:

a) Patients referred by family physicians who were not seen by a designated rheumatologist during the past six months,

b) patients referred by specialists other than those on the designated list of rheumatologists,

c) patients referred by family physicians as a result of a special mailing explaining the purposes of the trial (Appendix XI), and

d) patients who responded to a public appeal in the media, whose diagnosis was confirmed by their family physician.

## 3.13 Strategies Developed to Process Intakes

The strategies employed during the pretest for processing intakes

are described in detail in Appendix XII. Intakes were drawn from patients referred to the Society's home service who met initial selection criteria, as shown on the referral form and following interview with patient and referring physician. Those deemed eligible were then assigned a random number according to procedures provided, in confidence, to the secretary at that centre. The senior PT then allocated patients to IAs and treatment groups according to instructions also held in confidence.

Prognostic stratification prior to randomization was purposely omitted from the scheme at that stage as the numbers expected were too small for it to be effective (15 in each treatment group). Following baseline determinations by IAs, the criteria were reviewed blindly by the rheumatologist investigator on the team. Blind review at this stage followed randomization as it was expected that baseline determinations might take too long and would, therefore, deny immediate service to anxious patients. Pretest experience, in fact, demonstrated that this process took on the average three to four weeks. Stratification was attempted retrospectively and while it was found that by age it was not complex, stratification by disease severity was much more complex due to the multiplicity of factors that are likely to affect prognosis of RA patients, and no single and reliable measure that could predict prognosis was available at that time. Hence, the concept of stratification prior to randomization, a highly desirable

feature in the design of trials, was not considered feasible and, therefore, was never applied.

Pretest experience, therefore, confirmed our assumption that prognostic stratification will be difficult to put into effect and that blind review of criteria following randomization was necessary to avoid delays in the provision of services.

These changes constituted a major departure from the original design, their effect on the comparability of groups and numbers assigned to each will be discussed later.

In addition to the material outlined in Appendix XII, verbal instructions were given regarding the processing of patients who volunteered in response to publicity in the media. Those referrals were handled by one of the investigators who interviewed patient volunteers and their doctors on the phone for eligibility criteria, sought their consent and those deemed eligible were forwarded to the senior PT and secretary for further processing.

Baseline determinations were subject to information obtained by the IA which included physical measures of disease severity, function and results of blood tests and x-rays of the hands. This information and the reading of x-rays was gathered and followed by

a research assistant according to prespecified procedures (Appendix XIII) and reviewed blindly by the rheumatologists investigator using a "Final Selection Form" (Appendix VIII). This process adopted first in the pretest was not altered.

The blind review of criteria by the investigator included the following elements:

a) The ARA and New York criteria for diagnosis of RA,

b) criteria for disease severity such as three active joints or more, presence of nodules, morning stiffness over 15 minutes, high latex titre, x-ray erosions and ARA functional class II and III,

c) the ARA list of exclusions such as evidence of psoriasis, other collagen diseases, uric acid levels of 8 mgm.% or more,

d) other exclusions, such as ARA functional class I and IV, a rheumatological encounter in the past six months, other major sources of disability, hospitalization or surgery for RA in the past six months, inability to withdraw blood and have x-rays taken and issues related to the quality of the interview.

While this process of blind review as it pertains to disease

diagnosis and exclusions is not as stringent as the personal encounter, and may have resulted in certain patients admitted, who in fact do not have RA, it was deemed acceptable by a number of colleagues consulted.

3.14 The Independent Assessment

The IA interview, the questionnaire, and laboratory procedures performed satisfactorily during the pretest. Measures of disease severity by the IA were subsequently validated in a specially designed study[24]. Physician response to the trained PTs assessment during the pretest reinforced the need to measure doctor-patient interaction before and after the application of the experimental manoeuvre. This consisted of information on medical therapies undertaken, measures of salicylate levels, other health professional encounters, and patient overall satisfaction with care given (Appendices V and VI).

Cattell's 16 personality test (Appendix VII) introduced to detect the non-compliant, complaining type of patient did not perform well during the pretest as it resulted in a large number of refusals. A mood assessment based on 16 adjectives introduced by Moldofsky et al[34], was added to the IA questionnaire (Appendices V and VI).

## 3.15 Clinical Results of Pretest

The results of the pretest are interesting, although based on very small numbers. Of 36 intakes, only 11 completed the study (see Table 17). Eight of the 36 did not meet criteria for diagnosis of RA and eight others did not meet other criteria. Of the 36 intakes with a presumptive diagnosis of RA, 31 were tested for adequacy of serum salicylate levels. Of these, only one had a blood salicylate level in the therapeutic range. These findings reflect problems encountered by family physicians in diagnosing or treating RA, even in patients with advanced disease. Furthermore, salicylate data, support the investigators contention that family physicians, unless presented with clinical evidence of inflammatory activity, rarely maintain patients on salicylates in the therapeutic range. Poor patient compliance may be another contributing factor.

Of the 11 patients who completed the study, five were allocated to the experimental group and six to controls. Their prognostic indices and prior treatment patterns were roughly comparable. At the time of the second evaluation (four months after entry into the study), the control patients were as a group slightly worse, while the experimental patients had improved. Differences achieved statistical significance and favour the experimental group in the following variables: grip strength ($t_9 = 3.24$, $P < .02$); ARA functional class ($t_9 = 2.80$, $P < .05$),

TABLE 17

Summary of Intake Procedures During Pretest

| Procedure | Number | Exclusions |
|---|---|---|
| 1. Intakes | 36 | None |
| 2. Baseline Determinations | | RA Diagnosis |
| | | Other Exclusions |
| | | Withdrawal |
| | | No X-rays or Blood Sample |
| | | TOTAL |
| 3. Completed Study | | |
| Controls | 6 | |
| Study | 5 | |
| TOTAL | 11 | |

total functional score ($t_9 = 2.84$, $P < .02$) and personal care score ($t_9 = 3.33$, $P < .01$). The magnitude of the change in grip strength was an increase of greater than 50% in the experimental group, and a decrease of about 5% in the control group. Major changes in medical therapy occurred on five occasions in the experimental group and only once in the control. The number of tender joints, erythrocyte sedimentation rates and salicylate levels were all better in the experimental group, but these differences did not achieve statistical significance.

## 3.16 Discussion of Pretest Results

Although pretest results were based on a small sample of patients and are, therefore, not conclusive, they pointed to two important issues, one resulted in design modification, the other the development of a more efficient statistical device, the pooled index.

Based on the personal impressions of trained PTs who reported on scores of patients to family physicians during the pretest and in part supported by the clinical results discussed earlier, low compliance on the part of patients and physicians may be a major impediment to therapeutic success. Furthermore, it was their impression that a change in the attitudes of non-compliers was not likely to be achieved in four months. As a result a procedure was established to measure outcomes at one year, using the IA method, so that long-term results could be

measured more effectively. Approval for this additional cost was obtained in a subsequent submission to the funding agency.

The clinical measures applied to determine outcomes, were difficult to interpret, as marked improvement was noted in some and no change in others. The need to develop an efficient index of change was paramount. Perhaps more important, a composite index can be prespecified as the single variable which will be used to judge therapeutic adequacy. It also avoids the problems that arise when a number of individual variables are used, resulting in the investigator choosing those results which best support his argument.

A pooled index was developed[24] for possible applications in this and other studies, that summarizes four measures of inflammation (number of active joints, ESR, morning stiffness and grip strengths) and one measure of change in function.

The method of calculating the pooled index is described in Appendix XIV. The results of the validation study shown in Table 18 demonstrate the improvement achieved over 10 days of hospitalization on 33 patients with RA, and the sensitivity and reliability of the index in measuring treatment effects. The efficiency of the method can be further demonstrated by applying it to the results of the five experimental and six control patients who completed the pretest.

| | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) |
|---|---|---|---|---|---|---|---|---|
| Measure | n | Mean Value on admission | Mean Value after 10 days therapy | Treatment difference (3) - (2) | Standard deviation of treatment difference | Treatment effect in derived units: (4) - (5)* | Sensitivity t | Reliability R2** |
| Grip strength (mm. mercury) | 33 | 117.5 | 143.2 | + 25.7 | 26.20 | + 0.98 | 5.51 | .58 |
| Morning stiffness (minutes) | 32 | 113.6 | 48.0 | - 65.6 | 64.90 | + 1.01 | 5.84 | .48 |
| Sedimentation rate (mm/hr.) | 30 | 58.9 | 43.0 | - 15.9 | 19.85 | + 0.80 | 4.60 | .53 |
| IAs change score | 33 | - 3.0 | + 2.9 | + 5.9 | 6.98 | + 0.85 | 4.89 | .50 |
| Joint count | 33 | 17.5 | 13.1 | - 4.4 | 4.82 | + 0.92 | 5.29 | .53 |
| Pooled Index | 33 | - + | - | - | - | + 0.93 | 8.26 | .69 |

* Plus sign in derived units means improvement, minus sign indicates deterioration.

** The R2 values were calculated for the original measures by testing each against the mean of the other four, and for the "Pooled Index" by analysis of variance.

\+ Not appropriate to use the "Pooled Index" in low line of columns 2, 3, 4 and 5.

Although based on small samples, the treatment difference obtained, achieved statistical significance and favours the experimental group ($t_9 = 2.76$, $P < .05$).

## 3.17 Refinements in Sample Size

The sample size envisaged on submission was based on previous experience, predicting that 30% of patients will improve in ARA functional class and that an increased rate of improvement of about 15% should be detected with groups of 140 each. The validation study which measured treatment change before and after 10 days of therapy in an RDU on 33 RA patients demonstrated that one can anticipate approximately a change of 0.93 standard deviation units. Using the two-sided "t" test of a difference between two means, with $\alpha = 0.05$ and $\beta = 0.05$, we would require a sample size of 34 in each group. By making an allowance for dropouts during the experimental period, and since we anticipated in community patients a treatment difference of slightly lesser magnitude, a sample size of 40 in each group was considered as adequate.

This refinement in sample size, borne out of validation study experience, was of immense value, as at that time predictions of a required sample size three times as large, compounded with slow intakes, led to serious consideration of aborting the experiment.

3.18 Total Intakes, Allocations and Exclusions

The experimental period began in August 1974 and terminated in January 1977. Patient intakes terminated in January 1976. Table 19 provides a summary of intakes and exclusions following blind review of criteria by the investigators. Noteworthy is the almost balanced allocation when baseline determinations were taken, and the significant disparity between treatment groups following blind review. Also noteworthy is the nearly 50% rate of exclusions; of these a third were excluded for failing to meet criteria for diagnosis of RA.

These findings point to a weakness in the design worthy of discussion. Patient allocation following baseline determination by the IA (see Fig. 7) resulted in a proportionately larger number of exclusions amongst control patients (56.6% vis 40.6%) after blind review of all criteria by the investigator. We may, therefore, assume that the two population samples had different characteristics at the point of intake in spite of the almost balanced allocation at that stage (83 vis 91), and that these differences were possibly reduced following review of all criteria by the investigator (Appendix VIII). This outcome amply demonstrates that blind review preceeding allocation would have provided more balanced numbers between the groups.

Contributing to the high rate of exclusions is the proportion

TABLE 19

Summary of Intake Procedures

| Procedure | Number | Exclusions |
|---|---|---|
| 1. Physician and Patient Interview | | |
| Control | 85 | |
| Experimental | 93 | |
| TOTAL | 178 | |
| 2. Baseline Determination | | |
| Control | 83 | Refusals 2 |
| Experimental | 91 | Refusals 2 |
| TOTAL | 174 | TOTAL 4 |
| $X_2^2 = 4.44$ ($p = 0.1086$) $c = 0.16$ | | |
| 3. Blind Review of Criteria | | |
| Control | 36 | Exclusion 47 (56.6 %) |
| Experimental | 54 | Exclusion 37 (40.6 %) |
| TOTAL | 90 | TOTAL 84 (48.3 %) |
| $X_1^2 = 4.43$ ($p = 0.0353$) $c = .16$ | | |

* Percentage of exclusions following blind review by group.

(a third) of patients referred by family physicians as having RA who failed to meet diagnostic criteria. That trend was noticeable amongst pretest patients (50%), the lower rate achieved in the study population was probably the result of more stringent enquiry on the part of the doctor-patient interviewer. The high proportion of false-negatives is hopefully not matched by an equal number of false-positives, as this finding alone has major implications on the results of therapy at the primary care level.

## 3.19 Impressions of Trained PTs and Physicians of Experimental Patients

In spite of frustrations on numerous occasions, the trained PT overall impression is that the research effort provided them with a stimulating and challenging experience. Even if the analysis shows no improvement in the clinical indices, they consider themselves better physiotherapists as a result of their special training. A retrospective review of their treatment records revealed to their surprise that of doctors who were expected to respond to their assessments, 65% responded positively. Their impression was that this percentage would be considerably lower. Unfortunately the last four months of the experimental period were trying, both PTs (one gave four years, the other three years to the study) became despondent, probably attributable to "trial fatigue". Regardless of the outcomes of their intervention,

their contribution and dedication to this research effort was immense.

The physicians of experimental patients on telephone interview responded overwhelmingly in favour (97%) of the study. This was surprising as the PTs records revealed that 35 responded negatively or not at all. Analysis of treatment outcomes derived from the IA interview and factors related to patient-physician interaction may shed some light on this controversy.

## 3.20 Effects of Delays on Research Costs

The effect of delays (primarily due to a slow rate of intakes) has substantially increased the cost of this research effort. The most costly items in the budget were the personnel salaries of the trained physiotherapists. Table 20 provides a year-by-year record of the total funds requested for each year, the estimated cost to completion and actual expenditures to date. Included in these expenditures are the additional costs of the validation study and a study on "The Cost Effectiveness of In-Patient and Out-Patient Therapy for RA Patients". As the expenditures for these studies were combined under a single grant an estimate of the costs for each would be impossible to compute.

TABLE 20

Effect of Delays on Costs of Research

| Year | Funds Requested | Actual Expenditure | Projected Cost to Completion |
|---|---|---|---|
| 73-74 | $ 33,989 | $ 32,616.77 | $ 76,570 |
| 74-75 | 47,428 | 45,340.82 | 99,017 |
| 75-76 | 67,222 | 65,290.93 | 156,757 |
| 76-77 | 53,827 | 28,057.85 | 205,211 |
| 77-78 | 14,360 | - | 222,248 |
| 78-79 | 13,876 | - | 222,248 |
| | $228,702 | $171,306.36* | |

*Cumulative Total To Date

## Conclusion and Summary

The execution of this experimental design proved to be more complicated than envisaged, probably because it contained a number of features that were innovative to the field of rheumatology. Two other trials on RA in Toronto and one on a general arthritic population in London, Ontario (with which the author is associated in each as investigator) have duplicated certain aspects of this design. The execution of strategies for these trials is considerably facilitated through experience gained from this initial attempt.

Design features such as prognostic stratification, and blind review by the investigators preceeding allocation, which could not be incorporated in this design, were omitted also in these trials as they gave rise to the same difficulties during their protocols. The rheumatological literature does not provide, to date, any satisfactory prognostic measure for RA. Although studies of its natural history demonstrate that systemic features of the disease often herald a poor prognosis, their appearance in any particular person is unpredictable. Furthermore, blind review of intakes by the rheumatologist investigators in these trials may detect one of the systemic features (presence of nodules as determined by IA) and omit scores of others that may be present. Therefore, stratification by this single feature would have been unreliable. On the other hand that form of stratification is potentially more reliable and feasible when final

selection is based on a complete history and physical examination applie
in person by a trained rheumatologist. However, long waiting list
(two-three months on the average) and teaching responsi
by academic rheumatologists, could lead to further delays in provision
services to patients anxious to be relieved of their arthritic symptoms
By the same token, allocation preceding blind review of all criteria
(by rheumatologist investigator continues to be the strategy in
these trials, and may produce again a high rate of exclusions (68
shown in Table 19, page 89). The delivery of lab results obtained
RA, and the availability of the investigators for blind review
(three weeks on the average to process) was the primary reason for
incorporating this feature in their design.

A third source of [illegible]
rate of intakes during the pretest, [illegible]
that period. The change related to source of intake and
(see section 3.1) [illegible]
[illegible] was drawn from the practice of physicians
customarily do not refer patients to the Arthritis Society
and, therefore, could be regarded as more "representative"
with RA on primary care, a disturbingly large proportion of these
(close to 80 ) responded to trial publicity in the media. The volunteer
bias of these patients may lead to difficulties in the interpretation
outcomes. The compliance measures introduced in the [illegible]

salicylate levels, doctor-patient interaction, mood assessment - [illegible] before and after the application of the experimental and control manoeuvres will be instrumental in the interpretation of results. Assuming that majority of these patients are to be found low compliers before the higher compliance and a favourable outcome in the experimental group may change a perceived liability in the design to an asset.

Perhaps the greatest benefit to be derived from this research effort is its by-products. Chief amongst these are: the application of the IA method to the field of rheumatology and the development of the pooled index, as an efficient statistical device, summarizing all available measures of inflammation in RA. The adoption of this design by other investigators in the field is encouraging, with further experience and refinements, what began as a modest research trial on effects of specially trained PTs on outcomes of RA therapy may find applications in scores of health care trials related to this condition and the field of rheumatology.

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APPENDIX I

## ARA FUNCTIONAL CLASS

Definitions:

I Complete - ability to carry on all usual duties without handicaps.

II Adequate - for normal activities despite handicap of discomfort or limited motion of one or more joints.

III Limited - only to little or none of duties of usual occupation or self-care.

IV Incapacitated - largely or wholly bedridden or confined to wheelchair; little or no self-care.

APPENDIX II

Dear Dr. :

Re: Your Patient

The Arthritis Society, is conducting a study of the effectiveness of its community based physiotherapy Home Service Program. The study will involve a health status assessment using a standard questionnaire, a detailed evaluation of the condition of joints, an x-ray of the hands and blood tests. A report of these evaluations will be forwarded to you which we hope will assist you with treatment decisions. A second assessment will be made four months later. Our hope is to evolve a more useful community program for patients with arthritis and we ask your co-operation.

Your patient fulfills the required criteria for this clinical study and has given her consent by phone. She is free to withdraw from the study at any time. Your consent duly signed and returned (as per attached self-addressed envelope) will be greatly appreciated.

Thank you for referring your patient to us.

Sincerely,

Study Coorinators

Dr. H.A. Smythe.

Mr. Antoine Helewa

PHYSICIAN'S CONSENT

I understand that specially detailed assessments of who is under my care will be made as part of a study of the effectiveness of the community care program of The Arthritis Society, and the project has my:

- Agreement and support

I disagree Dr. .....

APPENDIX III

Dear :

The Arthritis Society, is conducting a study of the effectiveness of its community based physiotherapy Home Service Program. The study will involve a health status assessment using a standard questionnaire, a detailed evaluation of the condition of joints, an x-ray of the hands and blood tests. A report of these evaluations will be forwarded to your family physician to assist him with treatment decisions. A second assessment will be made four months later. You are free to withdraw from the study at any time. Our hope is to evolve a more useful community program for patients with arthritis and we ask your co-operation.

For your information Dr. has already given his consent by phone.

Sincerely,

Study Coordinators

Dr. H.A. Smythe

Mr. Antoine Helewa

PATIENT CONSENT FORM

The specially detailed assessments necessary for The Arthritis Society study have been explained to me, and I agree to co-operate with this project. I understand that I am free to withdraw at any time.

DATE..... Signed (Patient).....

Witness.....

APPENDIX IV.

## SELECTION CRITERIA FOR INDEPENDENT ASSESSORS

1. Woman age 25-50 with no professional background in the health field.

2. With a good command of the English language.

3. Minimum education: a high school diploma; maximum: a university bachelor degree.

4. In good general health, particularly with good vision and steady hands.

5. Prepared to learn how to withdraw blood.

6. With a valid driver's licence, and her own car.

7. Interested in a well paid part-time job, but does not depend on her work for a living.

8. Able to relate well to people, particularly those disabled with arthritis.

9. Resident of Metropolitan Toronto, Ontario.

APPENDIX V

INDEPENDENT MEASUREMENT

FOR

RHEUMATOID ARTHRITIS SUBJECTS

INITIAL QUESTIONNAIRE

| 0 | 1 | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | |
| Card No. | | Random No. | | | | | Patient No. | | | Respondent No. | | | Interv No. | |

Time Interview Began _____ a.m. p.m. [ ][ ] 17 18

Date of Interview _____

Patient's name Mr. Mrs. Miss _____ Age _____

Address _____

_____

Next of kin (excluding spouse)

_____

Address _____

Closest Friend _____

Address _____

Your O.H.I.P. No. _____

Number of Dependent children in family under 18 living at home _____ 37 [ ][ ]

Referring G.P. _____

Name of Interviewer

## SECTION 1 - GENERAL INFORMATION

INTERVIEWER: READ TO RESPONDENT:

"I would now like to ask you a few questions about your total disease duration. It is extremely important in this study that we determine as accurately as possible, the length of time you have had problems with your joints. Take your time answering the following questions and try to be as accurate as possible."

1. Can you tell me how old you were when you first noticed pain in your joints?

   88. Don't know
   Age _____ 99. No answer

   47

   RECORD ANY VERBATIM COMMENTS GIVEN BY THE RESPONDENT

   _____

   _____

   _____

   _____ 49

2. Of your total disease duration, how many months or years have you been completely free of pain in your joints?

   _____ (months) _____ (years) 51

   RECORD ANY VERBATIM COMMENTS GIVEN BY THE RESPONDENT

   _____

   _____

   _____

   _____ 54

3. Looking back, from today, how many months or years have you had continuous pain in your joints?

   _____ (months) _____ (years) 56 57

   RECORD ANY VERBATIM COMMENTS GIVEN BY THE RESPONDENT

   _____

   _____

   _____

   _____ 59

4. Have you seen a specialist for your arthritis in the last 6 months?

   1. Yes 2. No
   8. Don't know 9. No answer 61

5. IF YES: Could you give me his name and address please?

   Name _____ _____ Name

6. Do you have any major illness or health problem other than arthritis?

   1. Yes
   2. No
   8. Don't know
   9. No answer

7. IF YES:

   Could you describe this major illness?

   _____ ☐☐☐

   _____

   _____ ☐☐☐

   8888. Don't know
   9999. No answer

Card No. ☐☐ ☐☐
1 2

8. Were you hospitalized for any reason during the last 6 months?

   1. Yes
   2. No
   8. Don't know
   9. No answer

☐ 6

9. IF YES:

   Could you tell me the reason for your hospitalization?

   _____ ☐☐☐

   _____

   _____

   _____

   8888. Don't know
   9999. No answer

10. Has Dr. _____ (Write in name of referring G.P. From Page 1) told you what kind of arthritis you have?

    1. Yes

11. IF YES:

Can you tell me what he called it or how he described it to you?

_____

_____

_____

8888. Don't know
9999. No answer

12. Has any other doctor told you what kind of arthritis you have?

1. Yes _____
2. No
8. Don't know
9. No answer

— Skip to Question 15.

13. Could you give me his name and address please?

Name _____

Address _____

_____

88. Don't know
99. No answer

14. Can you tell me what he called it or how he described it to you?

_____

_____

8888. Don't know
9999. No answer

15a Have you taken any pain for your arthritis during the last 4 months.

1. Yes _____
2. No
8. Don't know
9. No answer

— Skip to Question 32

b IF YES:

16. Are/were they –

1. Plain aspirin
2. Buffered aspirin
3. Enteric coated aspirin
4. Aspirin combined with other analgesics
8. Don't know
9. No answer

□ 36

17. These aspirin that you are were taking, are/were they –

1. 5 grain pills
2. 10 grain pills
3. Other (specify) _____
8. Don't know
9. No answer

□ 37

18. How many of these pills are are/were you taking a day?

_____

(RECORD VERBATIM)

88. Don't know
99. No answer

□□ 38

19. Were these pills recommended to you by Dr. _____ (Write in name of referring G.P. from front page)?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to question 21

□ 40

20. How many did he recommend you take a day?

_____

(RECORD VERBATIM)

88. Don't know
99. No answer

□□ 41 42

21. Were aspirin recommended to you by any other doctor?

1. Yes
2. No

22. What is this doctor's name and address?

Name _____

Address _____

_____

88. Don't know
99. No answer

23. How many did this doctor recommend you take a day?

_____
(RECORD VERBATIM)

88. Don't know
99. No answer

24. INTERVIEWER: IF THE RESPONDENT ANSWERED YES TO BOTH QUESTION 19 AND 21, ASK THE FOLLOWING QUESTION. OTHERWISE SKIP TO QUESTION 25.

Of the two doctors you have just mentioned, which doctor was the first person to recommend that you take aspirin? (RECORD VERBATIM)

_____

25. Do you have any side effects from taking aspirins?

1. Yes
2. No
8. Don't know
9. No answer

26. IF YES:

What are these side effects?
(CHECK THE APPROPRIATE SIDE EFFECTS FROM THE FOLLOWING LIST AND SPECIFY ANY OTHERS MENTIONED BY THE RESPONDENT)

01. Stomach distress
02. Deafness
03. Ringing in the ears
04. other (specify) _____

_____

_____

27. Have you discussed these side effects with Dr. _____
(Write in the name of referring G.P. from front page)?

1. Yes
2. No
8. Don't know
9. No answer

28. IF YES:

Did this discussion prompt him to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

88. Don't know
99. No answer

29. Have you discussed these side effects with any other doctor?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 32

30. IF YES:

Could you please give me this doctor's name and address?

Name _____

Address _____

_____

88. Don't know
99. No answer

31. Did this discussion prompt the doctor to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication

32. "INTERVIEWER: QUESTIONS 32 THROUGH 39 HAVE TO DO WITH THE VARIOUS KINDS OF PILLS THAT THE SUBJECT IS TAKING. WHEN ASKING THESE QUESTIONS TRY AND GET THE SUBJECT TO ANSWER FROM MEMORY AND NOT FROM LOOKING AT THE LABELS ON THE CONTAINERS OF THE PILLS."

At present, are you taking any other kinds of pills for your arthritis that Dr. _____ (Write in the name of referring G.P. from front page) prescribed for you?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 34

☐ 6

33. Without looking at your pill containers, could you tell me what these pills are, how many you take a day and what you are taking them for?
(INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHEN THE RESPONDENT CANNOT PROVIDE AN ANSWER)

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 1. | | | | 7 8 |
| 2. | | | | 13 14 |
| 3. | | | | 19 20 |
| 4. | | | | 25 26 |
| 5. | | | | 31 32 |
| 6. | | | | 37 38 |

34. At present, are you taking any pills other than aspirin for your arthritis that have been prescribed for you by a doctor other than doctor _____ (REFERRING G.P.)

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 37

43

35. Could you give me this doctor's name and address?

Name _____

Address _____

_____

Name 44 45

Address 46 47

88. Don't know
99. No answer

0 4
1 2 Card No.

3 4 5 Patient No.

36. Without looking at your pill containers, could you tell me what these pills are you are taking, how many you take a day and what you are taking them for?
(INTERVIEWER: LIST INOFMRATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHEN THE RESPONDENT CANNOT PROVIDE AN ANSWER.)

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 1. | | | | 6 7 8 9 |
| 2. | | | | 12 13 14 15 |
| 3. | | | | 18 19 20 21 |
| 4. | | | | |

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 5. | | | | 30 31 32 33 |
| 6. | | | | 36 37 38 39 |

37. Are you regularly taking prescribed pills for any other condition?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 39 [42]

38. IF YES: Without looking at your pill containers, could you tell me what these pills are, how many you take a day, and what you are taking them for?
(INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHEN THE RESPONDENT CANNOT PROVIDE AN ANSWER).

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 1. | | | | 43 44 45 |
| 2. | | | | 49 50 51 |
| 3. | | | | 55 56 57 |
| 4. | | | | |

39. INTERVIEWER: IF THE SUBJECT HAS MENTIONED ANY PRESCRIBED PILLS SHE HAS BEEN TAKING, ASK THE FOLLOWING QUESTIONS. OTHERWISE SKIP TO QUESTION 40

In the last few questions, you have mentioned the prescribed pills that you have been taking. I would like to know if I may take a look at the labels on all the containers of prescribed pills that you have mentioned.

1. Yes
2. No
8. Don't know
9. No answer

[ ] 6

IF YES: (RECORD FROM LABELS)

| | Name of pills | Daily Dosage | Prescribing Doctor | | |
|---|---|---|---|---|---|
| 1. | _____ | _____ | _____ | [ ] 7 | [ ] 8 [ ] 9 [ ] 10 |
| 2. | _____ | _____ | _____ | [ ] 13 | [ ] 14 [ ] 15 [ ] 16 |
| 3. | _____ | _____ | _____ | [ ] 19 | [ ] 20 [ ] 21 [ ] 22 |
| 4. | _____ | _____ | _____ | [ ] 25 | [ ] 26 [ ] 27 [ ] 28 |
| 5. | _____ | _____ | _____ | [ ] 31 | [ ] 32 [ ] 33 [ ] 34 |
| 6. | _____ | _____ | _____ | [ ] 37 | [ ] 38 [ ] 39 [ ] 40 |
| 7. | _____ | _____ | _____ | [ ] 43 | [ ] 44 [ ] 45 [ ] 46 |
| 8. | _____ | _____ | _____ | [ ] 49 | [ ] 50 [ ] 51 [ ] 52 |
| 9. | _____ | _____ | _____ | [ ] 55 | [ ] 56 [ ] 57 [ ] 58 |
| 10. | _____ | _____ | _____ | [ ] 61 | [ ] 62 [ ] 63 [ ] 64 |

40. During the past year have you ever received any medication by injection from Dr. _____ (Write in name of referring G.P. from front page)

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 42

☐ 6

41. IF YES:

Can you give me the names of the medications, how frequently they were given, where they were given and what they were given for?
(INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHERE THE RESPONDENT CANNOT PROVIDE AN ANSWER).

| | Name of Medication | Frequency of Injections | Site of Injection | Reason for Injection |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

☐ 21

☐ 28

42. During the past year have you ever received any medication by injection from any other doctor?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 45

☐

43. IF YES:

Could you give me this doctor's name and address please?

Name _____

Address _____

_____

88. Don't know
99. No answer

44. IF YES:

Can you give me the names of these medications, how frequently they were given, where they were given and what they were given for? (INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHERE THE RESPONDENT CANNOT PROVIDE AN ANSWER).

| | Name of Medication | Frequency of Injections | Site of Injection | Reason for Injection | |
|---|---|---|---|---|---|
| 1. | _____ | _____ | _____ | _____ | ☐ 40 |
| | | | | _____ | ☐ 44 |
| 2. | _____ | _____ | _____ | _____ | ☐ 47 |
| | | | | _____ | ☐ 51 |
| 3. | _____ | _____ | _____ | _____ | ☐ 54 |
| | | | | _____ | ☐ 58 |
| 4. | _____ | _____ | _____ | _____ | ☐ 61 |
| | | | | _____ | ☐ 65 |

45. INTERVIEWER: IF THE RESPONDENT IS TAKING ANY PILLS (EXCLUDING ASPIRIN) OR RECEIVED INJECTIONS - ASK THE FOLLOWING QUESTIONS. OTHERWISE SKIP TO QUESTION 53.

Do you have any side effects from any pills, other than aspirin, that have been prescribed to you by any doctor?

1. Yes
2. No
8. Don't know — Skip to Question 53
9. No answer

68

46. IF YES:

Could you describe these side effects?

1. Yes
2. No
8. Don't know — Skip to Question 48
9. No answer

69

0 7 — Card No. (1 2)

Patient (3 4)

47. IF YES: - (SPECIFY)

| | Drug | Side Effects | |
|---|---|---|---|
| 1. | | | 6 7 |
| 2. | | | 12 13 |
| 3. | | | 18 19 |
| 4. | | | 24 25 |

48. Have you discussed these side effects with Dr. _____
(Write in the name of referring G.P. from front page).

1. Yes
2. No
8. Don't know
9. No answer

☐ 36

49. IF YES:

Did this discussion prompt him to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

☐☐ 37 38

88. Don't know
99. No answer

☐☐ 39 40

50. Have you discussed these side effects with any other doctor?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 53

☐ 41

51. IF YES:

Could you give me this doctor's name and address please?

Name _____ Name ☐ 42

Address _____

_____ Address ☐☐ 44 45

52. Did this discussion prompt this doctor to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

☐☐ 46 47

88. Don't know
99. No answer

☐☐

53. Have you had any other form of treatment for your arthritis during the last year?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 55

50

54. IF YES:

What kind of treatment is this?

_____ 51

_____ 52

55. INTERVIEWER: THE FOLLOWING QUESTION REFERS TO ANY KIND OF TREATMENT THE SUBJECT HAD (i.e. pills, injections, etc.) AND NOT SPECIFICALLY TO QUESTION 53.

In the past 4 months, has any treatment you have been receiving for your arthritis resulted in any changes, such as - (READ CHOICES)

a. A general change in the degree of pain you have

1. Yes - for the better
2. Yes - for the worse
3. No
8. Don't know
9. No answer

59

b. A change in the degree of fatigue you have

1. Yes - for the better
2. Yes - for the worse
3. No
8. Don't know
9. No answer

60

c. A change in your degree of mobility

1. Yes - for the better
2. Yes - for the worse
3. No
8. Don't know
9. No answer.

61

d. Any other changes (specify)

1. _____
   1. Yes - for the better
   2. Yes - for the worse
   3. No
   8. Don't know
   9. No answer

2. _____
   1. Yes - for the better
   2. Yes - for the worse
   3. No
   8. Don't know
   9. No answer

3. _____
   1. Yes - for the better
   2. Yes - for the worse
   3. No
   8. Don't know
   9. No answer

56. In the past 4 months, has your overall condition changed in any way, such as for the

   1. better
   2. worse

   3. or no change at all
   8. Don't know
   9. No answer

   → Skip to Question 2.01

57. By how much has your condition changed in the last 4 months?
   (READ CATEGORIES TO RESPONDENT

   1. 25%
   2. 50%
   3. 75%
   4. 100%
   8. Don't know
   9. No answer

58. What do you feel are the reasons for this change in your condition?
   (RECORD VERBATIM)

_____

_____

_____

## SECTION 2 - FUNCTIONAL CAPACITY

| 0 | 8 |
|---|---|
| 1 | 2 |

Card No.

### MOBILITY

2.01 Walking

a. Are you able to walk at all with or without help?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

→ Skip to Question 2.02

[ ] 6

b. When you walk, do you walk by yourself, without the help of a cane, crutches, walker or another person?

1. Yes
2. Yes - with difficulty
3. No - what kind of aid or assistance do your require? (specify) _____
8. Don't know
9. No answer

[ ]

[ ]

c. Are you able to walk within your home?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

→ Skip to Question 2.03

[ ] 9

d. Are you able to walk outside your home?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

→ Skip to Question 2.02

[ ] 10

e. Can you walk one block?

1. Yes
2. Yes - with difficulty
3. No

Poor C

f. Can you walk four blocks or more?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

Skip to Question 2.02

12

g. Can you walk one mile?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

Skip to Questior 2.02

12

h. Can you run several hundred yards?

1. Yes
3. No
8. Don't know
9. No answer

14

---

2.02 In the last 4 months, has your ability to walk changed in any way, such as for the

1. better
2. worse
3. or no change at all
8. Don't know
9. No answer

15

---

2.03 Use of Transport

a. If you had to, at this time could you travel in a bus, street car or train?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

16

b. If you had to at this time, could you travel by car or taxi?

2.04 In the last 4 months, has your ability to use transport changed in any way such as for the

1. better
2. worse
3. or no change at all
8. Don't know
9. No answer

18

---

2.05 Climbing

a. Are you able to climb stairs with or without help?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

→ Skip to Question 2.06

19

b. At this time, can you walk up 2 flights of stairs (16 steps)?

1. Yes
2. Yes - with difficulty

→ Skip to Question 2.06

3. No
8. Don't know
9. No answer

20

c. At this time, can you walk up one flight of stairs (8 steps)?

1. Yes
2. Yes - with difficulty

→ Skip to Question 2.06

3. No
8. Don't know
9. No answer

21

d. Are you able to walk up two to four steps?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

22

2.06 In the last 4 months, has your ability to climb stairs changed in any way, such as, for the

1. Better
2. Worse
3. Or no change at all
8. Don't know
9. No answer

☐ 23

---

2.07 Chairs and Transfers

a. Are you able to get from bed to (chair/wheelchair) and back again?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

☐ 24

b. Are you able to get up from an ordinary chair?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

☐ 25

c. If you had to, could you get up from the floor by yourself?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

☐ 26

2.08 In the last 4 months, has your ability to move out of bed, out of a chair, or get up from the floor changed in any way such as, for the

1. Better
2. Worse
3. Or no change at all
8. Don't know
9. No answer

---

PERSONAL CARE

2.09 Eating

a. At present, are you able to eat without the use of special utensils?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. At present, are you able to eat without the assistance of another person?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

c. At present, are you able to cut meat by yourself?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

d. At present, are you able to grip or carry glasses, cups, or pots?

1. Yes
2. Yes - with difficulty
3. No

e. At present, are you able to pour tea or coffee from a pot?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

32

---

2.10. In the last 4 months, has your ability to feed yourself changed in any way, such as for the

1. better
2. worse
3. or no change at all
8. Don't know
9. No answer

33

---

2.11. Dressing

a. At present, are you able to dress and undress completely?

1. Yes
2. Yes - with difficulty
3. No - What kinds of aids or assistance do you require? (specify)_____

34

8. Don't know
9. No answer

35

b. Can you manage all your buttons, zippers and fasteners?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know

c. Can you manage stockings or shoe laces?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

☐ 38

d. Can you manage all other activities related to dressing and undressing?

1. Yes
2. Yes - difficulty with some
3. Yes - difficulty with most
4. No
8. Don't know
9. No answer

☐ 39

e. Could you tell me which dressing activities are difficult for you or that you are unable to manage:(SPECIFY)

01. None
02. Not applicable (doesn't get dressed)

| Difficult | Unable to Manage |
|---|---|
| | |
| | |
| | |

☐☐ 40 41

☐☐ 42 43

---

2.12 In the last 4 months, has your ability to dress and undress changed in any way, such as for the

1. Better
2. Worse
3. Or no change at all

2.13 Washing and Grooming

a. Are you able to turn taps and faucets off tightly?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. Are you able to wash your face and hands?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

c. Are you able to brush your teeth?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

d. Are you able to apply makeup?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

e. Are you able to wash your hair?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

f. Are you able to comb your hair?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

g. Are you able to bathe in a bath tub?

1. Yes
2. Yes - with difficulty
3. No

h. Are you able to bathe witnout relying on a bath stool or bath tub board?

1. Yes
2. Yes - with difficulty
3. No — Skip to Question j

52

8. Don't know
9. No answer

i. Do you rely on showers?

1. Yes
2. Yes - with difficulty
3. No

53

8. Don't know
9. No answer

j. Are you able to scrub <u>all</u> parts of your body?

1. Yes
2. Yes - with difficulty
3. No
8. Don't kno
9. No answer

54

---

2.14 In the last 4 months, has your ability to wash and groom yourself changed in any way, such as for the

1. Better
2. Worse
3. Or no change at all
8. Don't know
9. No answer

55

---

2.15 <u>Toilet</u>

a. Are you able to use the toilet

1. Yes
2. Yes - with difficulty (includes raised toilet set or commode)
3. No (relies on bed pan or other means)
8. Don't know

WORK/PLAY ACTIVITIES

2.16 Special Hand and Arm Functions

a. Are you able to grip and turn a door knob or handle?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

57

b. Are you able to grip and turn a key?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

58

c. Are you able to use your fingers for fine work such as picking up change?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

59

d. Are you able to open jars with screw tops?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

60

e. Are you able to use a pen or pencil to write with?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

61

f. Are you able to use scissors for cutting or grooming your finger nails?

1. Yes
2. Yes - with difficulty
3. No
4. Not applicable
8. Don't know
9. No answer

62

g. Are you able to use scissors for cutting and grooming your toe nails?

1. Yes
2. Yes - with difficulty
3. No
4. Not applicable
8. Don't know
9. No answer

63

---

2.17 In the last 4 months, has your ability to perform these hand and arm functions changed in any way, such as for the

1. Better
2. Worse —
3. Or no change at all
8. Don't know
9. No answer

64

---

2.18 Work Outside the Home

a. Did you in the past work for pay or participate in a volunteer activity outside your home?

1. Yes
2. No
8. Don't know
9. No answer

65

b. Do you now work for pay or participate in a volunteer activity outside your home?

1. Yes
2. No
8. Don't know
9. No answer

66

INTERVIEWER: IF RESPONDENT ANSWERED YES TO (a) AND NO TO (b) ASK THE FOLLOWING QUESTION. OTHERWISE SKIP TO QUESTION (d).

c. Has this changed - (CHECK AS MANY AS ARE APPLICABLE)

1. Because of Arthritis
2. Due to retirement
3. Due to other reasons (specify)

_____ ☐ 67

8. Don't know
9. No answer

d. Have you ever tried to obtain employment in the past?

1. Yes
2. No ☐ 68
8. Don't know
9. No answer

e. Looking back, do you think that if you had wanted to, you could have obtained employment at any time in the past or present, in spite of your arthritis?

1. Yes ☐ 69
2. No
8. Don't know
9. No answer

f. If you had to, are you able, at present, to perform in either volunteer or paid employment outside your home?

1. Yes
2. No ☐ 70
8. Don't know
9. No answer

g. In the last 2 weeks, how many days were you confined to your home because of arthritis? (RECORD VERBATIM)

_____ ☐☐ 71 72
(# of days)

Work at Home

h. Are you able, at present, to work around the house doing such things as light house cleaning, washing clothes and doing minor home repairs?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

→ Skip to Question j

6

i. Are you able, at present, to do heavy work around the house such as washing windows, moving furniture, sweeping floors, digging the garden, mowing lawns, shovelling snow, and putting out the garbage?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

7

---

Rest Periods

j. How long can you work before you must take a half an hour break?
(RECORD VERBATIM)

_____ (minutes) _____ (hours)

8 9 10

2.19 In the last 4 months, has your ability to do light or heavy housework changed in any way, such as for the

1. Better
2. Worse
3. Or no change at all
8. Don't know
9. No answer

☐ 11

---

2.20 Play

a. Do you, at present, participate in any recreational activity or hobby

1. Yes ☐ 12
2. No
8. Don't know → Skip to Question 2.21
9. No answer

b. What activities or hobbies do you participate in?

1. Skiing
2. Tennis
3. Golf
4. Swimming
5. Walking
6. Activities, hobbies in the Home only -(specify)

_____

7. Other (specify) ☐

_____ ☐

8. Don't know
9. No answer

..21 In the last 4 months, has your ability to participate in recreational activities or hobbies changed in any way, such as for the

1. Better
2. Worse
3. Or no change at all
8. Don't know
9. No answer

☐ 15

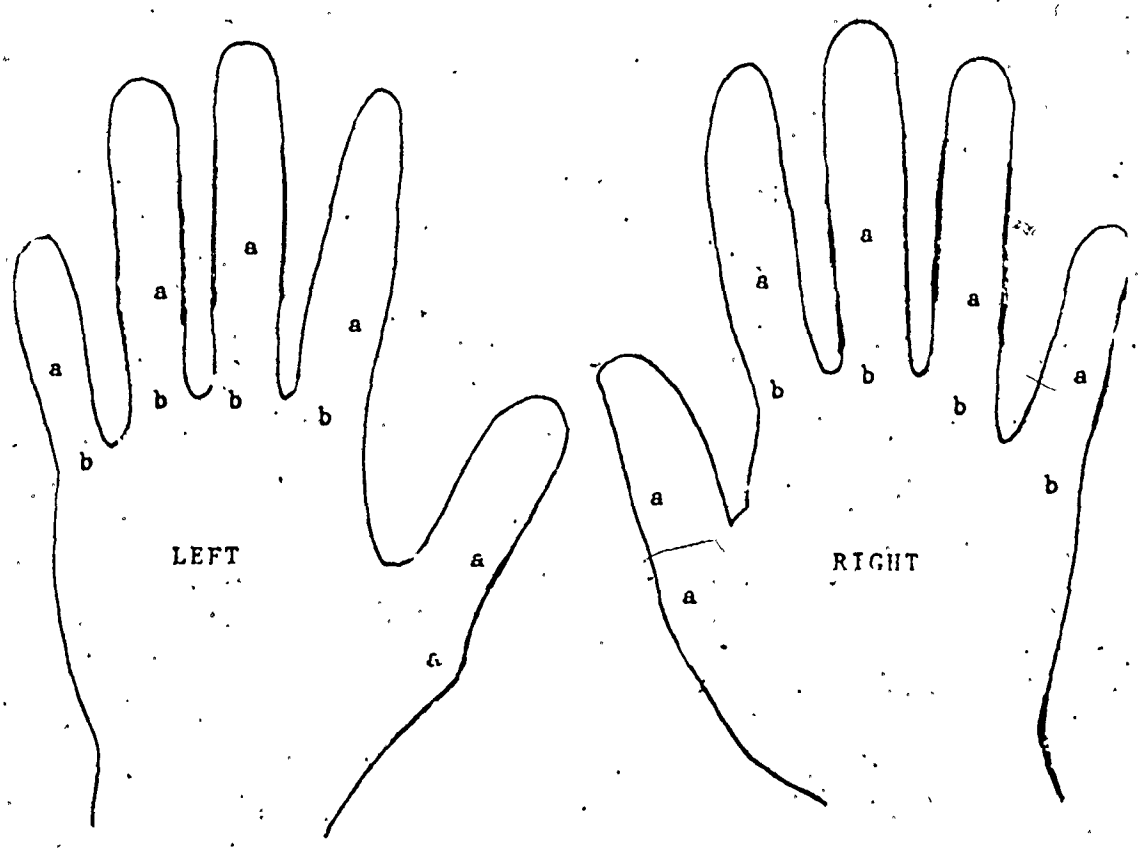
## SECTION 3 DISEASE ACTIVITY

Now I want to ask you about tenderness in the joints of your hand and wrist. I want to know only about tenderness with pressure directly on the joint, not tenderness present between joints or at a distance from the joints.

Below is a picture showing the left and right hands, with certain joints marked "a" and "b".

3.01 Do you experience any tenderness on side to side pressure in the joints marked "a"?

On front to back pressure of joints marked "b"?
(Circle the joints with pain or tenderness.)




Add number of joints circled _____ 16-17

INTERVIEWER: INDICATE THE ABSENCE OF ANY JOINTS DUE TO AMPUTATIONS

3.02 Now I'm going to mention other joints in which tenderness may be noticed. Do you have any tenderness in your left wrist on front to back pressure

1. Yes
2. No
8. Don't know
9. No answer

20

3.03 Any tenderness on pressure in your right wrist

1. Yes
2. No
8. Don't know
9. No answer

21

3.04 After you gently bend your left elbow fully, try to force it with the other hand a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

22

3.05 After you gently bend your right elbow fully, try to force it with the other hand a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

23

INTERVIEWER: IF ON ASKING THE FOLLOWING QUESTIONS, THE RESPONDENT IS UNABLE TO REACH HER KNEE, THEN TEST FOR PAIN YOURSELF.

3.06 After you gently bend your left knee fully, try to force it with your hands a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

24

3.07 After you gently bend your right knee fully, try to force it with your hands a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

☐ 25

3.08 Do you have any pain in your left ankle on movement or walking?

1. Yes
2. No
3. Not able to walk or move ankle
4. Don't know
9. No answer

☐ 26

3.09 Do you have pain in your right ankle on movement or walking?

1. Yes
2. No
3. Not able to walk or move ankle
8. Don't know
9. No answer

☐ 27

3.10 Is the front half of your left foot on walking....

1. Very painful
2. Somewhat painful
3. Not painful
4. Not able to walk or move ankle
8. Don't know
9. No answer

☐ 28

3.11 Is the front half of your right foot on walking.....

1. Very painful
2. Somewhat painful
3. Not painful
4. Not able to walk or move ankle
8. Don't know
9. No answer

☐ 29

3.12

a. During the last week, did you have morning stiffness in your joints or muscles when you got out of bed and started moving around?

1. Yes - always
2. Yes - usually
3. Yes - sometimes

4. No
8. Don't know
9. No answer

→ Skip to Question 3.13

30

b. After you got up and started moving around, how many minutes or hours during the last week did your morning stiffness last?
(RECORD VERBATIM)

_____ (minutes) _____ (hours)

31 32 33

---

3.13 INTERVIEWER: TEST PATIENT'S GRIP STRENGTH MEASUREMENT. INDICATE READING ON THE SCALE IN THE APPROPRIATE SPACE.

Right Grip _____

34 35 36

Left Grip _____

37 38 39

3.14 I would appreciate it, if you would now let me look at the back of your elbows for the presence of nodules.

INTERVIEWER - Are nodules present?

1. Yes
2. No
3. Subject refused
8. Don't know
9. No answer

40

3.15 Have you ever had a red scaly skin rash near your elbows, knees or scalp?

1. Yes ☐ 41
2. No
8. Don't know — Skip to Question 3.17
9. No answer

3.16 Were you told by your doctor that this rash was psoriasis?

1. Yes ☐ 42
2. No
8. Don't know
9. No answer

3.17 INTERVIEWER: WITHDRAW BLOOD NOW AND THEN ASK QUESTION 3.17 and 3.18

a. How many grades of formal schooling did you complete, starting with grade one? (RECORD VERBATIM)

_____ ☐☐ 43 44

3.18 I have one final question to ask you before we end this part of the interview. Here is a card with various income levels on it. Could you indicate please -

a. The letter which corresponds to your present yearly personal income

RECORD _____ ☐☐ 45 46
(See codes below)

b. Could you indicate the letter which corresponds to your total yearly family income please?

RECORD _____ ☐☐ 47 48
(See codes below)

CODES FOR QUESTION 3.18

| | |
|---|---|
| 01 - a | 09 - i |
| 02 - b | 10 - j |
| 03 - c | 11 - k |
| 04 - d | 12 - l |

## SECTION 4 - EVALUATION OF INTERVIEW

(TO BE COMPLETED AFTER THE INTERVIEW HAS BEEN COMPLETED)

4.01 Length of Interview _____ (minutes)

4.02 Was anyone other than the respondent present during any part of the interview?

1. Yes
2. No — Skip to Question 4.06

4.03 IF YES:

Who was it?

_____

4.04 Did anyone other than the respondent contribute information?

1. Yes
2. No

4.05 IF YES:

Give reason(s) why.

_____

_____

4.06 Was the level of comprehension on the part of the respondent

1. Unsatisfactory
2. Satisfactory
3. Excellent

4.07 Were there any major distractions during the interview?

1. Yes
2. No

4.08 IF YES:

What were they?

_____

4.09 Status of interview

1. Completed
2. Broken off
3. Refused to contribute some information
4. Total Refusal

66

4.10 For code 2,3, or 4, give reasons

_____

_____

_____

67

4.11 Were you able to draw blood?

1. Yes
2. No

69

4.12 IF NO:

Give reason

_____

_____

70

4.13 In your opinion, will the patient be able to have his x-ray taken?

1. Yes — Skip to Question 4.15
2. No

72

4.14 IF NO:

Give reasons

_____

_____

73

4.15 Provide the following information regarding x-rays.
Name of Facility where they will be taken.

_____

## Blood Test Results

4.16 . 1. E.S.R. Level _____ (6 7 8)
(FILLED IN BY INTERVIEWER)

2. LATEX FIXATION LEVEL _____ (9 10 11 12)

3. SERUM SALYCILATE LEVEL _____ (13 14)

4. URIC ACID LEVEL _____ (15 16 17)

4.17 GENERAL COMMENTS OF INTERVIEWER

(NOTE: DO NOT MENTION RESPONDENT'S NAME)

_____

_____ 18 19

_____

_____ 20 21

_____

_____

4.18 How did you feel about the respondent and the interview after the interview had been completed?

_____ 22 23

_____

_____ 24 25

_____

_____

## SECTION 5 - MOOD ASSESSMENT

(TO BE COMPLETED BY INTERVIEWER)

| DESCRIPTION | NOT AT ALL 0 | A LITTLE 2 | 3 | QUITE A BIT 4 | 5 | EXTREMELY 6 |
|---|---|---|---|---|---|---|
| ANGRY | | | | | | |
| ANXIOUS | | | | | | |
| APATHETIC | | | | | | |
| CALM | | | | | | |
| CRITICAL | | | | | | |
| DULL | | | | | | |
| ENERGETIC | | | | | | |
| ENTERPRISING | | | | | | |
| IRRITABLE | | | | | | |
| RELAXED | | | | | | |
| RESENTFUL | | | | | | |
| SARCASTIC | | | | | | |
| SLUGGISH | | | | | | |
| SUBMISSIVE | | | | | | |
| TENSE | | | | | | |
| WORRIED | | | | | | |

APPENDIX VI

# INDEPENDENT MEASUREMENT
# FOR
# RHEUMATOID ARTHRITIS SUBJECTS
# FINAL QUESTIONNAIRE

Time Interview Began _____ a.m. p.m. [17 18 19 20]

Date of initial interview _____ (day) _____ (month) _____ (year) [21 22] [23 24]

Date of final interview _____ (day) _____ (month) _____ (year) [27 28] [29 30]

Has the final interview been delayed by one week, past the 4 month deadline

1. Yes 2. No

IF YES: Why? 1. hospitalization 3. holiday
2. sickness 4. other (specify) _____

Patient's age _____

Patient's name Ms. Miss Mrs. _____

Address _____

_____

Telephone no. _____

Marital Status 1 - single 4 - separated
2 - married 5 - widowed
3 - divorced 6 - common law

Subjects O.H.I.P. NO. _____ [38 39 40 41 42 43]

Subjects weight _____

Subjects height _____ (feet) _____ (inches) ft. [49] [50 51]

Referring doctor _____

## SECTION 1 - GENERAL INFORMATION

1. During the past 4 months, how many visits have you received from the C.A.R.S. Physiotherapist?

_____ (number)

88. Don't know
99. No answer

2. Are you still receiving physiotherapy treatment at home?

1. Yes
2. No
8. Don't know
9. No answer

3. During the past month, about how often did you receive these visits? Were they -

0. none
1. once during the month
2. twice during the month
3. three times
4. four times
5. more than four times
8. Don't know
9. No answer

4. How often did you see your family doctor about your arthritis in the last 4 months? (RECORD SPECIFIC NUMBER)

_____ (number)

00. None
88. Don't know
99. No answer

5. Were you in contact by telephone **with** your family doctor about your arthritis in the last 4 months?

1. Yes

2. No
8. Don't know
9. No answer

— Skip to Question 6

IF YES: How many times? (RECORD SPECIFIC NUMBER)

_____ (number)

7. IF YES: Could you give me his or their names and address?

| | Name | Address |
|---|---|---|
| 1. | _____ | _____ |
| 2. | _____ | _____ |
| 3. | _____ | _____ |

8. Have you received any other health or social service for your arthritis other than C.A.R.S. physiotherapy?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 10

9. IF YES: Can you give me the name of the person or agency and the address?

| | Name | Address |
|---|---|---|
| 1. | _____ | _____ |
| 2. | _____ | _____ |
| 3. | _____ | _____ |

10. Did your doctor or specialist refer you for x-rays of your joints in the past 4 months? (NOTE: other than those taken of the hands 4 months ago).

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 12

11. IF YES: What did you have x-rayed? (RECORD VERBATIM)

_____

_____

_____

12. Did your doctor or specialist do any blood tests for your arthritis in the past 4 months?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 14

14. Did your doctor or specialist inject any of your joints in the past 4 months?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 16

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 1 | 2 | | | |
| Card No. | | Patient No. | | |

15. IF YES: Which joints and how often? (LIST ONE JOINT PER LINE)

| | Joints | How Often | |
|---|---|---|---|
| 1. | _____ | _____ | 6 |
| 2. | _____ | _____ | 9 |
| 3. | _____ | _____ | 12 |
| 4. | _____ | _____ | 15 |
| 5. | _____ | _____ | 18 |
| 6. | _____ | _____ | 21 |
| 7. | _____ | _____ | 24 |
| 8. | _____ | _____ | 27 |

16. Did you have any other laboratory tests for your arthritis during the past 4 months, other than blood tests?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 18

17. IF YES: (Specify) _____

_____

_____

18. Did your family doctor or specialist give you any new instructions about your arthritis in the last 4 months?

1. Yes

2. No
8. Don't know — Skip to Question 20
9. No answer

19. IF YES: (Specify) _____

_____

_____

20. Did you have any major illness or health problem other than arthritis in the last 4 months?

1. Yes

2. No
8. Don't know — Skip to Question 22
9. No answer

21. IF YES: Could you describe this major illness?

_____

_____

_____

8888. Don't know
9999. No answer

22. Were you hospitalized for any reason during the past 4 months?

1. Yes

2. No
8. Don't know — Skip to Question 29
9. No answer

23. IF YES: ASK

Were you hospitalized for your arthritis?

1. Yes

2. No

25. Was your hospitalization for -

1. tests
2. tests and medications
3. tests, medications and surgery
4. surgery alone

IF CODE 3 OR 4, ASK Q.26, OTHERWISE SKIP TO Q.28

26a. Did you have surgery for your arthritis?

1. Yes

2. No
8. Don't know
9. No answer

→ Skip to Question 28

26b. IF YES: What parts of your body did they operate on? (GET SPECIFICS)

_____
_____
_____
_____

→ Skip to Question 28

27. Could you tell me what you were hospitalized for?

_____
_____
_____
_____

28. Do you feel that you have benefitted from your hospitalization?

1. Yes
2. No
8. Don't know

IF YES: How? (RECORD VERBATIM)

_____
_____
_____
_____

29. Have you taken any aspirin for your arthritis during the last 4 months

1. Yes

2. No
8. Don't know — Skip to Question 47
9. No answer

30. At present, are you regularly taking aspirin for your arthritis?

1. Yes

2. No
8. Don't know — Skip to Question 34
9. No answer

31. Are they -

1. Plain aspirin
2. Buffered aspirin
3. Enteric coated aspirin
4. Aspirin combined with other analgesics
8. Don't know
9. No answer

32. These aspirins that you are taking, are they -

1. 5 grain pills
2. 10 grain pills
3. Other (specify) _____
8. Don't know
9. No answer

33. How many of these pills are you taking a day?

_____
(RECORD VERBATIM)

88. Don't know
99. No answer

34. Were these pills recommended to you by Dr. _____ (Write in name of referring doctor from front page)?

1. Yes

2. No
8. Don't know — Skip to Question 36
9. No answer

36. Were aspirin recommended to you by any other doctor?

1. Yes

2. No
8. Don't know
9. No answer

—Skip to Question 40

37. What is this doctor's name and address?

Name _____

Address _____

_____

88. Don't know
99. No answer

1 2 3 4 5

| 1 | 3 | | | |
|---|---|---|---|---|

Card No. Patient No.

38. How many did this doctor recommend you take a day?

_____
(RECORD VERBATIM)

88. Don't know
99. No answer

INTERVIEWER: IF THE RESPONDENT ANSWERED YES TO BOTH QUESTION 34 and 36, ASK THE FOLLOWING QUESTION. OTHERWISE SKIP TO QUESTION 40.

39. Of the two doctors you have just mentioned, which doctor was the first person to recommend that you take aspirin? (RECORD VERBATIM)

_____

40. Do you now, or did you in the past 4 months, have any side effects from taking aspirins?

1. Yes

2. No
8. Don't know
9. No answer

—Skip to Question 47

42. Have you discussed these side effects with Dr. _____
(Write in the name of referring doctor from front page)?

1. Yes
2. No
8. Don't know
9. No answer

43. IF YES: Did this discussion prompt him to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

88. Don't know
99. No answer

44. Have you discussed these side effects with any other doctor

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 47

45. IF YES: Could you give me this doctor's name and address?

Name _____

Address _____

_____

88. Don't know
99. No answer

46. Did this discussion prompt the doctor to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

88. Don't know
99. No answer

"INTERVIEWER: QUESTIONS 47 THROUGH 54 HAVE TO DO WITH THE VARIOUS KINDS OF PILLS THAT THE SUBJECT IS TAKING. WHEN ASKING THESE QUESTIONS TRY AND GET THE SUBJECT TO ANSWER FROM MEMORY AND NOT FROM LOOKING AT THE LABELS ON THE CONTAINERS OF THE PILLS."

47. At present, are you taking any other kinds of pills for your arthritis that Dr. _____ (Write in the name of referring doctor from front page) prescribed for you?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 49

48. Without looking at your pill containers, could you tell me what these pills are, how many you take a day and what you are taking them for?
(INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHEN THE RESPONDENT CANNOT PROVIDE AN ANSWER)

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 1. | | | | 31 32 |
| 2. | | | | 37 38 |
| 3. | | | | 43 44 |
| 4. | | | | 49 50 |
| 5. | | | | 55 56 |
| 6. | | | | 61 62 |

49. At present, are you taking any pills other than aspirin for your arthritis that have been prescribed for you by a doctor other than doctor _____ (Referring doctor from front page)?

1. Yes

2. No
8. Don't know
9. No answer

→Skip to Question 52

50. Could you give me this doctor's name and address?

Name _____

Address _____

_____

88. Don't know
99. No answer

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 1 | 4 | | | |

Card No. Patient No.

51. Without looking at your pill container, could you tell me what these pills are you are taking, how many you take a day and what you are taking them for?
(INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHEN THE RESPONDENT CANNOT PROVIDE AN ANSWER).

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 1. | | | | 6 7 |
| 2. | | | | 12 13 |
| 3. | | | | 18 19 |
| 4. | | | | 24 25 |
| 5. | | | | |

52. Are you regularly taking prescribed pills for any other condition?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 54

53. IF YES: Without looking at your pill containers, could you tell me what these pills are, how many you take a day, and what you are taking them for? (INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSE UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHEN THE RESPONDENT CANNOT PROVIDE AN ANSWER.)

| | Name of Pills | Daily Dosage | Reason for Medication | |
|---|---|---|---|---|
| 1. | | | | 43 44 |
| 2. | | | | 49 50 |
| 3. | | | | 55 56 |
| 4. | | | | 61 62 |
| 5. | | | | 67 68 |
| 6. | | | | 73 74 |

1 2 | 3 4 5

Card No. 1 5 | Patient No.

INTERVIEWER: IF THE SUBJECT HAS MENTIONED ANY PRESCRIBED PILLS SHE HAS BEEN TAKING, ASK THE FOLLOWING QUESTIONS. OTHERWISE SKIP TO QUESTION 55

54. In the last few questions, you have mentioned the prescribed pills that have been taking. I would like to know if I may take a look at the labe on all the containers of prescribed pills that you have mentioned.

1. Yes
2. No
8. Don't know
9. No answer

IF YES: (RECORD FROM LABELS)

| | Name of Pills | Daily Dosage | Prescribing Doctor | |
|---|---|---|---|---|
| 1. | _____ | _____ | _____ | 7 8 9 10 11 |
| 2. | _____ | _____ | _____ | 13 14 15 16 17 |
| 3. | _____ | _____ | _____ | 19 20 21 22 23 |
| 4. | _____ | _____ | _____ | 25 26 27 28 29 |
| 5. | _____ | _____ | _____ | 31 32 33 34 35 |
| 6. | _____ | _____ | _____ | 37 38 39 40 41 |
| 7. | _____ | _____ | _____ | 43 44 45 46 47 |
| 8. | _____ | _____ | _____ | 49 50 51 52 53 |
| 9. | _____ | _____ | _____ | 55 56 57 58 59 |
| 10. | _____ | _____ | _____ | 61 62 63 64 65 |

1 2 3 4 5

| 1 | 6 | | | |
|---|---|---|---|---|

Card No. Patient No.

55. During the past 4 months have you ever received any medication by injection from Dr. _____ (Write in name of referring doctor from front page)?

1. Yes
2. No
8. Don't know

56. IF YES: Can you give me the names of the medications, how frequently they were given, where they were given and what they were given for? (INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR REPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHERE THE RESPONDENT CANNOT PROVIDE AN ANSWER).

| | Name of Medication | Frequency of Injections | Site of Injection | Reason for Injection | |
|---|---|---|---|---|---|
| 1. | _____ | _____ | _____ | _____ | 7 8 |
| | | | | _____ | 11 |
| 2. | _____ | _____ | _____ | _____ | 14 15 |
| | | | | _____ | 18 |
| 3. | _____ | _____ | _____ | _____ | 21 22 |
| | | | | _____ | 25 |
| 4. | _____ | _____ | _____ | _____ | 28 29 |
| | | | | _____ | 32 |

57. During the past 4 months have you ever received any medication by injection from any other doctor?

1. Yes

2. No
8. Don't know
9. No answer

→ Skip to Question 60

58. IF YES: Could you give me this doctor's name and address please?

Name _____

Address _____

_____

88. Don't know
99. No answer

59. IF YES: Can you give me the names of these medications, how frequently they were given, where they were given and what they were given for?
(INTERVIEWER: LIST INFORMATION IN THE FOLLOWING CHART. PROBE FOR RESPONSES UNDER EACH RESPECTIVE COLUMN. INDICATE DON'T KNOW WHERE THE RESPONDENT CANNOT PROVIDE AN ANSWER).

| | Name of Medication | Frequency of Injections | Site of Injection | Reason for Injection | |
|---|---|---|---|---|---|
| 1. | _____ | _____ | _____ | _____ | 40 41 42 |
| | | | | _____ | 44 45 |
| 2. | _____ | _____ | _____ | _____ | 47 48 49 |
| | | | | _____ | 51 52 |
| 3. | _____ | _____ | _____ | _____ | 54 55 56 |
| | | | | _____ | 58 59 |
| 4. | _____ | _____ | _____ | _____ | 61 62 63 |
| | | | | _____ | 65 66 |

1 2 | 3 4 5
[1][7] [ ][ ][ ]
Card No. Patient No.

INTERVIEWER: IF THE RESPONDENT IS TAKING ANY PILLS (EXCLUDING ASPIRIN) OR RECEIVED INJECTIONS - ASK THE FOLLOWING QUESTIONS. OTHERWISE SKIP TO QUESTION 68.

60. Do you have any side effects from any injections or pills, other than aspirin, that have been prescribed to you by any doctor?

1. Yes
2. No
8. Don't know
9. No answer

→ Skip to Question 68

61. IF YES: Could you describe these side effects?

1. Yes
2. No

62. IF YES: (SPECIFY)

| | Drug | Side Effects | |
|---|---|---|---|
| 1. | _____ | _____ | 8 9 |
| 2. | _____ | _____ | 14 15 |
| 3. | _____ | _____ | 20 21 |
| 4. | _____ | _____ | 26 27 |
| 5. | _____ | _____ | 32 33 |

63. Have you discussed these side effects with Dr. _____ (Write in the name of referring doctor from front page)?

1. Yes
2. No
8. Don't know
9. No answer

64. IF YES: Did this discussion prompt him to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

88. Don't know
99. No answer

65. Have you ever discussed these side effects with any other doctor?

1. Yes

2. No
8. Don't know

66. IF YES: Could you give me this doctor's name and address please?

Name _____ Name

Address _____ Address

_____

67. Did this discussion prompt this doctor to - (READ CHOICES)

01. reduce the dosage
02. change your medication
03. take you off all medication
04. do nothing
05. do something else (specify)

_____

88. Don't know
99. No answer

68. INTERVIEWER: THE FOLLOWING QUESTIONS REFER TO ANY KIND OF TREATMENT THE SUBJECT HAD (i.e. pills, injections, or any other health service).

In the past 4 months, has any treatment you have been receiving for your arthritis resulted in any changes, such as - (READ CHOICE

a. A general change in the degree of pain you have?

1. Yes - for the better
2. Yes - for the worse
3. No
8. Don't know
9. No answer

b. A change in the degree of fatigue you have?

1. Yes - for the better
2. Yes - for the worse
3. No
8. Don't know
9. No answer

c. A change in your degree of mobility?

1. Yes - for the better
2. Yes - for the worse
3. No
8. Don't know
9. No answer

e. Any other changes (specify)

1. _____
   1. Yes - for the better
   2. Yes - for the worse
   3. No
   8. Don't know
   9. No answer

2. _____
   1. Yes - for the better
   2. Yes - for the worse
   3. No
   8. Don't know
   9. No answer

3. _____
   1. Yes - for the better
   2. Yes - for the worse
   3. No
   8. Don't know
   9. No answer

69. In the last 4 months, would you say your overall condition has changed to become -

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse

5. or has there been no change at all
8. Don't know
9. No answer

→ Skip to Question 2.01

70. By how much has your condition changed in the last 4 months? (READ CATEGORIES TO RESPONDENT)

1. 25% or less
2. 26% to 49%
3. 50% to 74%
4. 74% to 100%
8. Don't know
9. No answer

71. What do you feel are the reasons for this change in your condition? (RECORD VERBATIM)

_____

_____

_____

## SECTION 2 - FUNCTIONAL CAPACITY

| 1 | 2 |
|---|---|
| 1 | 8 |

Card No.

| 3 | 4 | 5 |
|---|---|---|
| | | |

Patient No.

### MOBILITY

2.01 Walking

a. Are you able to walk at all with or without help

1. Yes
2. Yes - with difficulty

3. No
8. Don't know
9. No answer

— Skip to Question 2.02

b. When you walk, do you walk by yourself, without the help of a cane, crutches, walker or another person?

1. Yes
2. Yes - with difficulty
3. No - what kind of aid or assistance do you require? (specify) _____
8. Don't know
9. No answer

c. Are you able to walk within your home?

1. Yes
2. Yes - with difficulty

3. No
8. Don't know
9. No answer

— Skip to Question 2.02

d. Are you able to walk outside your home?

1. Yes
2. Yes - with difficulty

3. No
8. Don't know
9. No answer

— Skip to Question 2.02

f. Can you walk four blocks or more?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

→ Skip to Question 2.02

g. Can you walk one mile?

1. Yes
2. Yes - with diffculty
3. No
8. Don't know
9. No answer

→ Skip to Question 2.02

h. Can you run several hundred yards?

1. Yes
3. No
8. Don't know
9. No answer

---

2.02 In the last 4 months, would you say your ability to walk has changed to become -

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.03 Use of Transport

a. If you had to, at this time, could you travel in a bus, street car or train?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. If you had to, at this time, could you travel by car or taxi?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

---

2.04 In the last 4 months, would you say your ability to use transport has changed to become -

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.05 Climbing

a. Are you able to climb stairs with or without help?

1. Yes
2. Yes - with difficulty

3. No
8. Don't know
9. No answer

→ Skip to Question 2.06

b. At this time, can you walk up 2 flights of stairs (16 steps)?

1. Yes
2. Yes - with difficulty

→ Skip to Question 2.06

c. At this time, can you walk up one flight of stairs (8 steps)?

1. Yes
2. Yes - with difficulty

→ Skip to Question 2.06

3. No
8. Don't know
9. No answer

d. Are you able to walk up two to four steps?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

---

2.06 In the last 4 months, would you say your ability to climb stairs has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.07 Chairs and Transfers

a. Are you able to get from bed to (chair/wheelchair) and back again?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. Are you able to get up from an ordinary chair?

1. Yes
2. Yes - with difficulty

c. If you had to, could you get up from the floor by yourself?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

---

2.08 In the last 4 months, would you say your ability to move out of bed, out of a chair, or get up from the floor has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

PERSONAL CARE

2.09 Eating

a. At present, are you able to eat without the use of special utensils?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. At present, are you able to eat without the assistance of another person?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

c. At present, are you able to cut meat by yourself?

1. Yes
2. Yes - with difficulty

d. At present, are you able to grip or carry glasses, cups, or pots?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

e. At present, are you able to pour tea or coffee from a pot?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

---

2.10 In the last 4 months, would you say your ability to feed yourself has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.11 Dressing

a. At present, are you able to dress and undress completely?

1. Yes
2. Yes - with difficulty
3. No - What kinds of aids or assistance do you require? (specify)

_____

_____

8. Don't know
9. No answer

b. Can you manage all your buttons, zippers and fasteners?

1. Yes
2. Yes - with difficulty
3. No

c. Can you manage stockings or shoe laces?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

d. Can you manage all other activities related to dressing and undressing?

1. Yes — Skip to Question 2.12
2. Yes - difficulty with some
3. Yes - difficulty with most
4. No
8. Don't know
9. No answer

e. Could you tell me which dressing activities are difficult for you or that you are unable to manage: (SPECIFY)

01. None
02. Not applicable (doesn't get dressed)

| Difficult | Unable to manage |
|---|---|
| | |
| | |
| | |
| | |

2.12 In the last 4 months, would you say your ability to dress and undress has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse

2.13 Washing and Grooming

a. Are you able to turn taps and faucets off tightly?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. Are you able to wash your face and hands?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

c. Are you able to brush your teeth?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

d. Are you able to apply makeup?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

e. Are you able to wash your hair?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

f. Are you able to comb your hair?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

g. Are you able to bathe in a bath tub?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know

h. Are you able to bathe without relying on a bath stool or bath tub board?

1. Yes
2. Yes - with difficulty

→ Skip to Question j

3. No
8. Don't know
9. No answer

i. Do you rely on showers?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

j. Are you able to scrub all parts of your body?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

---

2.14 In the last 4 months, would you say your ability to wash and groom yourself has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.15 Toilet

a. Are you able to use the toilet

1. Yes
2. Yes - with difficulty (includes raised toilet seat or commode)
3. No (relies on bed pan or other means)

WORK/PLAY ACTIVITIES

2.16 Special Hand and Arm Functions

a. Are you able to grip and turn a door knob or handle?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

b. Are you able to grip and turn a key?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

c. Are you able to use your fingers for fine work such as picking up change?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

d. Are you able to open jars with screw tops?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

e. Are you able to use a pen or pencil to write with?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

f. Are you able to use scissors for cutting or grooming your finger nails?

1. Yes
2. Yes - with difficulty
3. No
4. Not applicable
8. Don't know

g. Are you able to use scissors for cutting and grooming your toe nails?

1. Yes
2. Yes - with difficulty
3. No
4. Not applicable
8. Don't know
9. No answer

---

2.17 In the last 4 months, would you say your ability to perform these hand and arm functions has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.18 Work Outside the Home

a. Did you in the past work for pay or participate in a volunteer activity outside your home?

1. Yes
2. No
8. Don't know
9. No answer

b. Do you now work for pay or participate in a volunteer activity outside your home?

1. Yes
2. No
8. Don't know
9. No answer

c. Has this changed - (CHECK AS MANY AS ARE APPLICABLE)

1. because of Arthritis
2. due to retirement
3. due to other reasons (specify)

_____

8. Don't know
9. No answer

d. Have you ever tried to obtain employment in the past?

1. Yes
2. No
8. Don't know
9. No answer

e. If you had to, are you able, at present, to perform in either volunteer or paid employment outside your home?

1. Yes
2. No
8. Don't know
9. No answer

f. In the last 2 weeks, how many days were you confined to your home because of arthritis? (RECORD VERBATIM)

_____
(# of days)

---

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 1 | 9 | | | |

Card No. Patient No.

Work at Home

g. Are you able, at present, to work around the house doing such things as light house cleaning, washing clothes and doing minor home repairs?

1. Yes
2. Yes - with difficulty

h. Are you able, at present, to do heavy work around the house such as washing windows, moving furniture, sweeping floors, digging the garden, mowing lawns, shovelling snow, and putting out the garbage?

1. Yes
2. Yes - with difficulty
3. No
8. Don't know
9. No answer

---

Rest Periods

j. How long can you work before you must take a half an hour break? (RECORD VERBATIM)

_____ (minutes) _____ (hours)

---

2.19 In the last 4 months, would you say your ability to do light or heavy housework has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

---

2.20 Play

a. Do you, at present, participate in any recreational activity or hobby?

1. Yes

b. What activities or hobbies do you participate in?

1. Skiing
2. Tennis
3. Golf
4. Swimming
5. Walking
6. Activities, hobbies in the Home only - (specify)

_____

7. Other (specify)

_____

8. Don't know
9. No answer

---

2.21 In the last 4 months, would you say your ability to participate in recreational activities or hobbies has changed to become

1. a lot better
2. somewhat better
3. somewhat worse
4. a lot worse
5. or has there been no change at all
8. Don't know
9. No answer

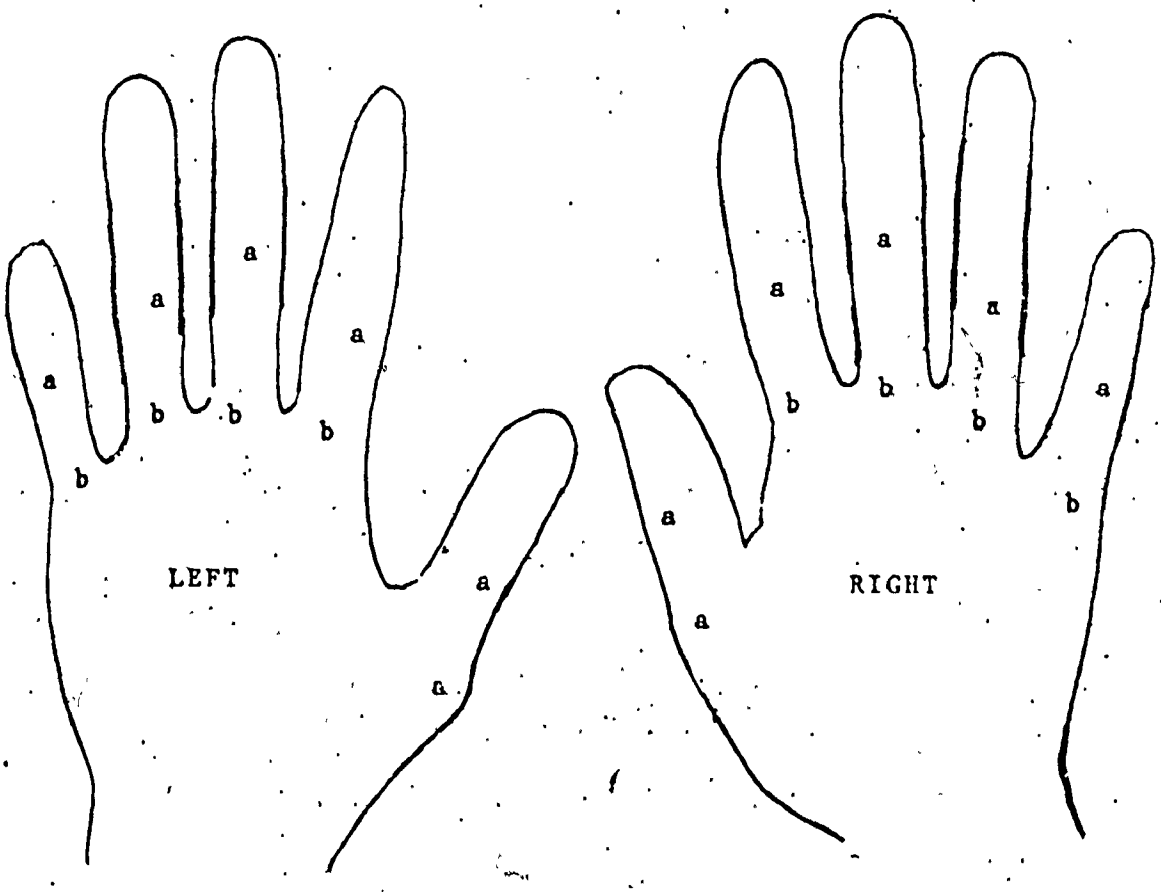
## SECTION 3 DISEASE ACTIVITY

Now I want to ask you about tenderness in the joints of your hand and wrist. I want to know only about tenderness with pressure directly on the joint, not tenderness present between joints or at a distance from the joints.

Below is a picture showing the left and right hands, with certain joints marked "a" and "b".

3.01 Do you experience any tenderness on side to side pressure in the joints marked "a"?

On front to back pressure of joints marked "b"? (Circle the joints with pain or tenderness.)




Add number of joints circled _____ 16 17

3.02 Now I'm going to mention other joints in which tenderness may be noticed. Do you have any tenderness in your left wrist on front to back pressure?

1. Yes
2. No
8. Don't know
9. No answer

3.03 Any tenderness on pressure in your right wrist?

1. Yes
2. No
8. Don't know
9. No answer

3.04 After you gently bend your left elbow fully, try to force it with the other hand a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

3.05 After you gently bend your right elbow fully, try to force it with the other hand a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

INTERVIEWER: IF ON ASKING THE FOLLOWING QUESTIONS, THE RESPONDENT IS UNABLE TO REACH HER KNEE, THEN TEST FOR PAIN YOURSELF.

3.06 After you gently bend your left knee fully, try to force it with your hands a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes
2. No
8. Don't know
9. No answer

3.07 After you gently bend your right knee fully, try to force it with your hands a little further. Does that forcing give you a sharp increase in pain? What if you straighten it fully and force it further?

1. Yes

3.08 Do you have any pain in your left ankle on movement, walking or when you put pressure on the floor?

1. Yes
2. No
8. Don't know
9. No answer

3.09 Do you have pain in your right ankle on movement, walking or when you put pressure on the floor?

1. Yes
2. No
8. Don't know
9. No answer

3.10 Is the front half of your left foot on walking, or when you put pressure on the floor -

1. very painful
2. somewhat painful
3. not painful
8. Don't know
9. No answer

3.11 Is the front half of your right foot on walking or when you put pressure on the floor -

1. very painful
2. somewhat painful
3. not painful
8. Don't know
9. No answer

3.12

a. During the last week, did you have morning stiffness in your joints or muscles when you got out of bed and started moving around?

1. Yes - always
2. Yes - usually
3. Yes - sometimes

4. No
8. Don't know — Skip to Question 3.13
9. No answer

b. Would you say that the morning stiffness you had today is typical of what you had during the rest of this week?

1. Yes
2. No
8. Don't know

IF YES:

c. On the average, how many minutes or hours of morning stiffness did you have today?'

_____ (minutes) _____ (hours) [ ][ ][ ] 32 33 34

d. On the average during the last week, how many hours or minutes of morning stiffness did you have?

_____ (minutes) _____ (hours) [ ][ ][ ] 35 36 37

---

3.13 INTERVIEWER: TEST PATIENT'S GRIP STRENGTH MEASUREMENT. INDICATE READING ON THE SCALE IN THE APPROPRIATE SPACE.

Right Grip _____ [ ][ ][ ] 38 39 40

Left Grip _____ [ ][ ][ ] 41 42 43

3.14 I would appreciate it if you would now let me look at the back of your elbows for the presence of nodules.

INTERVIEWER: Are Nodules present?

1. Yes
2. No
8. Don't know
9. No answer

[ ] 44

3.15 Have you ever had a red scaly skin rash near your elbows, knees or scalp?

1. Yes
2. No
8. Don't know
9. No answer

— Skip to Question 3.17

[ ] 45

3.16 Were you told by your doctor that this rash was psoriasis?

1. Yes
2. No
8. Don't know

## SECTION 4 - EVALUATION OF INTERVIEW

(TO BE COMPLETED AFTER THE INTERVIEW HAS BEEN COMPLETED)

4.01 Length of Interview _____ (minutes)

4.02 Was anyone other than the respondent present during any part of the interview?

1. Yes
2. No — Skip to Question 4.06

4.03 IF YES: Who was it?

_____

4.04 Did anyone other than the respondent contribute information?

1. Yes
2. No

4.05 IF YES: Give reason(s) why.

_____

_____

4.06 Was the level of comprehension on the part of the respondent

1. unsatisfactory
2. satisfactory
3. excellent

4.07 Were there any major distractions during the interview?

1. Yes
2. No

4.08 IF YES: What were they?

_____

_____

4.09 Status of interview

1. completed
2. broken off
3. refused to contribute some information

4.10 For code 2, 3 or 4 give reasons

_____

_____

_____

4.11 Were you able to draw blood?

1. Yes
2. No

4.12 IF NO: Give reason

_____

_____

## Blood Test Results

4.13 1. E.S.R. Level _____
(FILLED IN BY INTERVIEWER)

2. LATEX FIXATION LEVEL _____

3. SERUM SALYCILATE LEVEL _____

4. URIC ACID LEVEL _____

4.14 Number of physiotherapy visits at home to date.
(OFFICE USE ONLY)

_____
(number)

4.15 GENERAL COMMENTS OF INTERVIEWER

(NOTE: DO NOT MENTION RESPONDENT'S NAME)

4.16 How did you feel about the respondent and the interview after the interview had been completed?

## SECTION 5 - MOOD ASSESSMENT

(TO BE COMPLETED BY INTERVIEWER)

| DESCRIPTION | NOT AT ALL 0 | A LITTLE 2 | 3 | QUITE A BIT 4 | 5 | EXTREMELY 6 |
|---|---|---|---|---|---|---|
| ANGRY | | | | | | |
| ANXIOUS | | | | | | |
| APATHETIC | | | | | | |
| CALM | | | | | | |
| CRITICAL | | | | | | |
| DULL | | | | | | |
| ENERGETIC | | | | | | |
| ENTERPRISING | | | | | | |
| IRRITABLE | | | | | | |
| RELAXED | | | | | | |
| RESENTFUL | | | | | | |
| SARCASTIC | | | | | | |
| SLUGGISH | | | | | | |
| SUBMISSIVE | | | | | | |
| TENSE | | | | | | |
| WORRIED | | | | | | |

# 16 PF

**WHAT TO DO:** Inside this booklet are some questions to see what attitudes and interests you have. There are no "right" and "wrong" answers because everyone has the right to his own views. To be able to get the best advice from your results, you will want to answer them exactly and truly.

If a separate "Answer Sheet" has not been given to you, turn this booklet over and tear off the Answer Sheet on the back page.

Write your name and all other information asked for on the top line of the Answer Sheet.

First you should answer the four sample questions below so that you can see whether you need to ask anything before starting. Although you are to read the questions in this booklet, you must record your answers on the answer sheet (alongside the same number as in the booklet).

There are three possible answers to each question. Read the following examples and mark your answers at the top of your answer sheet where it says "Examples." Fill in the left hand box if your answer choice is the "a" answer, in the middle box if your answer choice is the "b" answer, and in the right-hand box if you choose the "c" answer.

EXAMPLES:

1. I like to watch team games.
   **a. yes, b. occasionally, c. no.**

2. I prefer people who:
   **a. are reserved,**
   **b. (are) in between,**
   **c. make friends quickly.**

3. Money cannot bring happiness
   **a. yes (true), b. in between, c. no (false)**

4. Woman is to child as cat is to:
   **a. kitten, b. dog, c. boy.**

In the last example there *is* a right answer—kitten. But there are very few such reasoning items.

Ask *now* if anything is not clear. The examiner will tell you in a moment to turn the page and start.

When you answer, keep these four points in mind:

1. You are asked not to spend time pondering. **Give the first, natural answer as it comes to you.** Of course, the questions are too short to give you all the particulars you would sometimes like to have. For instance, the above question asks you about "team games" and you might be fonder of football than basketball. But you are to reply "for the average game," or to strike an average in situations of the kind stated. Give the best answer you can at a rate not slower than five or six a minute. You should finish in a little more than half an hour.
2. Try **not** to fall back on the middle, "uncertain" answers except when the answer at either end is really **impossible** for you—perhaps once every four or five questions.
3. Be sure not to skip anything, **but answer every question, somehow.** Some may not apply to you very well, but give your best guess. Some may seem personal, but remember that the answer sheets are kept confidential and cannot be scored without a special stencil key. Answers to particular questions are not inspected.
4. Answer as honestly as possible what is true of **you.** Do not merely mark what seems "the right thing to say" to impress the examiner.

APPENDIX VIII

## SUMMARY OF DATA FOR INITIAL AND FINAL SELECTION

RESPONDENT NUMBER _____ PATIENT _____

AGE _____ DISEASE DURATION _____ Yrs. _____ Months

DATE OF INTERVIEW _____ Day _____ Month _____ Yr.

### I ARA CRITERIA FOR A DIAGNOSIS OF RA

(Check 1 = Yes, 2 = No)

a. 3 active joints and over ☐ (3)
Total Active _____

b. Symmetrical Involvement with Effusions ☐ (1)

c. A.M. Stiffness > 15 mins. ☐ (1)
A.M. Stiffness in mins. _____

d. Nodules ☐ (1)

e. Positive Rheumatoid Factor Test ☐ (1)
Latex fixation reading _____

f. Radiological Erosions ☐ (1)
Erosion Duration Index _____

Total Score

5 > Definite RA
7 > Classical RA

### II N.Y. CRITERIA FOR DIAGNOSIS OF RA

(1 = Yes, 2 = No)

a. Polyarthritis - 3 or more active joints (past or present) ☐ (1)

b. Distribution criterion; stiffness, deformity or active involvement of 2-4 PIP's bilaterally or 2-5 MCP's bilaterally or wrists bilaterally or 2-5 MTP's bilaterally ☐ (1)

c. Erosions (grade 2-4) by x-ray ☐ (1)

d. Positive Rheumatoid ☐ (1)

### III EXCLUSIONS (1 = Yes, 2 = No)

a. Seen by specialist on select list in past six months

b. Other major sources of disability

c. Hospitalization or major surgery in past six months

d. Psoriasis

e. Uric Acid Level > 8 mgm.

f. Other collagen diseases

g. Functional Class I or IV

### IV OTHER REASONS FOR EXCLUSION

(1 = Yes, 2 = No)

a. Interview > 90 minutes

b. Other contributing information

c. Comprehension unsatisfactory

d. Major distractions

e. Could not complete interview

f. Inability to withdraw blood

g. Inability to have x-rays taken

ACCORDING TO DATA LISTED - THIS PATIENT

1 - REJECTED - (See Items

2 - APPROVED

APPENDIX IX

PHYSICIAN RESPONSE FORM

FROM DR.: RE:

DATE: _____

REMARKS AND SUGGESTIONS:

_____
Physician Signature

APPENDIX A

# INDEPENDENT BEFORE-AFTER MEASUREMENT FOR SUBJECTS WITH RHEUMATOID ARTHRITIS

## INSTRUCTION MANUAL

I - Introduction
II - Interview Principles
III - Procedures

### I - Introduction

1. This measurement is designed to be taken by a person without medical training who will independently apply acquired techniques of assessing RA subjects on entry to the trial at four and 12 months. It will be used as a comparative measure of change in patients treated by two groups of physiotherapists (PTs): a) PTs trained to conduct total rheumatological assessments, b) PTs on regular Arthritis Society duties. The "Independent Assessors" (IAs) will remain unknown to the physiotherapist involved.

2. Two independent measurements will be conducted on each patient entered in the trial. The first precedes treatment, the second at four months and the third at 12 months, regardless of whether therapy has terminated or is continuing beyond that date. Two

specific interview forms are used entitled "Initial Questionnaire" and "Final Questionnaire". These are designed to provide information related to the patient's arthritis on admission to the trial, at four and 12 months. In addition, the measurements will include objective measures of disease severity relating to: a) grip strength, b) erythrocyte sedimentation rate, c) blood salicylate level, d) latex fixation, e) uric acid level, f) x-ray of the hands to quantitate erosive and destructive changes (initial questionnaire only), g) joint count, h) duration of morning stiffness, and i) a mood assessment.

3. The independent measurements, and the assessments performed by the trained PIs are comparable. The approach used is, however, different. Objective measures of disease severity relating to blood tests and x-rays of the hands will be made available to trained PIs in order to minimize duplication.

4. Under no circumstances will the remainder of independent findings be made available to attending therapists and doctors.

## II - Interview Principles

5. There are a few basic principles of interviewing which should be observed in the course of the collection of these data:

i) It is important to take sufficient time before staring the interview to gain the individual's confidence, and establish a relationship which will encourage her to give you full and complete answers. You should express your appreciation of the fact that she is volunteering her time to help in this research project,

ii) every question is to be asked as written. It is important not to deviate from the written form, specific instructions, however, may provide a certain amount of latitude,

iii) it is always appropriate to add marginal notes on the respondent's comments. Any detail that you think may be interesting or relevant should be recorded in the margins or on an additional sheet of paper. These can at times be extremely helpful and will be read with great care. If an additional sheet of paper is used, please be sure to put the individual's name and number on that sheet,

iv) it is important that you supply the individual respondent with sufficient understanding of what is going on so that she is not confused by subsequent events. For example, it is important to explain at the end of the interview that this

is a separate part of the study and that some of the same questions may later be asked by the doctor and physiotherapists,

v) if you are alert and sensitive to the reactions of your respondent you will easily be able to head off trouble by providing appropriate information as required.

III - Procedures

Handling of a Request for Assessment

6. All referrals are forwarded to The Arthritis Society, Toronto Service Centre at 25 Overlea Blvd., Thorncliffe Square, Toronto, Ont. M4H 1B1. For "regular" referrals the Senior Physiotherapist or her substitute in the area will determine, according to diagnosis and data provided, whether a patient meets the study's criteria. "Special" referrals are initially selected by physicians invited to assign patients to the trial. These are further screened by the Senior Physiotherapist.

7. The following are the initial selection criteria:

i) Women, age 18-65, residents of Metro Toronto, who after proper

explanation, consent to participate,

ii) with a presumptive diagnosis of rheumatoid arthritis,

iii) who are under the care of a family physician, and referred by him,

iv) not seen by a rheumatologist on a designated list for their arthritis, during the past six months,

v) who have no other major sources of disability interfering with musculo-skeletal function,

vi) who are encountering difficulties in the manage of their arthritis at home.

8. Where a patient meets the above initial criteria, the verbal consent of physician and patient are sought. A consent form is sent to the family physician, which he must sign and duly return to The Arthritis Society, Head Office. His signed consent is not essential for entering a patient to the study.

9. Once the verbal consent of patient and doctor is obtained, the Senior Physiotherapist will communicate to the IA by phone: the

patient's name, address and telephone number, random number and name of referring physician.

10. The IA will within 24 hours (excluding weekends and statutory holidays) arrange to see the patient at home.

11. Before starting the assessment, the patient is given the consent form to read, which should be duly signed and witnessed and sent to The Arthritis Society, Head Office with the completed questionnaire. Certain aspects of the consent form may require a further explanation.

12. Final selection and admission will be done by Dr. Smythe or his substitute following the receipt of initial questionnaire and results of laboratory tests and x-ray of the hands. In the event that a patient does not fulfill criteria for final selection, he will be withdrawn from the study, but will continue on routine care. The IA will be duly notified of the patient's status.

Materials

13. To conduct your measurement the following materials are supplied:

i) One attache case,

ii) one clip board and two writing pads,

iii) one modified sphygmo-manometer,

iv) instruction manual,

v) initial questionnaires and income chart,

vi) 20¢ stamps,

vii) large self-addressed envelopes,

viii) patient consent forms,

ix) signed requests for x-rays,

x) vacutainers with delivering tube marked "W.B.",

xi) vacutainers with delivering tube marked "Chem.",

xii) vacutainers for ESR with gray coloured stopper,

xiii) ESR rack and pipettes,

xiv) disposable needles,

xv) charge book for Metro Cab,

xvi) diary,

xvii) timer;

xviii) 200 bandaids,

xix) 300 alcohol swabs,

xx) holders for needles,

xxi) tourniquet (shock card).

Arrangements for X-Rays of the Hands

14. A list of x-ray facilities in Metro Toronto is provided from which you select one that is closest to the patient's residence. An appointment should be made by the IA following the questionnaire. A standard request for x-ray of the hands, already signed by Dr. Smythe, is sent with the patient. If a patient has no means of transportation, arrange through the Metro Cab Group of

Companies and charge to The Arthritis Society credit account #C324. When charging fares, fill in both sides of the charge form, the large section is given to the cab driver and the small section is sent to Head Office at month-end. The x-ray reports and films will be sent directly by the radiologist to the Society's Head Office, Attention: Dr. H. Smythe.

Blood Withdrawal and Disposition of Blood Samples

15. Blood withdrawal will be conducted by the Independent Assessor at the conclusion of the questionnaire. A kit is available which permits withdrawal into three separate vacutainers without removal of the needle.

16. Four different blood tests will be conducted:

i) Erythrocyte sedimentation rate - you will need 5 cc. for that test, or half a vacutainer. These are supplied without a delivery tube, have a grey coloured stopper and contain a potassium oxylate additive. The test will be conducted at the home of the IA within 90 minutes of withdrawal. A kit using the Macro method is supplied with a timer. Results of that test should be reported by the IA in the space allocated in the respective questionnaires,

ii) Latex fixation test - 5 cc. will be needed for that test to be placed in a vacutainer, marked "W.B.", supplied by the Public Health Laboratories. The attached request form should be filled as outlined,

iii) serum salicylate and uric acid tests - 10 cc. (full vacutainer) will be needed for these two tests to be placed in a vacutainer marked "Chem.", supplied by the Public Health Laboratories. The attached request form should be filled as outlined.

17. The blood samples should be placed in their respective containers and sealed. They are to be delivered to the Public Health Laboratories collection boxes at:

i) 360 Christie St. (West side between Davenport and Dupont),

or

ii) 6 Resources Rd. (off Islington exit to Highway 401),

iii) Laboratory - North York General Hospital (Leslie and 401 - hand over to Secretary at front desk for delivery to Provincial Laboratory).

18. Results of blood tests delivered to the laboratories are returned to The Arthtitis Society, Attention: Dr. H. Smythe.

Grip Strength Measurement

19. This measurement is of extreme value in assessing measures of change in disease activity. It is done using a modified blood pressure cuff, folded twice (i.e., into three sections) and secured in a cloth bag. The system is inflated to 20 mm. Hg. pressure, the patient holding his forearm unsupported, elbow at $90^{\circ}$, squeezes the bag hard with encouragement. Record the maximum level maintained by squeezing for a least two seconds, not on initial bounce. Grip strength value is entered in the appropriate section of the questionnaire.

What to Do with the Completed Forms

20. First, check if every question has been answered and that the answers are legible. If a question has been skipped, in accordance with instructions on the form, write "N/A" across it to indicate that it is "not applicable". Forward the initial questionnaire and patient consent form, duly signed and witnessed, to The Arthritis Society, Head Office, Attention: Mr. A. Helewa, using the self-addressed envelope in your possession.

APPENDIX XI

# THE ARTHRITIS SOCIETY AND UNIVERSITY OF TORONTO

## CO-OPERATIVE CLINICAL TRIAL

25 Overlea Blvd , Thorncliffe Sq , .
Toronto, Ont M4H 1B1
Telephone 421 7276

### REQUEST FOR HOME PHYSIOTHERAPY

Patient's Name Mrs / Miss (women only) Age

Address Telephone

(Metro Toronto and immediate Suburbs)

Check the following

Active R A Moderate Loss of Function No Other Sources of Disability

Not seen by rheumatologist during past 6 months Consented to participate

Other Diagnoses

Next Appointment With Me

(date)

Physician's Name Telephone

Address Date of Referral

Physician's Signature

APPENDIX XII

The Arthritis Society and The University of Toronto Co-operative Clinical Trial on the "Total Assessment of Rheumatoid Arthritis by Physiotherapists".

Instructions for Patient Selection and Randomization

(Distribution: Dr. H. Smythe, Mr. A. Helewa, Coordinators - Carolyn Frost, Senior Physiotherapist - Johanne Dursley, Secretary at the Toronto Service Centre - Marilyn Sloan, Questionnaire Consultant)

Patient Selection

1. Patients selected for this trial are obtained from two sources:

   i) Regular referrals - patients who referred for regular service in Metro Toronto, who meet initial selection criteria. Referrals arrive by mail at the Society's Toronto Service Centre, 25 Overlea Blvd., Thorncliffe Square, Toronto, Ont. M4H 1B1,

   ii) special referrals - are patients who meet initial selection criteria referred by a sample of family physicians in Metro

Toronto, invited specifically to refer patients to the trial. These are again forwarded by mail to the Society's Toronto Service Centre.

2. The process of patient selection and randomization will be initially the responsibility of the Senior Physiotherapist and the Secretary assigned to that Centre; each will be following specified procedures unknown to each other. Final acceptance to the trial will be determined by Dr. H. Smythe, Project Coordinator, who will have no knowledge of the method of randomization used initially. These procedures must be adhered to eliminate selection biases.

Selection Criteria

3. Initially all patients must meet the following selection criteria:

i) Women between the age of 18 and 65, residents of Metro Toronto, who after proper explanation consent to participate,

ii) with a presumptive diagnosis of rheumatoid arthritis as stated on the request form,

iii) who are under the care of a family physician or specialist*

*Except those on list of designated specialists.

and referred by him - seeking his consent first,

v) who, during the past six months have not been seen for their arthritis, by a designated rheumatologist,

vi) who are encountering difficulties in the management of their arthritis at home.

Procedures for Initial Selection

4. Regular referrals - based on data provided on the request form the Senior Physiotherapist will:

i) Seek the consent of the referring physician by phone explaining that: "Mrs. X, whom you have referred to us for service appears to meet the criteria for an Arthritis Society clinical trial, established to determine the effectiveness of its Home Service Program. This will involve an initial visit by a trained person, repeated at four and 12 months, who will conduct an interview, take a blood sample and arrange for x-ray of the hands to be taken at a local facility. The therapist will be reporting her findings and provide you with results of blood tests, x-ray of the hands and other measures of disease severity. With your permission we would like to

include her in the trial. Our staff on initial contact will seek her consent". If the physician agrees, the Senior will inquire if in his opinion the diagnosis of RA is confirmed, whether the patient has been seen by a designated specialist for their arthritis during the past six months, and whether they suffer from any other major sources of disability,

ii) the Senior will then seek the patient's consent, explaining as in i) above, the purpose of the trial and inquire about consultation by a designated specialist. The patient is informed that Dr. X has given his consent.

5. Following the consent of patient and doctor, a consent form with a self-addressed envelope (addressed to The Arthritis Society, Head Office, Attention: Mr. A. Helewa), is sent to the doctor for his signature.

6. Special referrals - as explained under item E. ii) these referrals are patients who meet initial selection criteria, obtained from a sample of family physicians in Metro Toronto, invited specifically to choose patients for the trial. Each family physician on that list will be contacted by Mr. A. Helewa informing him briefly of the purpose of the trial. This will be followed with an explanatory letter, special referral forms and a card on which selection

criteria are listed. Patient seen in that family physician's practice within a three-month period from initial contact, and who agree to participate, will be referred to The Arthritis Society, Toronto Service Centre on a special request form.

Patient Randomization

7. All referrals (regular or special) who are deemed to have met the initial selection criteria by the Senior Physiotherapist will be forwarded to the Secretary of the Toronto Service Centre who will assign to each a random number obtained from randomly selected sheets, ("A MILLION RANDOM DIGITS" - Random Corp.) following instructions as provided in confidence. The number will be entered on the top right hand corner of the request form using a ball point pen. She will then make a zerox copy of that request form and forward it to the attention of Mr. A. Helewa at The Arthritis Society, Head Office.

Assignment to Independent Assessors

8. The Senior Physiotherapist will assign a patient number (in numerical order) and then inform one of three Independent Assessors assigned to a geographic location of Metro Toronto, providing the patient's name, random number, patient's number,

address and telephone number, and the name of referring physician. The IA, if necessary, will again explain the project to the patient and obtain her signed consent. This assessment will be conducted within two working days of receipt of information.

Assignment to Physiotherapists

9. The Senior Physiotherapist guided by the random number and instructions provided to her in confidence will allocate the patient to either experimental or control physiotherapist. The randomization code will be only known to her and Mr. Helewa.

10. Assignments to experimental physiotherapist are first made by phone followed by mailing of the request form. Patients residing East of Dufferin St., are allocated to Mrs. Mary Jane Stepinac, those residing West of Dufferin St., are allocated to Mrs. Pat Ward. Assignments to the control physiotherapists will be according to the geographical location in which they are working at that time.

Final Selection and Admission to the Trial

11. This will be done by Dr. Smythe when the results of the Independent Assessors' initial assessment have been obtained. It will be based on information obtained from the IA Questionnaires and laboratory

results. The reasons for excluding patients from the trial are as follows:

i) Patient fulfills less than five ARA criteria for a diagnosis of RA, or less than two of the New York criteria for a diagnosis of RA,

ii) patient has a condition, or finding which is on the list of exclusions for RA diagnosis according to ARA criteria, or has psoriasis;

iii) patient's disease severity is too minor to be influenced by therapy, i.e., is in Functional Class I, by ARA criteria, or has fewer than three actively inflamed joints,

iv) patient's disease severity is too great to be readily influenced by out-patient therapy, i.e., is in Functional Class IV, by ARA criteria,

v) difficulties encountered by the Independent Assessors which may prevent completion of the interview or blood withdrawal, inability to have x-rays of the hands taken, major distractions or lack of comprehension on the part of patient.

12. All patients initially selected and who subsequently do not meet final criteria will be maintained on file and the reason for exclusion listed.

Assignment of Other Patients Referred to the Toronto Service Centre

13. All other patients who are not entered in the trial will be assigned to either the trained or traditional therapist depending on caseload and geographic location. It is essential that the two groups of therapists maintain a well-balanced caseload between them, however, consideration must be given to the larger geographic area covered by the experimental therapists.

# PROCEDURE FOR FINAL PATIENT SELECTION

# AND DATA VERIFICATION BY RESEARCH ASSISTANT

1. Sources of Referral

Patients are referred: i) directly by their family physician or specialist (except rheumatologists on exclusive list) to Arthritis Society service in Toronto; ii) indirectly, through publicity in the media, whereupon if they meet initial criteria, it is verified with family physician.

Written physician and patient consent is sought and patient is randomly allocated to study or control group. (See instructions re patient selection and randomization.)

Upon receipt of referral form copy from Overlea, a study file is opened by research assistant, and placed under "Entered" section awaiting receipt of clinical data.

2. Recording of Data

The independent assessment provides demographic, diagnostic, prognostic and data on inflammation, instrumental in final selection process.

a) Data from independent assessment, necessary for selection is transferred to form titled "Summary of Data for Initial and Final Selection". (Form A) Specific calculations are made for this purpose re disease duration and active joint counts.

b) Check Chart: Data from I.A. which is now on final selection sheet is transferred to Check Chart.

c) I.A is reviewed for any omissions.

d) As well laboratory data is received from two other sources; blood tests (performed by provincial lab on salicylate levels, latex fixation and uric acid) and x-rays of hands taken at a local facility.

e) Blood tests are recorded on Final Selection Sheet, Check Chart, and in corresponding area in I.A. These results are also sent to referring physician of control patients by C.A.R.S Administrative Secretary.

f) X-ray film and report are placed in appropriate envelope with patient name and project number recorded in upper corner. This is then noted on Check Chart. Form B is prepared for X-ray Erosion Count and attached to x-ray envelope.

3. Final Patient Selection

a) Smythe reads x-rays and notes Erosion Duration Index on form B, determines if patient meets all selection criteria and signs final selection sheet. (Form A).

b) Research Assistant records on Check Chart, the erosion count, the number of A.R.A. and N.Y. criteria met, final selection decision; and if patient is admitted to the study, the patient number.

c) Final selection decision is recorded on form $C^1$ or $C^2$ and mailed to the independent assessor, who will record in her calendar the date for the next assessment.

d) Study Files are updated according to patient's final selection status, either active or rejected.

e) According to group assigned (study or control) and socio-economic status, patient is designated a flag shape and colour which is pinned on map (in study co-ordinator's office) at point of patient's residence.

4. Ongoing Procedure

a) As the physiotherapists see patients, the research assistant will be responsible for obtaining copies of letters and data sheets sent by trained physiotherapists to referring physician.

b) At four months the research assistant checks with I.A. re second interview, obtains data, as above and enters on check chart. Also processes each assessment for omissions or errors.

## Calculation of the Pooled Index

1. Clinical observations were averaged to give the mean result for each measure. Thus "mean grip strength" was the mean of 10 separate components; the right and left hand grip strength recorded by each of five observers.

2. The treatment difference for each patient was obtained by subtracting the final value from the initial value for each of the separate measures used (grip strength, morning stiffness, ESR, change in functional capacity, modified joint count).

3. For each measure the mean treatment difference and standard deviation of a group of differences were calculated.

4. The mean treatment differences were divided by the group standard deviation to obtain the derived (standard deviation) units. For analysis of variance, each individual observation was similarly converted to derived units.

5. The transformed measures each had a common initial value (zero), a common standard deviation (one), and a similar mean and range. Improvement was always given a positive sign, deterioration a negative sign; for example, reduced morning stiffness was an improvement and scored positively.

6. The pooled index was the mean calculated from the five separate transformed values.

In the validation study, the divisors (standard deviations) were: modified joint count 4.82; grip strength 26.20; morning stiffness 64.90; sedimentation rate 19.85. From the same data, it was determined that appropriate divisors for the ARA joint count were 8.68 and for the Lansbury articular index 37.34.