Arthritis Research

July 2002

Notes From the Director Research Results...Where your Data Goes

We think that all of you who help so much by completing the research questionnaires might like to know about the results of our studies, and why what you tell us is so important.

This year's major publication regarding treatment of rheumatoid arthritis came from the National Data Bank for Rheumatic Diseases (NDB). Dr. H. Choi and his colleagues at Harvard University together with Dr. Frederick Wolfe and the National Data Bank reported in the Lancet Medical Journal that methotrexate increased life expectancy among persons with RA who used that treatment. This important study – the very first to show that RA treatment can do more than just relieve symptoms – received national press coverage and international recognition.

The NDB will present more than 20 abstracts at the national American College of Rheumatology meeting in 2002,

including presentations on rheumatoid arthritis, osteoarthritis, and fibromyalgia. In 2001, the NDB presented more research results than any other U.S. university or research group. Many of these presentations have been accepted for publication in medical journals. One way that research is presented at national research meetings is by poster. A poster (see the poster below that has been reduced in size) fills an entire bulletin board. At the research meeting, NDB staff stands by the poster, explains the results to the meeting attendees, and answers all questions.

The poster below is about treatment of Rheumatoid Arthritis. It's a little too small for you to read, but if you send us an email (info@arthritis-research.org) we'll send you a bigger copy, or you can go to the NDB web site and download it yourself (www.arthritis-research.org). For a complete listing of NDB research presentations and publications, go to the web site and click on "Manuscripts".

DISEASE SEVERITY AND TREATMENT OF RHEUMATOID ARTHRITIS IN 2001: RESULTS FROM A US LONGITUDINAL STUDY OF 6293 PATIENTS F. Wolfe¹, K. Michaud¹, J. Messer², H. Choi³

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Introduction	UMARU/Biologics/Prednisone	Current Ever	NSAIDS	Current Other	C	ument	ALINSADI	Criticalb	All GI Drugs	Proton Puma Inhibitore
Introduction	DMARD/Biologics/Prednisone	81.6%(93.4%)	NSAIDS	62.9% Analg	esics	19.3%	4 1	21	4 1	2
While it is known that almost all natients with RA receive	DMARD/Biologics	78.1%(90.9%)	COX-2 Specific	28.7% Opic	ds	9.0%				
DMARDs, there is considerable uncertainty concerning the	DMARDS	72.7%(90.5%)	Celecoxib	17.6% Hy	frocodone	7.8%	4			5-
use of combination therapy and the use of prednisone	Methotrexate (all forms)	49.8%(72.3%)	Rofecoxib	11.4% Ox	codone	1.5% 🛔		a *1	· · · · · · · · · · · · · · · · · · ·	
and the use of combination merupy and the use of preampone.	Methotrexate (oral)	36.9%(53.4%)		Non	Opiods 3	13.1%) () () () () () () () () () (3 -
 Similarly, there is considerable uncertainty as to the 	Hydrowchiocourine	22 6%/54 9%)	Non-Specific	36.6% An	taminonben 3	n 0% Č		e	· 2 ·	
extent and kind of analgesic and GI therapy used by RA	Methotrevate (injectable)	13 5%(21 6%)	Ibuncofen	82% 48	A APAP/mdeine/		2			× ·
patients.	Lefupornida	11.05((20.7%)	Nanovan	9.0% Per	now mhone mix	2.6%				
Finally, little is known of the result of such therapy in the	Suffereinzion	6 15((22 19))	Acoirio*	2.6% Tes	madel 4 1%		0 12 24 24		6 12 A A	6 12 24 26
community, as measured by outcomes such as the HAQ.	Gold injection	2 26(27 28)	Naturnationa	3.4%	110000 4.170		Months Enformatio	Months	Months M2 Stockers	Norths Other Gi Medications
We used data from a large prospective longiturinal study.	Application 4.00	10.000	Disisferen	0.4% 01.0*		7.04	-55 -	15.4	24 -	a 4
of DA outcomes is the UE to armide insight into these	Azamopine 1.8%	(6.0%)	Dicipienac	2.4% GLD	120.0	17.376				
include in the US to provide insight into these	Minocycline	1.5% (7.3%)	Suindac	2.2% PPB		90.2%			.15	
INIethods	Auranotin	0.4%(10.9%)	Salsalate	1.9% Off	eprazore	8.9% §		a 11	i	2
As part of an ongoing longitudinal study of RA, 6293	Cyclosporine 0.4%	(3.5%)	Meloxicam	1.9% Lar	soprazole	6.1%			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
US RA natients treated by community rheumatologists	Penicillamine 0.1%	(8.4%)	Etodolac	1.7% Est	meprazole	2.4% 2		£	. é	4
completed 1 or more questionnaires administered by a	Cyclophosphamide	0.1% (0.4%)	Oxaprozin	1.6% Ra	peprazole	1.8%			- 20.	
detailed nostal survey at 6-month intervals in 2001			Piroxicam	1.1% Pa	toprazole	1.6%				
	Biologics	20.5%(27.2%)	Diclofenac -	H2 ii	hibitors	9.4%				· · · · · · · ·
 Data from the most recent questionnaire is presented. 	Etanercept	14.2%(19.6%)	Misoprostol	1.1% Ra	nitidine	4.9%	Months	Months	Months	Months
and the rates are determined by drug use in the last month	Infliximab	6.4%(10.5%)	Ketoprofen	1.0% Fai	notodine	2.8%				
of the 6 month period. Rates for the full 6 month period are			Indomethacin	0.6% Cir	etidine	1.3%	Figure 1 Change in N	SAID therany during previous	Figure 2, Change in GL thera	ny during previous 36
approximately 3% greater that the rates in the Tables	Predoisone	28 05(66 95)	Eluthiocofeo	0.3% Niz	atidine 0.5%		riguro n. onungo in re	or the thorapy during provided	rigaro 2. onango in or alore	p) daning provided do
			Toimetin	0.3% Othe	r Gi douns	7.9%	36 months.		months.	
Table 4 DA therease is 0004			Eenoorofee	0.1% An	acida 6 6%	1.474				
Table 1. RA therapy in 2001			i unoproteri	0.176 741	actus 0.374		-	10 7 P D		
			Meciofenamate	0.1% Mid	oprostol	1.1%	Resu	uits (continued)		
Table 2. Combination therapy in 2001				Su	raifate	0.5%		· · · ·		
				Misr	GL damas	8.2%	As illustrated in Table 2. p.	atients on prednisone had HAQ scores that		
Results				Misc	GI drugs	8.2%	 As illustrated in Table 2, pr were, on average, 0.3 units his 	atients on prednisone had HAQ scores that oher. RA patients on combination therapy		
Results				Misc	. Gi drugs	8.2%	 As illustrated in Table 2, pr were, on average, 0.3 units hip had more abnormal HAQ score 	atients on prednisone had HAQ scores that gher. RA patients on combination therapy res (~0.1 unit) and more frequently used		
Results	\			Gluco	GI drugs samine	8.2%	 As illustrated in Table 2, pr were, on average, 0.3 units high had more abnormal HAQ score provingence. Higher HAQ score 	atients on prednisone had HAQ scores that gher. RA patients on combination therapy res (~0.1 unit) and more frequently used as were able seen among users of analogsic	4	
Results Table 1 shows the distribution of NSAID, DMARD, Biologie Application and Cl therapy groups BA estimate	Therapy	Rece	iving HAQ	Gluco	GL drugs samine HAQ On HAQ	8.2% 8.4% Not On	 As illustrated in Table 2, pr were, on average, 0.3 units his had more abnormal HAQ score prednisone. Higher HAQ score and GL druge 	atients on prednisone had HAQ scores that gher. RA patients on combination therapy res (~0.1 unit) and more frequently used es were also seen among users of analgesic	La contractere a la con	
Results Table 1 shows the distribution of NSAID, DMARD, Biologic, Analgesic, and GI therapy among RA patients for the final divide meeting the DMD/Dhibartise thereauren	Therapy	Rece Users Predri	iving HAQ isone All Patients	<u>Misc</u> Gluco s 95% Cl	GI drugs samine HAQ On HAQ Prednisone Pred	8.2% 8.4% Not On nisone	 As illustrated in Table 2, pr were, on average, 0.3 units hij had more abnormal HAQ score prednisone. Higher HAQ score and GI drugs. 	atients on prednisone had HAQ scores that gher. RA patients on combination therapy res (~0.1 unit) and more frequently used es were also seen among users of analgesic	A Latente	
Results Table 1 shows the distribution of NSAID, DMARD, Biologic, Analgesic, and GI therapy among RA patients during the last study month. DMARD/biologic therapy was used to 17 481 - DMARDe biologic therapy was	Therapy	Users % 9	iving HAQ isone All Patients 6 (mean)	Misc Gluco s 95% Cl [Low High]	Gl drugs samine HAQ On HAQ Prednisone Pred (mean) (m	8.2% 8.4% Not On nisone ean)	 As illustrated in Table 2, pa were, on average, 0.3 units his had more abnormal HAQ score prednisone. Higher HAQ score and GI drugs. Figure 1 demonstrates that 	atients on prednisone had HAQ scores that gher. RA patients on combination therapy res (~0.1 unit) and more frequently used es were also seen among users of analgesic at while NSAID use has remained constant	Presson	
Results • Table 1 shows the distribution of NSAID, DMARD, Biologic, Analgesic, and GI therapy among RA patients during the last study month. DMARD biologic therapy was used by 76 15, DMARDs by 72 7%, and biologicable 32 03 5%.	Therapy	Users Predra % 9	iving HAQ iisone All Patients 6 (mean)	<u>Misc</u> Gluco s 95% Cl [Low High]	Gl drugs semine HAQ On HAQ Prednisone Pred (mean) (m	8.2% 8.4% Not On nisone ean)	 As illustrated in Table 2, pr were, on average, 0.3 units hij had more abnormal HAQ scor prednisone. Higher HAQ score and GI drugs. Figure 1 demostrates tha over the last 36 months, decre 	atients on prednisone had HAQ scores that gher. RA patients on combination therapy res (-0.1 unit) and more frequently used es were also seen among users of analgesic at white NSAID use has remained constant seases in traditional NSAIDs (naproxen) have		
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Results • Table 1 shows the distribution of NSAD, DMARD, Biologic, Anaglesi, and Gi Brenzy among RA patients during the last study month. DMARD,biologic threnzy was used by 78 fits, MARDS by 72 TA, and biologics by 20 St. 2 Shows min the study of the study month. Shows the study of the state study of the study of t	Therapy One Drug only Methotrexate (MTX) Hydroxychloroquine (HCQ	Rece Users Predr % 9 45.9 29.7 24.2 30.8) 8.1 21.7	tving HAQ isone All Patients 6 (mean) 1.03 1.06 0.84	<u>Misc</u> Gluce s 95% Cl [Low High] [1.00 1.06] [1.02 1.09] [0.78 0.90]	<u>GI drugs</u> samine HAQ On HAQ Prednisone Pred (mean) (m 1.26 1.25 0.99	8.2% 8.4% Not On nisone can) 0.94 0.97 0.79	 As illustrated in Table 2, pr were, on average, 0.3 units hi had more abnormal HAQ scor predinisone. Higher HAQ scor and Gi drugs. Figure 1 demonstrates tha over the last 38 months, decre occurred at the time when ver- seen. 	atients on prednisome had HAQ scores that bler: RA patients on combination therapy res (~0.1 unit) and more frequently used ses were also seen among users of analgesic ut white NSAID use has remained constant eases in traditional NSAIDs (naproxen) have y large increases in the use of COX-2 can be		Patient State
Results • Table 1 shows the distribution of NSAID, DMARD, Biologic, Analgesic, and Gi Interpy among PA patient discipation of the strength of the strength of the used by 78.1 Ny, MARDE by 72.7 xm, and the biologic by 20 Six 21.6% were not receiving any DMARD/biologic treatment. • As shown in Table 2, mono DMARD Biologic (DB) therapy was used by 45.5%, Contribution DB mempy was	Cne Drug only Metholrexate (MTX) Hydroxychioroquine (HCQ Etanercept (ETA)	Rece Users Predri % 9 45.9 29.7 24.2 30.8) 8.1 21.7 4.7 25.9	iving HAQ isone All Patients 6 (mean) 1.03 1.06 0.84 1.09	<u>Misc</u> Gluco s 95% Cl [Low High] [1.00 1.06] [1.02 1.09] [0.78 0.90] [1.00 1.17]	GL drugs samine HAQ On HAQ Prednisone Pred (mean) (m 1.26 1.25 0.99 1.30	8.2% 8.4% Not On nisone ean) 0.94 0.97 0.79 1.01	 As illustrated in Table 2, pr were, on average, 0.3 units hi had more abnormal HAQ scor and GI drugs. Figure 1 demonstrates ha over the last 36 months, decr occurred at the time when ver- seen. GI drugs are used by 37.3' 	atients on prednisone had HAQ scores that before: RA patients on combination therapy es (~0.1 unit) and more frequently used es were also seen among users of analgesic the swere also seen among users of analgesic the swere also seen in the seen COX-2 can be write increases in the user of COX-2 can be %, and PPIs by 20.2%. Figure 2 shows that		
Results Table 1 shows the distribution of NSAID, DMARD, Biologic, Analges, and O Theracy among RA patients during the last study month. DMARD/biologic therapy was used by 78.1%, DMARD by 72.7%, and biologic by 035%, 21.9% were not receiving any DMARD/biologic Tellar Martin and State 2, among DMARD/Biologic (DB) therapy was used by 45.5%, Combination DB Therapy was used by 23.2%. The preventing can be further subset into the prevention of the prevention of the thready was used by 23.5%.	Cne Drug only Methotrexate (MTX) Hydroxychionoquine (HCQ Etanercept (ETA) Leftunomic (LEF)	Users Predr % 9 45.9 29.7 24.2 30.8 8.1 21.7 4.7 25.9 3.9 42.0	HAQ iisone All Patient: (mean) 1.03 1.06 0.84 1.09 1.15	Misc Gluco s 95% Cl [Low High] [1.00 1.06] [1.02 1.09] [0.78 0.90] [1.00 1.17] [1.06 1.25]	<u>Gl drugs</u> samine HAQ On HAQ Prednisone Pred (mean) (m 1.26 1.25 0.99 1.30 1.40	8.2% 8.4% Not On nisone can) 0.94 0.97 0.97 1.01 0.98	 As illustrated in Table 2, pr were, on average, 0.3 units hi had more abnormal HAQ scor and GI drugs. Figure 1 demonstrates that over the last 38 months, decr occurred at the time when ver- seen. GI drugs are used by 37.3 the increase in PPIs has been 	atients on prednisone had HAQ scores that giver. RA patients on combination therapy res (~0.1 unit) and more frequently used es were also seen among users of analgesic at white NSAID use has remained constant esses in traditional NSAIDs (naprocer) have y large increases in the use of COX-2 can be %, and PPIs by 20.2%. Figure 2 shows that a the expense of H2 blockers and other G1		Market Contraction of the second seco
Results • Table 1 shows the distribution of NSAID, DMARD, Biologic Analges, and O Therapy among PA patients during the last study month. NDMARD:blockgic therapy was 22.15% when the checking any DMARD/blockgic therapy was 22.5% when the checking any DMARD/blockgic therapy 21.5% when the checking any DMARD/blockgic therapy 22.5%. This percentage can be further subset into 150% that includes TNF therapy and 172% using	Therapy Methotexate (MTX) Hydroxychloroquine (HCQ Etanercey (ETA) Leffunomice (LEF) Sulfasalazine (SSZ)	Users Predm % 9 45.9 29.7 24.2 30.8) 8.1 21.7 4.7 25.9 3.9 42.0 1.4 186	tving HAQ iisone All Patients 6 (mean) 1.08 0.84 1.09 1.15 0.96	Misc Gluco s 95% Cl [Low High] [1.00 1.06] [1.00 1.07] [1.00 1.25] [0.80 1.12] [0.80 1.12]	GL drugs samine HAQ On Prednisone HAQ Prednisone 1.26 1.25 0.99 1.30 1.40 1.57	8.2% 8.4% Not On nisone ean) 0.94 0.97 0.79 1.01 0.98 0.82	 As ilustrated in Table 2, p were, on average, 0.3 units hith had more abnormal HAQ scor predinizone. Higher HAQ scor and GI drugs. Figure 1 demonstrates tha over the last 36 months, decr occurred at the time when ver- seen. GI drugs are used by 37.3 the increase in PPIs has been drugs. 	atlents on prednisone had HAQ scores that here. RA patients can combination therapy es (~0.1 unit) and more frequently used is wre also also around units of analgesic tt while NSAID use has remained constant eases in traditional NSAIDs (approxen) have jurge increases in the use of COX-2 an be %, and PPIs by 20.2%. Figure 2 shows that at the expense of H2 blockers and other Gi		
Results • Table 1 shows the distribution of NSALD, DMARD, Blooge Analyses and 0 lineary awards TA patients Blooge Analyses and 0 lineary awards TA patients used by 74.1%, DMARDs by 72.7%, and biologics by 50.5%, 21.5% were not exceeding any DMARDbiologic testimate. • As shown in Table 2, mono CMARDBiologic Bloogen by 50.5%, Bloogen DB analyses, and the strengt an	Therepy Methotexate (MTX) Hydroxychiroquine (HCZ) Entanercept (ETA) Leftunomice (LEF) Suttasalazine (SSZ) Gold nijection	Rece Users Predry 46.9 29.7 24.2 30.8 8.1 21.7 4.7 25.9 3.9 42.0 1.4 18.6 1.2 164	eving HAQ issone Al Patients (mean) 1.03 1.06 0.84 1.09 1.15 0.96 4.66	Misc Gluco s 95% Cl [Low High] [1.00 1.06] [1.02 1.09] [0.78 0.90] [1.00 1.17] [1.06 1.25] [0.80 1.12] [0.80 1.12] [0.89 1.04]	Gi drugs samine HAQ On HAQ Prednisone Pred (mean) (m 1.26 1.25 0.99 1.30 1.40 1.57 1.27 1.67	8.2% 8.4% Not On nisone ean) 0.94 0.97 0.99 1.01 0.98 0.82 0.78 1.44	 As ilustrated in Table 2, p were, on average, 0.3 units hith had more abnormal HAG scor predinisone. Higher HAG scor and Gl drugs. Figure 1 demonstrates the over the last 36 months, decre occurred at the time when very seen. Gl drugs are used by 37.3 the increase in Pyls has been drugs. 	alients on predinisone had HAQ accres that pair. RA patients in combination threapy es (~2) trult) and more threapwinty used server also users mong users of analysis: of white NAQD use has remained constant users in tradicions NAQDs (naprocess) have y large increases in the use of COX-2 can be %, and PPIs by 20.2%; Figure 2 shows that a the expense of H2 blockers and other G1 blockers.		
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Results • Table 1 shows the distribution of NSAID, DMARD, Biologic, Analges, and O Theraya manifest particular to the start and the start and start a	Theracy <u>One Drug only</u> <u>Methodecate (MTX)</u> Hydroxytholonquine (HCQ Etanencept (ETA) Leflunomide (LFF) Sultastazine (SS2) Gold typedion Infliximab (IFX)	Race Users Predri % 9 45.9 29.7 3.9 42. 30.8 8.1 21.7 4.7 25.9 3.9 3.9 1.4 18.6 1.2 16.4 0.8 49.0 26.7 33.3	eving HAQ isone All Patients 6 (mean) 1.03 1.06 0.84 1.09 1.15 0.96 0.87 1.55	Misc Gluco 5 95% Cl [Low High] 1.00 1.06] (1.02 1.09] (0.78 0.90) (1.00 1.17) 1.06 1.17] (0.80 1.12] (0.69 1.04] (1.37 1.72] (1.03 1.10]	Gl drugs samine HAQ On HAQ Prednisone Pred 126 Pred 128 0.99 1.30 1.40 1.57 1.27 1.66 1.24	8.2% 8.4% Not On nisone ean) 0.94 0.97 0.79 1.01 0.98 0.82 0.78 1.44 0.97	 As ilustrated in Table 2, p were, on average, 0.3 units h had more abnormal HAG scor predhisone. Higher HAG scor or and GI drugs. Figure 1 demonstrates tha over the last 36 months, decre occurred at the line when very seen. GI drugs are used by 37.3 the increase in PPIs has been drugs. Figure 3 ilustrates the 36 iluse of MTX, the mainstay of P 	alients on predinisone had HAQ access had as (-0.1 unit) and more frequently used es were also seen among users of analgesic at white NSAID use has remained constant esses in traditional NSAIDs (napprocent) have esses in traditional NSAIDs (napprocent) have a set as a set of the set of the set of COX.2 and y large increases in the use of COX.2 are had at the expense of H2 blockers and other GI month changes in DMARDhiologic therapy.		
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Costs of Medical Care and Arthritis

In the National Data Bank questionnaires we have asked several different kinds of questions. The first type of questions deal with how well you are doing in term of function, pain, fatigue and work. You might not have realized it, but the second kind of questions deal with costs of your medical care. Each medical visit, hospitalization, or medication has a cost attached. When we receive your replies to the questionnaire we calculate medical costs for the 6-month period of the questionnaire. Just so you know, during the last 6 months costs ranged from 0 to \$83,000, with an average cost of \$4,300.

If we know your medications and how you are doing, and also know the costs, we can sometimes calculate what's called cost-effectiveness. This has become a very important area for research, and the results of such research have a lot to do with how easy or how difficult it might be for you to get the care you need. In the following paragraphs we want to explain a little more about costs and cost-effectiveness, using data you have supplied in your questionnaires

Our drugs: how well do they work? Are they worth it?

There have been many advances in arthritis treatment over the last few

decades. Drugs have become safer and more effective. But all of this has come at a price, and often a big dollar price.

Many people want to know if arthritis drugs are 'worth it.' But more than that, they want to know if a specific arthritis drug, for example Celebrex, Vioxx, or

Enbrel, is worth it. Who are these

people? First of all, they might be you, if you have to pay for the drug out of your pocket. They might be your insurance company. If your insurance

company or your HMO decides the drugs are not worth it, you might not be able to get them at all or you might have to pay much more for them than for other drugs that your insurance company

thinks are better values. If you go to a

VA hospital or to a military base you

us to judge how well a drug is doing. We have picked out four drugs from all of the drugs that are available to illustrate some points about effectiveness. But you shouldn't come away from these graphs thinking that this is the actual effectiveness of the drug, and remember, these graphs only represent a few drugs. All of the other available arthritis drugs have been left out.

Here's how to read the graphs. People in the NDB classify their satisfaction with the drug into 4 categories: poor, fair good, and excellent. The 'fraction' is the proportion of people who rated the drug in each category. Multiply the fraction by 100 to get the percent (.4 = 40%). OK, ready to go? One way to judge effectiveness is to see which drug has the fewest poor or fair responses. Prilosec, the drug for heartburn and ulcers (upper left), is the most effective drug using that criterion. In fact, it's the drug with the highest level of effectiveness of all the drugs in the NDB. Its average score, assuming that poor = 1 and excellent = 4, is 3.2. All of the other drugs have more poor or fair responses. Conclusion: people like prilosec, and they like it a lot.



Figure 1 - Drug Satisfaction from NDB Data

might not be able to get the drug at all, and if you are over 65 you'll have to pay for them anyway, except for a quirk in the law that lets Medicare pay for Remicade.

For starters, look over at the graph (Figure 1) of satisfaction with specific drugs that came from your questionnaire answers when you first enrolled in the National Data Bank for Rheumatic Diseases (NDB). Satisfaction is a rough way for What about DMARDs (Disease Modifying Agent for Rheumatic Disease) that are used for rheumatoid arthritis? Methotrexate has a satisfaction score of 2.9, while Enbrel's score is 3.2. If you look at the graph (Figure 1) you'll see that Enbrel has about 39% of people who are very satisfied, but methotrexate has only 22%. But when you consider both good and very good, the satisfaction rate for methotrexate is 75% versus 77%. So you might conclude that Enbrel is a little better than methotrexate, and, in fact, that is what controlled clinical trials have found.

Now, lets factor in the costs. As shown in the table (Figure 2), the monthly cost of methotrexate is \$46 while the monthly cost of Enbrel is \$1,235, almost \$1,200 difference. In addition, it costs \$15.86 for each unit of satisfaction for methotrexate and \$398.39 for each satisfaction unit for Enbrel. Put another

Drug	Cost per Month	Satisfaction Score	Cost per Unit of Satisfaction
Prilosec (20 mg)	\$125	3.3	\$37.87
Naproxen (1000) mg)	\$17	2.9	\$5.86
Methotrexate (15 mg)	\$46	2.9	\$15.86
Enbrel (injections)	\$1235	3.1	\$398.39

Figure 2 - Drug	Costs and Sati	sfaction Scores
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way, for the same amount of effectiveness Enbrel costs 88 times as much. Here's still another way to think about it. If everyone switched from methotrexate to Enbrel, the satisfaction score would change by 0.3, but the monthly cost would increase by approximately \$1,200.

Let's next think about anti-inflammatory drugs (NSAIDs). As shown in the Table, naproxen (Aleve) costs \$17 per month, but Vioxx and Celebrex cost from \$75 to \$178 (depending on dose) or from 4.4 times to 10 times as much. Celebrex and Vioxx reduce the risk of ulcers compared with naproxen, but they are not more effective.

So is it worth it? There is no clear answer to that question. Suppose that cost was no object, that either you or your insurance company had unlimited money. Then the answer would be simple: it's worth it. But suppose that you had to pay for the medication yourself. Or just suppose that an insurance company had a limited amount of money and had to decide how best to spend it to do the most good. Should they spend it on an expensive heart drug or diabetes drug, or should they spend it on an arthritis drug?

The first way to try to understand this question is to measure effectiveness accurately. There are two ways to measure effectiveness. One way uses your reports on function, pain, and similar factors. With information such as this we can report overall cost-effectiveness in term of the dollars per unit of function improvement or reduction in pain. It's easy to understand that if medications can reduce your pain in half for a cost of \$1,000 dollars that it would be worth it. One problem with pain and function as a measure of effectiveness is that it cannot be used to compare the effectiveness of drugs for different illnesses (i.e. heart drugs vs. arthritis treatment). If we want to show that insurers or governments should pay for arthritis treatments we need to have a way to compare the treatments using a scale that is the same for all illnesses.

The second way to measure effectiveness allows us to do this. The measurements are called utilities. You may remember that one question we ask in every questionnaire is for you to value your 'health state.' It's called the 'health thermometer.' With this question, everyone rates his or her health state as a number between 0 and 100, with 100 being perfect health and 0 being death. To make it easier for us, we rescale this number to be between 0 and 1 instead of 1 and 100. You might be interested that the average health state for rheumatoid arthritis is 0.66. It's 0.57 for people who have fibromyalgia. This means that people with fibromyalgia rate their health as being about 15% worse than the health of people with rheumatoid arthritis. Now lets use this utility measurement. Suppose you can be expected to live for 20 more years, and we have a treatment that increases your health so your utility score increases from

0.57 to 0.77 and is maintained at that level for 20 years. Multiplying 20 years times 0.2 (the

improvement), the total improvement is 4 units. We call ...pain and function as a measure of effectiveness cannot be used to compare drugs for different illnesses...

these units "QALYs" for Quality Adjusted Life Years. One way of interpreting the 4 QALYs is to say that, on average, you would be arthritis free for 4 of the 20 years of your life. If we have the QALYs and the cost of the treatment, we can then calculate how much it costs to gain 1 QALY. People are often willing to pay as much as \$50,000 for 1 QALY. In England, health authorities used QALYs to determine the cost-effectiveness of drugs like Enbrel and Remicade.

Is that all there is? No. There is one important fact we left out. The interpretation of QALYs depends on your point of view. If you were an insurance company with an interest predominantly in making money for your stockholders, you might have a perspective quite different from society as a whole, which might be very interested in making people well enough to return to work. If you were a person with arthritis, you might have a very different idea about how much to pay for each QALY, and how much it was all worth. So utilities and QALYs can't solve the issues of how much improvement is worth, but they do give us an accurate idea of costs and cost-effectiveness so that we can come to appropriate conclusions about treatment and its worth. **QALYs and the NDB.** The NDB has a special position (with your help, of course) in establishing the cost-effectiveness of arthritis treatment because the true assessment of drug effectiveness comes from users of drug (like you) rather than from the artificial setting of clinical trials. With this as background, we want to tell you about the QALY project.

The QALY Project

One way to obtain utilities is with the "health state" questionnaire we mentioned above. But it is not the best way.

The best way is to give people with and without arthritis, descriptions of people with arthritis, and then ask just what the utility should be. We do it this way because people without arthritis may be thought of as having society's point of view while people with arthritis have the point of view of persons with the illness. Later this summer, we will send everyone a CD-ROM that will enable you to make utility assessments on 5 different people. If you have a computer and a little time, we think you will find this to be fun, and it will be very helpful for medical research. We hope you will want to help, and we think you will enjoy being a direct part of medical research.

Web Quest: On-Line Once Again!

We are happy to announce our second on-line research questionnaire. The first WebQuest was a success with over 1000 questionnaires completed. Thanks to everyone who participated and gave us feedback to make the on-line questionnaire more efficient and user-friendly.

Our goal this time is to make the WebQuest faster and more convenient, and in general, easier to use. Here are some new features you can expect to see:

Error Reporting: The new WebQuest will report errors as you go. So, if you make a mistake you will know instantaneously and can make the correction. This means you will not have to reanswer ALL the questions on the page to fix one or two problems.



Medication Information: All your medication information from your previous questionnaire will be automatically displayed. You will not need to tell us your medications you were taking last time so this section should go much faster. (*Right now this* only applies to people who completed the online questionnaire for the last phase. We are working to provide this option for everyone using the WebQuest soon.)

Question Examples: A new feature had been added to help you answer specific questions by giving examples. This will help if you have any problems, or a question is unclear or confusing.

Visual Navigator: A visual display off to the left hand-side of the screen will help you navigate through the entire questionnaire. It will indicate where you are as well as how far you have to go.

Snack Break: We have also changed the WebQuest to give you the option to stop and come back later even if you are in the middle of a page. All your answers will be saved and you can start where you left off.

Skipping Questions: The WebQuest will skip specific questions that do not apply to you. For example, if you don't currently smoke, you will not be asked "How many packs per day". This will make the questionnaire shorter and allow you to move through it faster.

Your enthusiasm and detailed feedback have really helped shape the on-line questionnaire. Please continue to send us your comments; we love to hear from you.

Everyone who completed the WebQuest last time will be automatically emailed a new invitation. If you are new to the web, or interested in trying the on-line

questionnaire, please email us at **info@arthritisresearch.org** or call us at 1-800-323-5871. We

will send you everything you need to get started.

Important concerns about your privacy

The questionnaire and email process is absolutely private and secure. We will never give your email address to anyone. *Never means never*. When you access our web site you will do so with a special code we will send to you. Only you will have that code and therefore only you can see your data. For those of you who still may have concerns, we have installed a full range of security measures so that no one can break into the web site and get at the data. If you'd like more information on our security email us at info@arthrithis-research.org

National Databank for Rheumatic Diseases

Arthritis Research Center Foundation, Inc.

Getting it Straight From the Source: FAQs

FAQs, as people who use computers know, are Frequently Asked Questions. The NDB gets a lot of FAQs and other comments, and believe it or not we read every one of them. Unfortunately we are unable to respond to everyone's question individually, so here are some of the questions and some answers from Dr. Wolfe.

1) Who gets to see the information I provide? Is it shared with pharmaceutical companies? All information you provide is absolutely confidential. No non-research person ever sees your information, and that includes pharmaceutical companies. We do allow medical researchers to see the data for research purposes, but only after all individual identifying information (e.g., name, address, telephone number) is removed. You can be assured of absolute privacy and confidentiality.

2) Why do you ask for personal information such as income, health insurance, and employment? Your income

and health insurance may be affected by your arthritis. In addition, your access to medical care or your ability to afford medication may depend on income and health insurance. In the same way, arthritis and work are related. Sometimes it may seem to you that your answers may not be helpful or not be needed. However, it is only by studying all people with arthritis that we are able to understand the relationship

between arthritis, income, health insurance,

and work; and the cost of arthritis can only be measured when such information is available.

3) Why are so many questions repeated in my questionnaire? Although we strive to keep the questionnaire as short as possible, we often have to ask about the same subject in

different ways. A good example of this can be seen in questions about your function and about fatigue. Because most medical researchers use standard questionnaires, we *must* use these questionnaires too. Examples of such questionnaires are the SF-36 and the Health Assessment Questionnaire (HAQ). If we were to change any of the questions or eliminate some that appear to be 'the same,' then we could not score the questionnaires and no one would accept our analyses. So we sometime have use questionnaires that seem to be repetitious. There is a bright side to this, however. Your replies have allowed us to develop a much shorter and better HAQ questionnaire. We hope soon to be able to drop the longer

questionnaire. In addition, your answers to our research questionnaire have shown that a single question about fatigue is just

Three \$1,000 Awards to Arthritis Research Participants:

Return your research questionnaire within two weeks of receiving it and be eligible for one of three \$1,000 awards. The research data bank can best contribute to research when the mailed questions are completed and returned as soon as possible. Anyone who completes the questionnaire within two weeks of receiving it will be eligible for the award – given as a token of our gratitude in help with arthritis research. The winners from the last questionnaire were Marcia Hatfield of Muncie, IN., Vera Staton of Agency, MO, and Doris Bradshaw of Morgantown, NC. Congratulations to all ! as good as much longer questionnaires. We presented this information at the international European meeting this June, and we believe that medical researchers may now switch to shorter questions. Right now we plan to shorten the next questionnaire by dropping the longer fatigue and sleep questionnaires.

4) Why is the questionnaire so long? The length of the questionnaire is our toughest problem. For each 6-month questionnaire we try our best to eliminate items. But there are key items that are crucial to arthritis research. Are the drugs safe? Which treatments are best? What are the true costs of arthritis? What are the outcomes of arthritis – outcomes such as functional ability, pain, fatigue, work ability, and joint surgery? How do treatments alter these outcomes? We hope that because you have arthritis you will understand how important these questions are, and that you'll forgive us if the questionnaire is a little long. Take your time in completing the questions. We really thank you very, very much.

*Don't forget to send us your e-mail address for the new on-line surveys.

$oldsymbol{A}$ Special Thanks!

We wanted to say a BIG thank you to everyone that participated in the NSAID supplement questionnaire last phase. You have been a huge help and we appreciate your responses. We offered a chance to win \$100 for returning the questionnaire as soon as possible. Below are the winners:

Edith Postoian
William Campbell
Karen Steidl
Wanda Vonsick
Genevieve Morphet
Rosemary Perlmutter
Judith Cliffe
Maggie Dyer
Vincenza Pannell
Martha Downing

Traverse City, MI Riverside, CA Bowbells, ND Louisville, KY Rochester, NY Green Valley, AZ LaPorte, TX Gilbertsville, PA W.Warwick, RI Collowhee, NC

FOR MORE INFORMATION OR TO PARTICIPATE

Arthritis Research Center Foundation, Inc. 1035 North Emporia • Suite 288, Wichita, KS • 67214 Director -- Frederick Wolfe, MD Executive Director -- Kathleen Urbansky please call 1-800-323-5871 ext. 133

or email info@arthritis-research.org

News from the NDB Staff:

We are pleased to welcome two new employees to the NDB, Gayle Fisher and Barbara Kelly. Gayle, a retired elementary teacher, has been with the NDB over a year and worked in several positions before becoming a full time caller. Gayle finds the people she talks with on the telephone to be a delight to visit with. Barbara, a retired interior decorator has also been with the NDB for just over a year as a full-time caller. She says she enjoys working with people on a daily basis, helping them with the questionnaire, and never having to leave her desk.

We had a very special addition this year – Congratulations to Rebecca and Jeremy Schumacher on the birth of their daughter Heather Rae on February 13, 2002. Rebecca has been with the NDB for just over a year. Originally from North Dakota, she is quickly getting used to motherhood and the hot, windy Kansas summers. Congratulations to all our new additions.



Dr. Fred Wolfe, director of the NDB, presenting NDB results in Geneva. To the right is Dr. Ravinder Maini of the Kennedy Institute in London. Professor Maini is the inventor of Remicade.

In Brief, what's coming...

Many of you have asked for information about new medications or treatments, and what other things are happening in arthritis research. So, we have added this section to the newsletter hoping these items will be of interest to you.

✦ There are now at least 3 new anti-TNF treatments for RA that are at advanced stages of research testing. One of them, D2E7, is expected to be submitted to for approval to the FDA late this year. ✦ Kineret, an IL-1 RA treatment, is now being tested in osteoarthritis as well.

✤ Two new Cox-2 NSAID drugs are expected to be available within the next year. One of them is already available in Europe.

✦ Three pharmaceutical companies are working on completely new treatments for fibromyalgia, and one may be submitted to the FDA for approval this year.

If you have any questions or would like additional information please contact us at 800-323-5871 or email info@arthritis-research.org