Jeffrey Modell jm Foundation

Economic Impact Study

Comparing
Undiagnosed and Diagnosed Patients
with Primary Immunodeficiencies

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Economic Impact Study

Objective of Study

Economic impact associated with undiagnosed Primary Immunodeficiency patients during 12 month period prior to diagnosis and post diagnosis/treatment.

Description of Study

Retrospective, prevalence based cross sectional analysis, assessing medical costs of undiagnosed, and diagnosed/treated PI patients. Hospital in-patient and outpatient costs, and pharmaceutical costs, annualizing resource utilization included.

Focus of Study

Most prevalent Primary Immunodeficiency disorders, including Common Variable Immune Deficiency, selective IgA deficiency, hypogammaglobulinemia, IgG subclass deficiencies and other antibody defects, together representing > 50% of patient base.

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Methodology for Economic Impact Study

1) Hospital charges, length of stay data obtained from Hospital Cost and Utilization Project (HCUP), Nationwide Inpatient Sample (NIS), under the auspices of the Agency for Healthcare Research and Quality (AHRQ).

2) Data collected by individual States and provided to AHRQ.

3) Principal diagnosis based on clinical classification software (CCS).

4) Charges based on hospital accounting reports from Centers for Medicare and Medicaid Services (CMS). Charges represent hospital billings, not hospital costs or percentage of costs actually collected by hospitals.

5) Unit of analysis for HCUP data is hospital stay; based on discharge data, per patient (a patient admitted to the hospital, multiple times in one year, was counted ,each time, as separate discharges.

6) The study assumes <u>minimum</u> frequency of adverse events re: infections and hospitalizations.

7) Costs related to Severe Combined Immune Deficiency (SCID) not included in the study. Experts report costs of repeated/prolonged ICU admissions in connection with SCID total $1 million or more.

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Methodology for Economic Impact Study

8) Antibody replacement therapy (IVIG) costs not included. Where warranted, IVIG treatment may add costs between $25,000-$35,000 annually. If IVIG therapy is effective, costs of infections and hospitalizations are substantially reduced. Overall, the costs for diagnosing and treating patients with IVIG remain less than 50% of costs in comparison with undiagnosed patients.

9) Study does not include costs of patient/ parents' lost wages', diminished productivity, transportation, and other related costs of care for an undiagnosed child.

10) Study does not include Quality Adjusted Life Years (QALYs) benefits or extended life expectancy accrued to diagnosed and treated patients.

11) "In-patient" information : HCUP website: www.hcup.ahrq.gov /www.hcupnet.asp.

12) "Outpatient" information : Aetna website: www.member.aetna.com/member . Charges are based on "in network" coverage. "Out of network" costs are 2 to 4 times greater.

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Average Annual In-patient Costs of Disease Specific Conditions Re: PI PatientEpisod

Condition	Average Length of Hospital Stay (in days)	Mean Hospital Charges
- Pneumonia	5.7	$21,386
- Chronic obstructive pulmonary Disease and bronchiectasis	4.9	$17,442
- Skin and tissue infections	4.7	$14,567
- Viral infections	3.4	$11,485
- Acute bronchitis	3.2	$ 9,888
- Respiratory infections	2.7	$ 9,515

Average Annual Out-patient Costs of Disease Specific Conditions Related to Primary Immunodeficiencies Per Patient Per Year

Condition	Annual Costs
- Acute sinusitis	$2,712
- Acute bronchitis	$3,188
- Acute infections	$2,950
- Bacterial pneumonia	$7,529
- Severe bronchitis	$3,518
- Acute infections	$5,708
- Chronic infections (30 days)	$1,090
- High severity skin infections	$2,002

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Comparative Costs Per Patient Per Year
Pre-period and Post-period

Acute Infections:
Average cost of acute sinusitis: $2,712
Average cost of acute bronchitis: $3,188
Average cost of acute infections: $2,950
Number of acute infections in the pre-period: 6.4
Number of acute infections in the post-period: 1.8
Difference in number of acute infections: 4.6

Savings: $13, 570

Severe Infections:
Average cost of Pneumonia: $7,259
Average cost of Bronchitis: $3,518
Average cost of severe infections: $5,708
Number of severe infections in the pre-period: 4.3
Number of severe infections in the post-period: 0.6
Difference in the number of severe infections: 3.7

Savings: $21,119

Physician/ Hospital Visits:
Physician visits: $86 - $235
Average: $125
Number of physician/hospital visits pre-period: 70.9
Number of physician/hospital visits post-period: 11.8
Difference in number of visits: 59.1

Savings: $7,387

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Comparative Costs Per Patient Per Year

Pre-period and Post-period

Bacterial Pneumonia:

Average cost of bacterial pneumonia: $7,529

Number of pneumonias in the pre-period: 2.8

Number of pneumonias in the post-period: 0.6

Difference in number of pneumonias: 2.2

Savings: $16,564

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Chronic Infections:

Assumption: 30 day period

Physician visits: 4 @ $125 = $500

Antibiotics: 500 mgm Cipro daily = $450

Laboratory tests: $140

Average cost of chronic infections for 30 days: $1,090

Number of days of chronic infections in pre-period: 44.7

Number of days of chronic infections in post-period: 12.6

Difference in number of days with chronic infections: 32.1

Savings: $1,166

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Comparative Costs Per Patient Per Year

Pre-period and Post-period

Antibiotic costs 2006 (AWP Red Book):

1. Amoxicillan	$0.43	x2 per day
2. Zithromax	$8.79	x1 per day
3. Cephalexin	$1.23	x2 per day
4. Amoxicillin/Potassium Clavulanate	$3.75	x2 per day
5. Trimethoprim/Sulfamethoxazole	$0.68	x2 per day
6. Levaquin	$11.86	x1 per day
7. Ciprofloxacin	$5.37	x2 per day
8. Fluconazole	$8.75	x1 per day
9. Doxycycline	$1.34	x1 per day
10. Penicillin VK	$0.38	x4 per day

Average antibiotic cost per day: $4.25

Number of days on antibiotics in pre-period: 166.2

Number of days on antibiotics in post-period: 72.9

Difference in days: 93.3

Savings: $515

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Comparative Costs Per Patient Per Year

Pre-period and Post-period

Hospitalizations:

Average length of stay: 6.5 days
Average direct cost: $7,529
Average cost of hospital day: $1,158
Number of days in hospital in the pre-period: 19.2
Number of days in hospital in post-period: 5.1
Difference in days: 14.1

Savings: $16,328

School/Work Days Missed:

Average daily salary in the U.S. in Dec. 2006: $136.40
Number of days missed in the pre-period: 33.9
Number of days missed in the post-period: 8.9
Difference in days: 25

Savings: $3,410

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Summary

Economic Consequences of the Most Frequent Conditions Affecting Patients with Primary Immunodeficiencies

Pre-Period Compared to Post-Period

Condition	Cost per episode/ per day	# of episodes pre-period	Cost prior to diagnosis	# of episodes post-period	Costs After diagnosis	Annual Savings
-Acute Infections	$2,950 (per episode)	6.4	$18,880	1.8	$5,310	$13,570
-Severe Infections	$5,708 (per episode)	4.3	$24,544	0.6	$3,424	$21,119
-Bacterial Pneumonia	$7,529 (per episode)	2.8	$21,081	0.6	$4,517	$16,564
-Chronic Infection	$36.33 (per day)	44.7	$1,623	12.6	$457	$1,166
-Physician/Hospital/ ER Visits	$125 (per visit)	70.9	$8,862	11.8	$1,475	$7,387
-Hospitalizations	$1,158 (per day)	19.2	$22,233	5.1	$5,905	$16,328
-Antibiotics	$4.25 (per day)	166.2	$706	72.9	$309	$397
-School/Work Days missed	$136.40 (per day)	33.9	$4,623	8.9	$1,213	$3,410
Totals per patient:			$102,552		$22, 610	$79,942

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Results of Study

1) **Each undiagnosed patient with an underlying Primary Immunodeficiency disease costs the healthcare system an average of $102,736 annually.**

2) Each diagnosed patient with a recognized Primary Immunodeficiency disease costs the healthcare system an average of $22,696 annually.

3) The economic impact to the healthcare system of diagnosing a patient with an underlying Primary Immunodeficiency disease in contrast to not diagnosing patients, **represents average savings of $79,942 per patient per year**.

4) The U.S. National Institutes of Health (NIH) estimates that **at least 500,000 cases of Primary Immunodeficiency remain undiagnosed in the United States.**

5) **The economic impact of undiagnosed Primary Immunodeficiency patients to the healthcare system in the United States totals over $40 billion annually.**

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Thank You

We look forward to collaborating

and working with you

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