

# **Hospital Usage of Intravenous Immunoglobulin: A 2006 Survey of Pharmacy Directors**

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# Table of Contents

<b>Summary of Findings from the Immune Deficiency Foundation's</b> .....	3
<b>2006 Survey of Hospital Pharmacies On Intravenous Immunoglobulin Use</b> .....	3
<b>Background and Objectives</b> .....	4
<b>Research Methods and Procedures</b> .....	5
Sample Objective and Design.....	5
Pretest of Contact/Screening Procedures and the Survey Instrument.....	5
Field Dates, Interview Length, Contact Protocols, and Interviewer Selection .....	6
Incidence of Dispensing Pharmacies and Data On Other Pharmacies .....	6
<b>Detailed Findings</b> .....	8
IVIG Dispensed and 2006-2005 Comparisons .....	8
Changes – IVIG Dispensed .....	9
Treatment of Different Conditions .....	10
P&T Committees and Priority Protocol .....	12
Priority Protocol .....	13
Group Purchasing Organizations (GPOs) .....	14
Purchasing IVIG, Availability and Price.....	16
Brand Selection .....	18
Awareness of Product Pedigree.....	18
Prices Paid for IVIG and Insurance Reimbursement.....	19
Obtaining Insurance Approval for IVIG and Treating Patients with Approval.....	24
Hospitals Turning Away Patients Needing IVIG.....	25
Conclusions .....	26
<b>Appendix A: Hospitals Treating Indication/Condition in Past Four Weeks with IVIG and Average Number of Times IVIG Was Dispensed in Hospitals Where it Was Dispensed at Least Once (Total N=85)</b> .....	27
<b>Appendix B1: The 2006 IDF (CATI) Questionnaire</b> .....	31
<b>Appendix B1: 2006 IDF Follow-Up Survey</b> .....	47
<b>Appendix C: Survey Response Data</b> .....	54

## **Summary of Findings from the Immune Deficiency Foundation's 2006 Survey of Hospital Pharmacies On Intravenous Immunoglobulin Use**

The survey was conducted by telephone during August–October, 2006 with 310 randomly selected pharmacies in the United States serving 100+ bed hospitals which currently dispense IVIG. In the process of identifying eligible pharmacies, interviews were also completed with non-dispensing pharmacies to determine if they ever dispensed IVIG and, if so, when they stopped and why. The main objectives of this research were to investigate current uses of IVIG and recent changes in treatment patterns in order to determine the extent to which IVIG usage and treatment might have been affected, directly or indirectly, by recent changes in Medicare reimbursement policy.

Eighty-six percent of hospitals with 100 or more beds treat patients with IVIG. Among hospitals using IVIG, 71% report treating patients with primary immune deficiency diseases (PIDD), while somewhat fewer use IVIG to treat other on-label indications (57%) and other conditions (39%). But IVIG supply is tight. Nearly all 100+ bed hospitals contract with a Group Purchasing Organization (GPO) to provide IVIG and most of them (84%) receive an allocation of the product, but only 28% report that their allocation allows them to meet all current needs. Nevertheless, relatively few hospitals (37%) have a Patient and Treatment Committee to determine which patients are to be treated under established priority protocols, and even fewer (27%) have priority protocols specifying which patients are to be treated first. Of those that do, primary immune deficiency is by far the top priority condition. Since 2004, the amount of IVIG dispensed for PIDD patients has increased faster than the amount used to treat other conditions. This is consistent with the increased number of Medicare patients found in the IDF's patient survey whose infusion site has been switched to outpatient facilities.

Many hospitals report that it has become more difficult to get the amount of IVIG they need, regardless of their supplier. Approximately half report that prices have increased since the beginning of the year (48-61%, depending on the type of supplier). The average price paid by hospitals for liquid IVIG is \$63/gram which is 4% higher than the Medicare reimbursement rate. The average price paid by hospitals for the lyophilized product is \$58/gram, which is 15% higher than the Medicare reimbursement rate. Three of every ten hospitals pay more for liquid IVIG than they are reimbursed by Medicare, and 57% pay more for the lyophilized product. A majority of hospitals report that patients with Medicare only (62%) and patients with Medicare and supplemental coverage (51%) have inadequate reimbursement for the IVIG they must purchase. Thirty percent report the shortfall after Medicare payment to be at least 20%; 45% report it as at least 10% of their cost. Some private insurers also constitute a problem in reimbursing hospitals: 49% of pharmacists feel that half or more of their third-party insurers are failing to provide adequate reimbursement for IVIG purchases.

Nearly one-third of hospitals (32%) have had to turn away some patients in the first eight months of 2006 – more often because of unavailability of IVIG than due to inadequate insurance reimbursement. However, a substantial proportion (41%) remain uncertain or doubtful about continuing to treat patients in the future given current insurance reimbursement policy. If the shift of Medicare patients to hospital infusion settings continues along with limits on IVIG reimbursement, hospitals might become increasingly reluctant to provide treatment. Primary immune deficiency patients, as well as others needing IVIG, face a difficult future unless the inter-related problems of cost and product availability are ameliorated.

# Hospital Usage of Intravenous Immunoglobulin: A 2006 Survey of Pharmacy Directors

## Background and Objectives

Primary Immune Deficiency Disorder (PIDD) patients rely upon a regular supply of immunoglobulin, usually administered intravenously (IVIG), to treat their condition. Growing evidence suggests that these patients have experienced special difficulties since the beginning of 2005 in obtaining adequate dosages of their preferred IVIG product or have had to defer treatments and/or transfer to a less convenient treatment site - either because the product was unavailable, or because of problems with insurance approval or reimbursement, or for a combination of those reasons.

The Centers for Medicare and Medicaid Services (CMS), which set Medicare insurance policy, reduced reimbursement rates for IVIG treatments in private doctors' offices, effective January 1, 2005, which appears to have increased demand for infusions at hospital facilities. Reductions in reimbursement for treatments in hospital outpatient facilities were applied one year later, beginning January 1, 2006. The new rates are based on the formula ASP+6 (average selling price plus 6%). This works out to \$60.65 per gram for liquid IVIG and \$50.53 per gram for lyophilized IVIG at the time of this survey. Both amounts are lower than the average prices paid by hospitals (reported below).

The CMS reimbursement rate changes are suspected of being a significant cause of the problems in obtaining treatments. If true, the changes will logically impact PIDD patients on Medicare first and most directly. Yet, it is well known that Medicare reimbursement rates are not infrequently emulated by private insurers, so the impact of the policy changes is likely to also "trickle down" to non-Medicare PIDD patients needing IVIG.

This report, developed for the Immune Deficiency Foundation, a non-profit organization that advocates for PIDD patients, presents results from a survey of hospital pharmacies conducted in late Summer and early Fall of 2006 to investigate current uses of IVIG, recent changes in treatment patterns and related issues with a primary focus on determining how much identified changes might be directly or indirectly related to the recent revisions in Medicare reimbursement and how much to product unavailability or other factors. This report is based on one of three national surveys conducted in tandem by the Foundation to investigate patient access to therapy and insurance-related problems. The two other surveys targeted PIDD patients and physicians who treat PIDD patients with IVIG.

The research reported here is based upon a survey of 310 telephone interviews with pharmacy directors at hospital pharmacies which dispense IVIG. The sample was randomly selected from U.S. hospitals with 100 or more beds. Most of the interviews were targeted at pharmacies which serve at least some outpatients with IVIG - those receiving treatments at infusion suites, chemo clinics, or other outpatient programs. In addition to the 310 interviews with hospital pharmacies currently dispensing IVIG, the survey conducted abbreviated interviews with non-dispensing pharmacies identified during the screening to determine if they dispensed IVIG in the past and, if so, when and why they stopped.

## Research Methods and Procedures

This section describes the survey methodology including sampling approach, mode of data collection, pretest of instrument and contact procedures, field dates and average interview length, survey response rate information, profiles of the final, obtained sample by bed size and outpatient/inpatient status, incidence of IVIG-dispensing pharmacies, and some information about the small number of pharmacies which do not dispense IVIG: if those pharmacies dispensed IVIG in the past, and if so, when and why they stopped.

### Sample Objective and Design

The goal of the survey was to complete at least 300 interviews by telephone with hospital pharmacy directors (or their surrogates able to answer questions about IVIG use). The survey's target population was defined as pharmacies serving general purpose U.S. hospitals with at least 100 beds. Because the study's objective concentrates on hospital outpatient treatment, an upper limit was placed on the number of interviews conducted with pharmacies dispensing IVIG only for inpatient use: No more than 50 of the 300 interviews to be completed could be with pharmacies serving only hospital inpatients; at least 250 had to be with pharmacies serving at least some outpatients.

The starting sample consisted of a sufficient number of randomly selected 100+ bed hospitals to reach the goal of 300 completed interviews with IVIG dispensing pharmacies which serve those hospitals. This sample was purchased from a reputable list broker that compiles accurate, up-to-date, and complete hospital lists.

### Pretest of Contact/Screening Procedures and the Survey Instrument

The developers anticipated two significant challenges to achieving a successful survey. The first was formulating questions which would comprehensively address the study's objectives that most responding pharmacy directors could answer, that could be administered economically and not consume an inordinate amount of respondents' time during working hours (impeding cooperation and thoughtful response).

The second challenge was to construct an efficient introductory and screening script for the interviewers that would (a) lead them to the hospital's pharmacy director and (b) ascertain whether any pharmacy serving the hospital currently dispenses IVIG for outpatient use (and, if more than one, which pharmacy dispenses the most). These challenges were compounded by the difficulty of reaching individuals qualified to provide reliable answers to these questions in the midst of their typically busy work schedules.

To address these challenges, a pretest consisting of 20 interviews was conducted in advance of the main survey. The pretest proved effective with respect to both sets of challenges. The pretest revealed that some questions solicited data that was too detailed for respondents to provide in the course of a telephone interview. To remedy the problem, response categories were modified to allow answers falling into broader ranges and some questions (those asking the number of times IVIG was dispensed in the past four weeks to treat a long list of specific conditions) were administered via a mailed or faxed follow-up form that respondents were asked to fill out and return. Respondents were offered a \$25 monetary incentive for participating in this follow-up data collection, to be paid upon receipt of the completed form.

The pretest also provided useful guidance in terms of re-crafting an introductory script that would efficiently lead interviewers to the hospital's pharmacy director. Finally, it identified respondent confusion about the terms "outpatient" and "outpatient facilities," so the script was clarified to read "... patients getting IVIG at hospital infusion suites, chemo clinics, and other outpatient clinics or programs at your hospital." These changes reduced the time required to reach qualified respondents and made it a smoother and more effective screening process overall.

#### Field Dates, Interview Length, Contact Protocols, and Interviewer Selection

The main survey was conducted from September 22 – October 30. Follow-up forms sent to respondents to be filled in were accepted through December 8.<sup>1</sup> The telephone interviews averaged just over 17 minutes. Up to ten call attempts were made to reach and interview qualified respondents. Re-contact appointments were scheduled as necessary. A toll-free number was set up so that respondents could call in at their convenience to do the interview or ask questions about the survey. Interviewers were recruited based on their general health care research experience and their expertise and experience interviewing pharmacists. Interviewers were also trained on the specifics of this particular study and monitored periodically throughout the field period.

A follow-up survey, mailed out to telephone survey respondents agreeing to participate, collected data on past-month frequency of IVIG use for a long list of specific conditions. As many as three reminder calls were made to pharmacists initially agreeing to participate in the follow-up survey. Recruits who said they had not received the form or that it was lost were sent a replacement, and a subsequent reminder call was scheduled if the completed form was not received within a week of the replacement mailing. Statistical results from the follow-up survey are presented in Appendix A. Copies of the main and follow-up survey questionnaires are presented in Appendix B.

Detailed survey response rate information on the main and follow-up surveys is reported in Appendix C.

#### Incidence of Dispensing Pharmacies and Data On Other Pharmacies

Of the 359 hospital pharmacies successfully screened for IVIG use, 310 of them (86%) reported that they currently dispense IVIG. Of the remaining 49 that do NOT currently dispense the product, six indicated that the pharmacy had dispensed it in the past but discontinued doing so. One other was not sure if the pharmacy had ever used IVIG. None of the six which had discontinued IVIG had dispensed the product since the beginning of 2005. All of those six were smaller hospitals (less than 200 beds). Nine of the 49 non-dispensing hospital pharmacies were mistakenly not asked if they had ever dispensed IVIG and could not be reached in attempted recontacts.

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<sup>1</sup> Due to a skip logic error in the CATI program, which affected responses to one key question, some respondents had to be re-contacted to obtain this information (recontacts occurred November 30 – December 11).

## Profile of Dispensing Pharmacies Interviewed

Two key characteristics of hospitals in this survey are size (number of beds) and the type(s) of patients served by the pharmacy (inpatient only, outpatient only, both). Table 1 presents the distributions of these hospital attributes among dispensing pharmacies:

**Table 1**  
**IVIG Dispensing Hospitals by Size and Patient Types**

	100-199 Beds	200-299 Beds	300+ Beds	TOTAL
Inpatient and Outpatient	95	58	76	229
Inpatient Only	28	11	8	47
Outpatient Only	30	2	0	32
Don't know / Refused	2	0	0	2
<b>TOTAL</b>	<b>155</b>	<b>71</b>	<b>84</b>	<b>310</b>

Among the 310 dispensing hospital pharmacies, 229 of them (74%) serve both inpatients and outpatients, 47 serve just inpatients (15%), 32 (10%) serve only outpatients, and two respondents were not sure. The distribution of hospitals by bed size (column totals) shows that half of the hospitals (155) are in the smallest group, and the rest are roughly split between 200-299 beds and 300 or more beds. Hospitals serving inpatients only tend to be smaller, on average, than those serving both inpatients and outpatients. Those serving only outpatients fall mostly in the smallest group (100-199 beds).

## Detailed Findings

### IVIG Dispensed and 2006-2005 Comparisons

One objective of this research is to determine the amount of IVIG that hospitals are using and if this amount has increased, decreased, or remained the same compared to 2005.<sup>2</sup> The implicit hypothesis is that hospital use of IVIG has increased, especially for outpatients, as the number of Medicare patients (and possibly others) are shifted from previous treatment sites to hospital infusion suites and similar venues.

**Table 2**  
**Grams of IVIG Dispensed in the Average Month (%)**

	Outpatient Use (n=263)	Inpatient Use (n=278)
Less than 100 grams	38%	50%
100 – 499 grams	42	34
500 – 999 grams	8	7
1,000+ grams	6	4
Don't know	5	4

Source: Q11, Q8

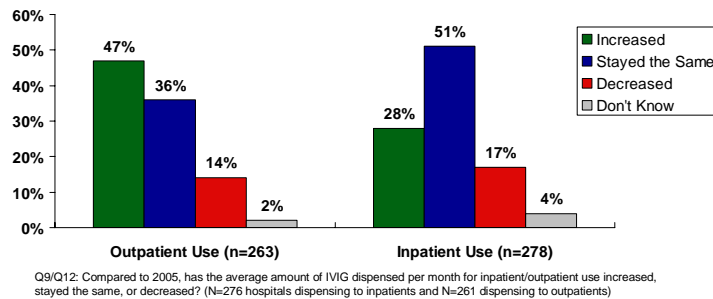
Monthly use of 500 or more grams of IVIG is uncommon (Table 2). Instead, the largest number of pharmacies prescribing for hospital outpatients use 100-499 grams/month, and most of the rest use less than 100 grams. More IVIG is used to treat outpatients than inpatients. Half of the hospital pharmacies dispensing for inpatients use less than 100 grams/month, and about one-third use 100-499 grams monthly. In the 47 hospitals treating inpatients only, the average amount of IVIG dispensed is even lower (not shown in table). More than two-thirds of those hospitals (68%) use less than 100 grams per month.

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<sup>2</sup> The number of times per month hospitals dispense IVIG for specific medical conditions, asked in the mailed out follow-up survey, is presented in Appendix A.

## Changes – IVIG Dispensed

Figure 1: Past Year Change in IVIG Dispensed



Source: Immune Deficiency Foundation

Volume increases in IVIG dispensed have occurred at more hospitals than volume decreases (see Figure 1). While this is true for both groups, it is especially the case with outpatient use of IVIG. Comparing monthly outpatient IVIG use in 2006 and 2005, 47% of the pharmacists said outpatient usage has increased, while 14% said it has decreased. Twenty-eight percent of the pharmacists said inpatient usage of IVIG has increased, and 17% said it has decreased. Among smaller hospitals - those with 100-199 beds - about the same proportion reported increased and decreased use for inpatients. In hospitals treating inpatients only, the ratio of increased use to decreased use is about even (23% to 21%). This pattern of changes is consistent with the shift of Medicare patients to outpatient infusion facilities – a finding from the IDF’s companion survey of patients.

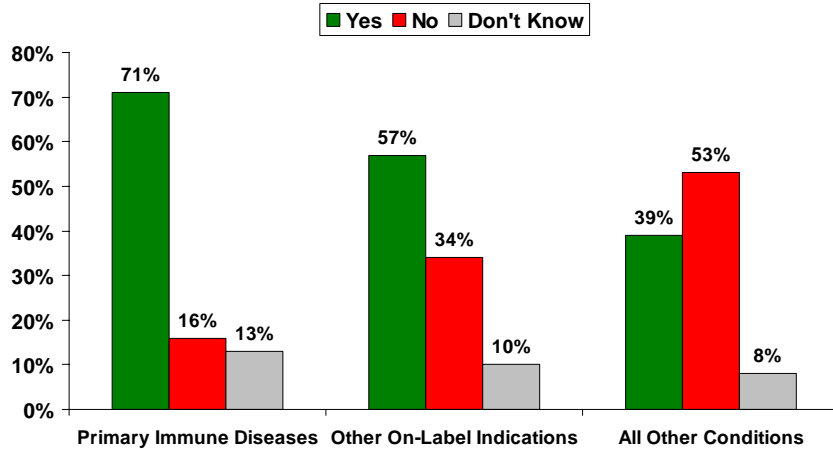
The main reason for the increase in outpatient consumption of IVIG was demand: 73% of hospitals cited having a larger number of outpatients needing the product. The main reasons given by the smaller number of hospitals experiencing decreased use of IVIG for outpatients in 2006 were product availability (50%), decreased patient demand (34%), and cost factors (16%); 11% mentioned insurance reimbursement and 13% cited other reasons.

The reasons given for changes in the amount of IVIG dispensed for inpatient use are similar. Hospitals using more IVIG for inpatients in 2006 cited increased patient demand (78%) as the main reason. Also mentioned by smaller numbers were increased availability of the product (14%), changes in reimbursement (12%), cost factors (6%), and other reasons (12%). Hospitals experiencing decreased usage for inpatients mentioned product unavailability (51%) and decreased patient demand (43%) as the main reasons. Much smaller numbers noted changes in reimbursement (9%), cost factors (6%), or other reasons (13%).

In short, hospitals with increased usage of IVIG was mostly a result of increased inpatient and outpatient demand.

Treatment of Different Conditions

**Figure 2: Uses of IVIG to Treat Specific Conditions**



Q14/Q17/Q20: Is IVIG used in your hospital to treat [TYPE OF DISORDER]? Base: All hospitals (N=310)  
 (In hospitals treating outpatients, the question referred to outpatient use.)

Source: Immune Deficiency Foundation

Over seven of every ten hospitals treat PIDD patients with IVIG (71%) – which is more than the number using IVIG for other on-label indications (57%) or for all other conditions (39%) (Figure 2). Table 3 displays how often monthly IVIG is used to treat each of these types of conditions as well as the average amount of IVIG dispensed.

**Table 3  
 Times IVIG Dispensed and Percent Dispensing 100+ Grams  
 In Last Four Weeks by Condition Type  
 (hospitals treating condition with IVIG)**

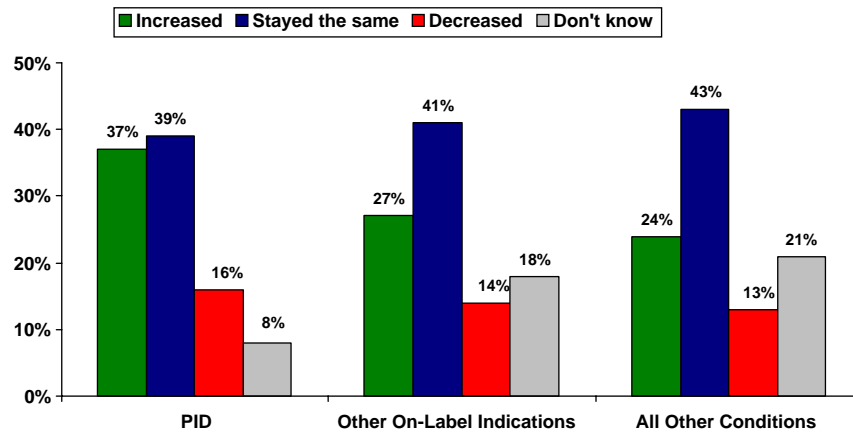
Condition Type	Mean Times Dispensed	Dispensed 100+ grams
PIDD (n=220)	4.1	41%
Other on-label indications (n=177)	2.2	35%
All other conditions (n=120)	3.1	35%

Source: Q15, Q18, Q21

Not only do more hospitals treat PIDD patients with IVIG (than treat patients with other conditions), it is also used more often in those hospitals (and slightly more total volume of the product is consumed) compared to its use to treat other kinds of conditions. Hospitals treating PIDD patients with IVIG dispense the product approximately four times per month, on average, and about two-

fifths of those hospitals (41%) use 100 grams or more per month. IVIG is used to treat other on-label indications an average of about twice monthly, and just over one-third of the hospitals use 100 grams or more to treat these disorders. Hospitals treating all other types of conditions do so an average of approximately three times per month, and just over one-third of them use 100 grams monthly to treat these other conditions.<sup>3</sup> These figures would be lower if all hospitals were included in the calculations – not just hospitals treating the respective type of condition.

**Figure 3: Change in Amount of IVIG Dispensed Type of Condition**



Q23a-c: Compared to 2004 - that is, to about two years ago – would you say that the amount of IVIG dispensed to treat [CONDITION] has increased, stayed the same, or decreased? Base: All hospitals (n=310)

Source: Immune Deficiency Foundation

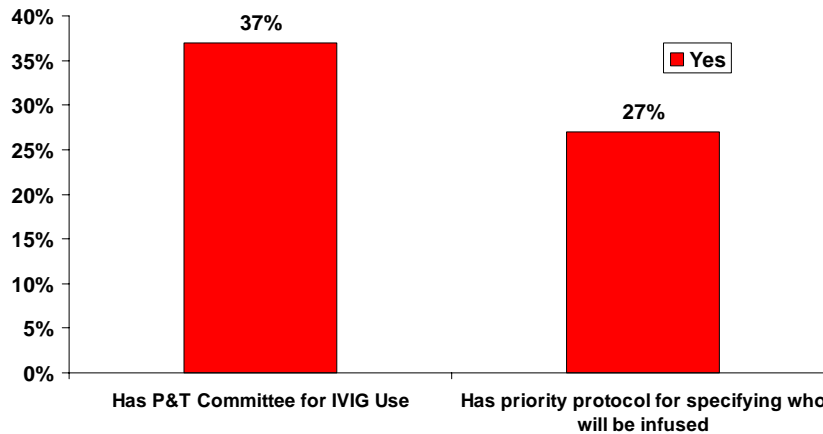
More hospitals report increased usage of IVIG to PIDD patients than for other on-label indications and other types of conditions (Figure 3) – again in line with the higher number of PIDD patients on Medicare receiving infusions at outpatient facilities. Nevertheless, the quantity of IVIG dispensed is up in the other two condition categories as well, as indicated by more hospitals reporting increased than decreased usage.

<sup>3</sup> The mailed follow-up survey of participating pharmacists (final n=85) generated the following averages of IVIG amounts dispensed, by condition type, in the past 4 weeks: PIDD: 188 grams (n=49); other on-label indications: 158 grams (n=43); neurological, auto-immune, and other conditions: 237 grams (n=34).

## P&T Committees and Priority Protocol

Hospital Patient and Treatment (P&T) committees determine which patients are to be treated under established priority protocols. P&T Committee decisions can be critically important to patients awaiting treatment, especially when IVIG availability is problematic.

**Figure 4: Hospitals with Patient and Treatment Committees, Priority Protocols**



Q24: Does your hospital have a P and T (Patient and Treatment) Committee that determines which patients will be treated with IVIG? Q25: Does your hospital have a priority protocol specifying which patients will be infused? Base: All hospitals (n=310)

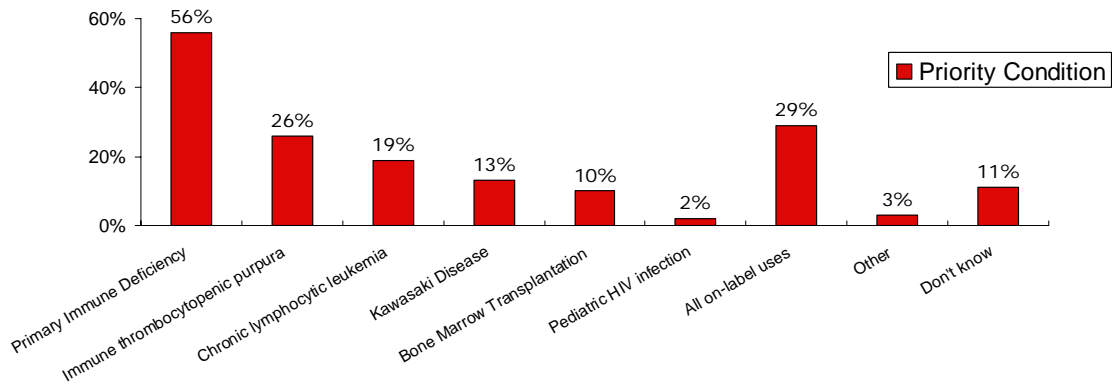
Source: Immune Deficiency Foundation

Thirty-seven percent of hospitals have a Patient and Treatment (P&T) Committee for determining which patients will be treated with IVIG, 60% do not, and 3% of the respondents did not know. Twenty-seven percent have a priority protocol specifying which patients will be infused, 70% do not, and the rest did not know (Figure 4). Larger hospitals are more likely to have priority protocols: 42% of those with 300 or more beds have them, compared to 27% of hospitals with 200-299 beds and 19% of hospitals with 100-199 beds.

Of the minority of hospitals that have a priority protocol, three-quarters say that their priorities are based, at least in part, on indications or conditions, 29% base it on the health status of patients, and one-quarter factor in supply. (Respondents could give multiple answers.) Among the relatively small number of hospitals with priority protocols, 56% of these hospitals report giving priority to Primary Immune Deficiency conditions – the more commonly mentioned priority -- 26% to Immune Thrombocytopenic Purpura, 19% to Chronic Lymphocytic Leukemia, 13% to Kawasaki Disease, 10% to Bone Marrow Transplantation; 29% say all on-label uses are given priority. (Figure 5)

Priority Protocol

Figure 5: Priority Conditions for IVIG Infusions



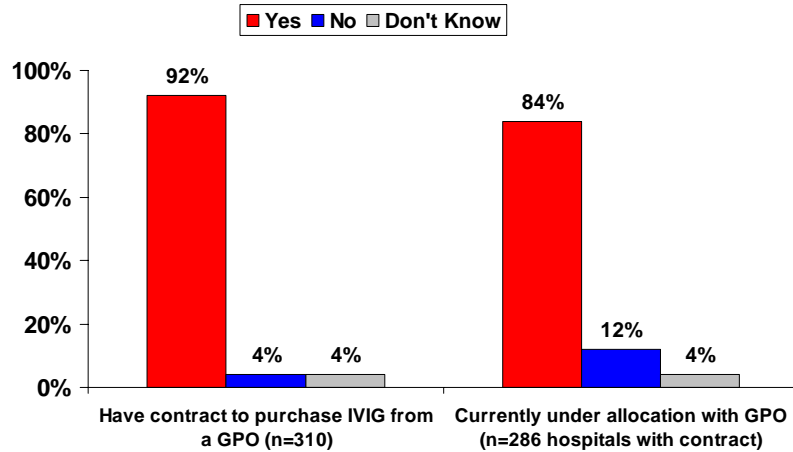
Q 27: Which indications/conditions have priority? (N=62 hospitals basing their priority on indications)  
(Percentages can sum to more than 100% because of multiple responses.)

Source: Immune Deficiency Foundation

## Group Purchasing Organizations (GPOs)

Nearly all hospital pharmacies (92%) have a contract to purchase IVIG from a GPO; 4% said they do not, and 4% were not sure (Figure 6).

**Figure 6: Hospitals Under Contract with a GPO, Under Allocation with a GPO**



Q28: Do you have a contract to purchase IVIG from a GPO?

Q29: Are you currently under allocation with your GPO?

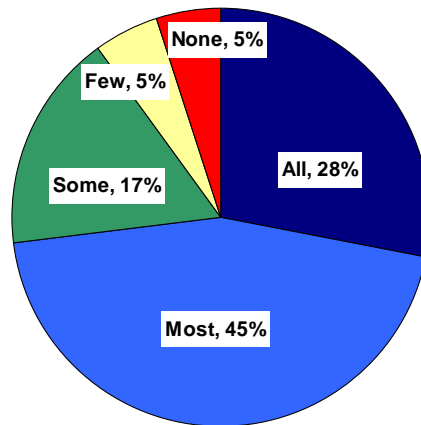
Source: Immune Deficiency Foundation

Hospitals that have contracted with a GPO have been purchasing IVIG from that organization, on average, for six years. Fifteen percent reported being with their current GPO for two years or less, 22% have been with their current GPO for 3-4 years, 21% for 5-6 years, and the rest (29%) have had a contract with their current GPO for more than six years; 5% did not know how long they have been with their current GPO.

Group Purchasing Organizations (GPOs) continued

Most pharmacies having a contract with a GPO receive an allocation for IVIG (84% - see Figure 6). Seventy-three percent of them report that this allocation meets all (28%) or most (45%) of their needs. However, for the rest, their allocation falls short, 17% saying it meets “some” of their needs, 5% saying “few,” and 5% saying it meets “none” of their recent needs for IVIG (Figure 7). Thus, more than one-quarter of the hospitals receiving an allocation from their GPO are not getting all or most of the IVIG they need from that relationship.

Figure 7: Needs Met by GPO Allocation



Q30: Does your allocation meet all, most, some, few, or none of your recent needs? Base: Hospitals with GPO contract (N=241)

Source: Immune Deficiency Foundation

The 72% of pharmacies whose needs are not being completely met by their current allocation were next asked how much more IVIG they would need, in additional grams per month. The mean shortfall is 220 more grams. (The median additional amount needed is much less, approximately 80-85 grams extra.)<sup>4</sup> One in every five hospitals said they would need more than 200 grams additional per month, 16% said they would need an 101-200 more grams, 25% said 51-100 more grams/month, and 29% indicated needing 50 grams or less extra per month to meet their current needs. One in ten pharmacists was not sure how much more IVIG the hospital would need.<sup>5</sup>

<sup>4</sup> PIDD patients receive about 30 grams of IVIG per month, on average. Other patients using IVIG might receive more or less than that amount.

<sup>5</sup> Hospitals serving only inpatients were somewhat less likely than those serving outpatients (though still likely) to have a contract with a GPO (79%), to receive an allocation (70%), to have purchased IVIG from a GOP in the past year (55%), but somewhat more likely to have their needs met by their allocation (38%).

## Purchasing IVIG, Availability and Price

Hospitals purchased IVIG from various sources, in 2006, including GPOs. Through the Summer (by late September), hospital pharmacies made IVIG purchases from the following sources (Table 4):

**Table 4**  
**Hospitals Purchasing IVIG from Source and**  
**Mean % of Aggregate 2006 Purchase from Source**

	Purchased from in 2006 (n=310)	Mean % purchased (n = hospitals answering question = 308)
From a GPO	71%	55.8%
Directly from manufacturer	29%	6.8%
From a contractual distributor	63%	29.9%
From a non-contractual distributor	29%	5.9%
From some other source	6%	<u>1.6%</u>
		100%

Source: Q33a-d, Q34a-d

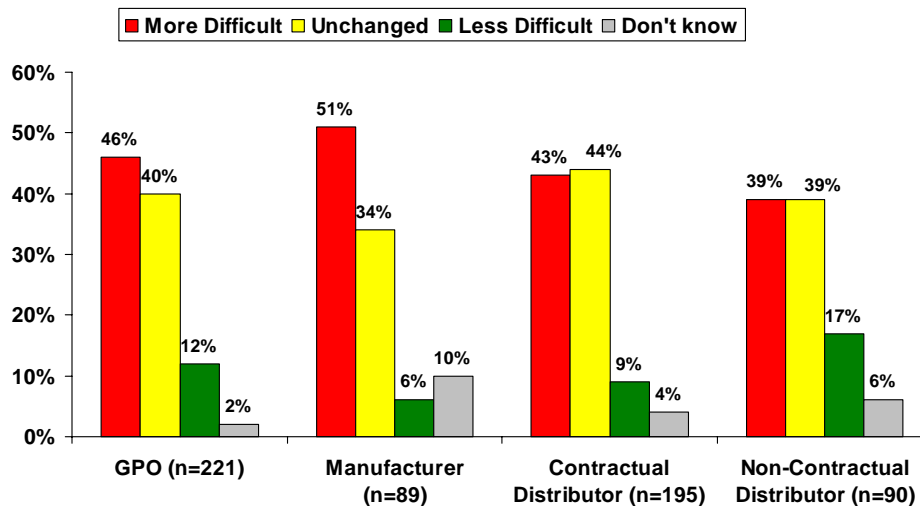
The first column of numbers in Table 4 shows the proportion of hospitals that bought any IVIG from those sources in 2006. Obtaining the product from a GPO is the most popular source during the first three-quarters of 2006, as more than seven of every ten hospital pharmacies made IVIG purchases from their GPO. Contractual distributors ranked second, with 63% of hospitals having made a purchase from that source. Manufacturers, non-contractual distributors and other sources were less commonly used.

Over half of all IVIG purchased during the first 8-9 months of 2006 (about 56%) was from GPOs, as shown in the second column of numbers in Table 4. Almost 30% was bought from contractual distributors. Smaller proportions of total IVIG purchased came directly from manufacturers, from non-contractual distributors and other sources.

Pharmacy directors were also asked, for each source used, if it has become more difficult or less difficult to obtain the amount of IVIG they need since the beginning of the year. Depending on the source, between 39-51% said that obtaining the amount of IVIG they need has become more difficult in 2006, as shown in Figure 8. While this is most true for hospitals buying product directly from manufacturers, it is also very much the case for those obtaining IVIG from GPOs and from contractual and non-contractual distributors. As for the two most important sources, 47% of hospitals indicated that getting all of the IVIG they need from GPOs has become more difficult, and 43% said getting a sufficient quantity from contractual distributors has become more difficult in 2006. Twelve percent and 9% of pharmacists say that getting IVIG has become easier from GPOs and contractual distributors.

These results should not be construed as signaling that hospitals currently face a severe IVIG availability problem. That would be a misinterpretation and inconsistent with other data presented earlier (e.g., in Figure 7). A more accurate reading is that pharmacy directors perceive product availability as *becoming* more of a problem in recent months, even if it is not close to a serious situation for most hospitals now. In other words, while most hospitals appear to be getting all or most of what they need, the trend is in the negative direction.

## Figure 8: Change in Difficulty of Acquiring IVIG Since Beginning of 2006

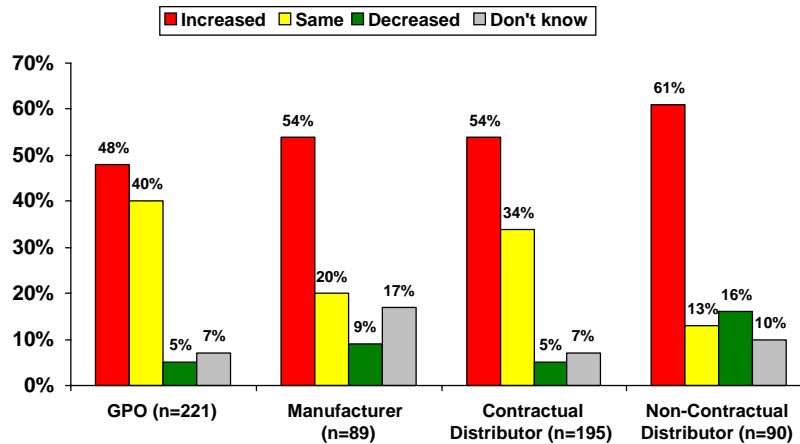


Q37a-d: Since the beginning of 2006, has it become more difficult or less difficult to get the amount of IVIG needed from that source?

Source: Immune Deficiency Foundation

When pharmacists were asked if prices have gone up, down, or stayed the same in 2006, nearly half or more than half (depending on the source asked about) said prices have increased and few reported price declines (Figure 9). Focusing again on the two sources which hospitals are most likely to buy from, 48% who buy from a GPO said their GPO's price for IVIG had gone up (5% reported a price decline), and 54% buying from contractual distributors said those prices had gone up (5% said the price had gone down). Similar patterns apply to prices charged by manufacturers and non-contractual distributors. Hospital size seems to matter only for purchases from contractual distributors, where larger hospitals (300 or more beds) are less likely to report that prices have increased than hospitals with fewer beds: 35% as compared with 48%.

## Figure 9: 2006 Change in Price for IVIG by Supplier Type



Q36a-d: Since the beginning of 2006, has the price for IVIG from [SOURCE] gone down, stayed about the same, or gone up?

Source: Immune Deficiency Foundation

High or increased prices might be one reason many pharmacists report greater difficulty in obtaining the IVIG their hospital needs, but it is not the only reason. For example, among hospitals buying from a GPO whose prices have been stable or declined, 37% reported that the product has been more difficult to obtain (10% responded “less difficult”). Among hospitals buying from a contractual distributor whose prices have been stable or declined, 35% reported that IVIG has been more difficult to obtain (7% responded “less difficult”). Thus, problems obtaining the product are not just a function of higher prices. Instead, they are probably due, at least in part, to how much payers, including Medicare, are willing to pay and to other difficulties obtaining the product which are not solely a function of price per se. (Data on actual prices paid for IVIG are presented and discussed in a subsequent section.)

### Brand Selection

Different PIDD patients need different types of IVIG. One suspected consequence of recent increased product demand and tight supply has been substitution of brands - for some patients, having to switch to a less preferred product. While most hospitals are able to obtain more than one brand of IVIG, nearly one-third (32%) reported being able to get only one. Smaller hospitals (fewer than 200 beds) are somewhat more likely to be restricted to one brand (39%) than larger hospitals (25%). Overall, 36% of hospital pharmacies are able to purchase two brands, 28% can get more than two brands of IVIG, and the remaining 3% are not sure.

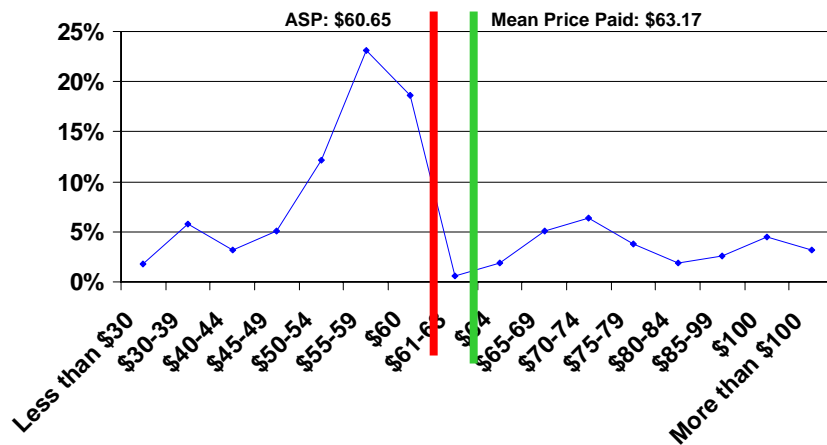
### Awareness of Product Pedigree

A drug’s “pedigree” refers to the history of its distribution including who had custody of it at different stages from production through purchase by the pharmacy. Awareness of a drug product’s pedigree helps guarantee its safe and effective use. Pharmacists were asked if they know the pedigree for each brand of IVIG they reported purchasing for hospital use. In the aggregate, respondents knew the pedigree of only 32% of the IVIG products their pharmacy currently uses. This low figure reveals significant potential for products of unknown efficacy or safety to enter the medical distribution chain.

## Prices Paid for IVIG and Insurance Reimbursement

Cost of medical products and treatments can impact the availability and quality of care that patients receive. This reality applies regardless of how much patients pay out of pocket and how much is covered by their insurance. As reported earlier, prices for IVIG have increased this year for many hospitals. This section presents current price data paid by hospital pharmacies as well as the adequacy of insurance reimbursements.

### Figure 10: Average Price Per Gram for Liquid IVIG



Q45. What is the average price your office or care facility pays for 1 gram of liquid IVIG?  
 Base: Hospitals who could answer N=156

Source: Immune Deficiency Foundation

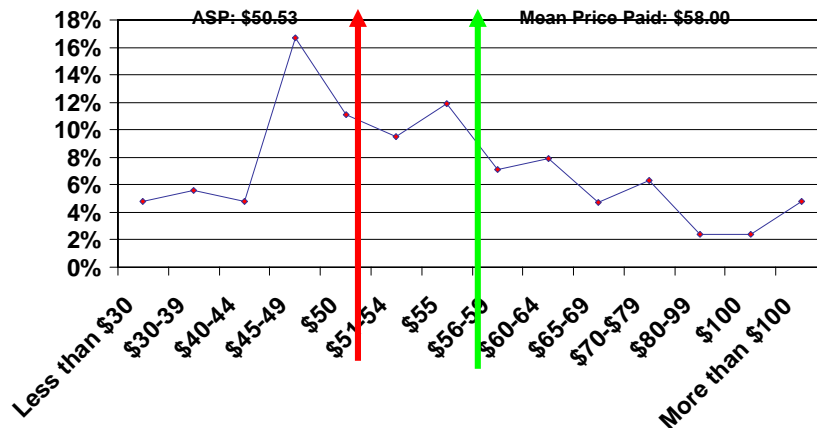
The prices that hospitals pay per gram for liquid IVIG, the current average price paid (red vertical line), and the ASP reimbursement amount (green vertical line) are shown in Figure 10. The ASP rate, revised downward in 2006, applies to Medicare patients. As illustrated by the gap between these two lines (horizontal distance), on average, hospitals are losing \$2.52 for each gram of liquid IVIG used for Medicare patients. Three out of every ten pharmacies (30%) report paying a higher price per gram of liquid IVIG than the current Medicare reimbursement rate.

For purchases of liquid IVIG, there are no statistically significant differences in price paid for hospitals buying from a GPO, compared to those who do not, and for those buying direct from a manufacturer, compared to those who do not. Hospitals buying liquid IVIG from contractual distributors pay less, on average, than those who do not (\$59 vs. \$68). Hospitals buying from non-contractual distributors pay more, on average, compared to those who do not (\$66 vs. \$59). Both of these differences are statistically significant at the .90% confidence level.<sup>6</sup>

<sup>6</sup> Readers should bear in mind that these comparisons are somewhat inexact: In each case, hospitals buying from a particular source are being compared with hospitals that DON'T buy from that source. However, buyers who purchase IVIG from a particular source don't necessarily buy exclusively from that source; rather, they may buy from several types of sources. This means that the prices shown are NOT average prices PAID TO THAT PARTICULAR SOURCE. Instead, they represent average prices paid by hospitals WHO BUY ANY IVIG FROM THAT SOURCE AND (IN MOST CASES) ALSO BUY SOME IVIG FROM SOME OR ALL OF THE OTHER SOURCES. (The survey did not ask pharmacists how much their hospital pays for purchases from particular sources - only the overall average price paid for liquid IVIG and the overall average price paid for lyophilized IVIG.) However, one can infer from differences that hospitals that DO NOT buy from a particular source are disadvantaged (if they pay more) or advantaged (if they pay less) relative to hospitals that DO buy from that source.

The gap between price paid and ASP reimbursement is even greater for lyophilized IVIG: \$7.47/gram (Figure 11). In other words, hospitals are, on average, losing this amount for each gram of the product purchased for Medicare patients. Fully 57% of hospitals using lyophilized IVIG are paying more per gram than the Medicare reimbursement rate. (The Medicare reimbursement for lyophilized IVIG was also revised downward in 2006.)

**Figure 11: Average Price Per Gram for Lyophilized IVIG**



Q46. What is the average price your office or care facility pays for 1 gram of lyophilized IVIG?  
 Base: Hospitals who could answer N=126

Source: Immune Deficiency Foundation

For purchases of lyophilized IVIG, hospitals buying from a GPO pay less, on average, than those who do not (\$54 vs. \$62 - significant at the 90% confidence level). Those buying lyophilized from non-contractual distributors pay MORE, on average, than those who do not (\$62 vs. \$52 - significant at the 95% confidence level). Footnote 6 also applies here.

Strictly speaking, the ASP reimbursement rate applies to patients with Medicare insurance. However, as has occurred in the past for other drugs and services, private insurance companies (third-party insurers) sometimes follow Medicare’s lead, in this case, by also reducing reimbursement rates. Thus, it might not be surprising that the survey found many hospitals reporting rate declines for IVIG by their third-party payers (Table 5). Half of the respondents did not know the answer to this question. (If the missing responses – the “Don’t Knows” - are distributed proportionately, then the other numbers would double, making the percentage of private insurers believed to have reduced reimbursements much larger.)

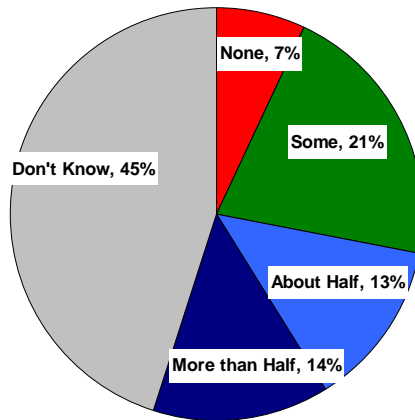
**Table 5  
 Pharmacy Directors Reporting How Many of Their  
 Third-Party Payers Have Reduced Reimbursement in 2006**

None	7%
A few	4%
Some	16%
Most	9%
All or Almost all	14%
Don't know	50%

Source: Q38

When pharmacy directors were asked how many of the private insurance companies they are familiar with fail to provide adequate IVIG cost reimbursement, only 14% (26% if the “Don’t Know” responses are excluded) felt that “more than half” of third-party (private) insurers fail to reimburse adequately, and 13% (23% excluding the “Don’t Knows”) reported that “about half” fail to reimburse adequately (Figure 12). Thus, among those who could answer the question, only about half (51%) thought that a majority of insurance companies who reimburse them for IVIG provide adequate payment. Adequate reimbursement by third-party insurers is, thus, more the exception than the rule.

Figure 12: Number of Private Insurance Companies that Fail to Reimburse Adequately for Purchase of IVIG

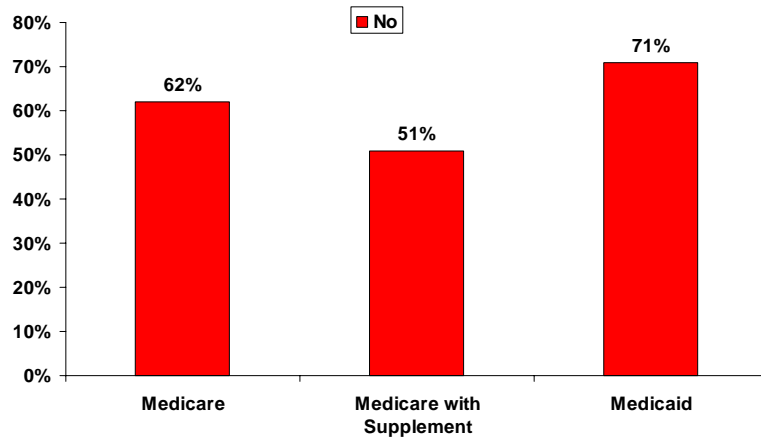


Q43: Thinking about the third-party insurers (private insurance companies) with whom you've had some experience, how many of them would you say fail to provide adequate reimbursement for the purchase of IVIG? Base: All hospitals (n=310)

Source: Immune Deficiency Foundation

Pharmacists who could answer the question (61% of them) were evenly split over whether Medicare with supplement provides adequate reimbursement (49% yes, 51% no), but most felt that Medicare alone, and Medicaid even more so, provide inadequate reimbursement: 38% yes, 62% no for Medicare; 29% yes, 71% no for Medicaid (Figure 13).

Figure 13: Adequacy of Reimbursement for  
IVIG by Type of Government Insurance



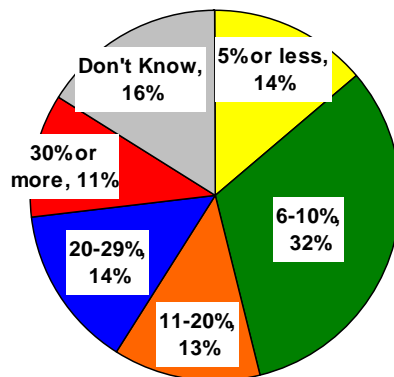
Q42a-c: Are you adequately reimbursed to purchase IVIG for patients who carry the following insurance coverage? Base: All hospitals ("Don't Know" excluded from base)

Source: Immune Deficiency Foundation

These perceptions are not inconsistent with the considerable numbers of hospitals, reported above, who pay more per gram for IVIG than they are now reimbursed by Medicare.

Pharmacists who said that they are not receiving adequate reimbursement for IVIG by Medicare were asked how much of their cost is not being covered, on average.<sup>7</sup> Figure 14 shows that the most common response was 6-10%. However, this modal answer gives a misleadingly low impression of the shortfall. When the “Don’t know” answers are excluded from the calculations, three of every ten pharmacists reported that 20% or more of their cost is not reimbursed, and 45% of them reported a shortfall of over 10% of their cost. At the low end, 17% of those answering said that 5% or less of their cost is not currently being covered by Medicare.

### Figure 14: IVIG Cost Not Covered by Medicare

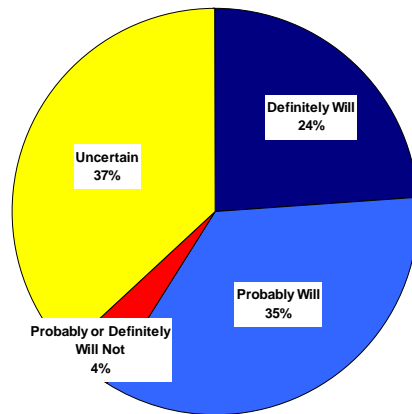


Q44: How much of your total cost, on average, to purchase IVIG is not covered by current reimbursement rates for Medicare? Is it about...? (N=79 hospitals not adequately reimbursed)  
Source: Immune Deficiency Foundation

<sup>7</sup> Due to an error in the interview, pharmacists who earlier indicated not being adequately reimbursed by Medicare were not asked this question in the original interview. When the error was discovered, efforts were made to recontact those respondents. Of the 116 pharmacists who should have been asked the question, 79 of them were reached and answered the question.

Since many hospitals are not being fully reimbursed for treating Medicare patients with IVIG in addition to facing declining payments from private insurance companies, it should not be surprising that over two of every five hospitals feel it is either unlikely that they will be able to continue treating patients (4%) or are uncertain about providing future treatment (37%) (Figure 15).

Figure 15: Expectation About Treating Patients in the Future With IVIG



Q52: Given present IVIG reimbursement practices, do you feel that your hospital definitely will, probably will, probably will not, or definitely will not be able to continue to treat patients who require treatment, or are you uncertain? Base: All hospitals (N=310)

Source: Immune Deficiency Foundation

### Obtaining Insurance Approval for IVIG and Treating Patients with Approval

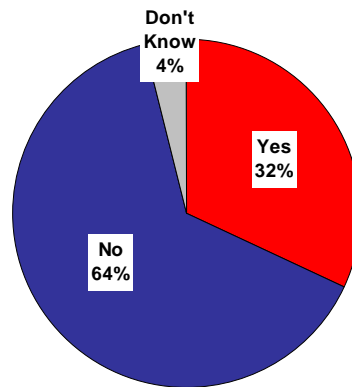
Most hospitals have not had significant problems obtaining insurance approval in the past year for patients needing IVIG. While only about half of the pharmacists (51%) were familiar enough with this matter to know the answer, of those who could answer how difficult this has been for their hospital, 7% said the hospital has had “a lot of difficulty”, and another 24% reported that the hospital has experienced “a moderate amount of difficulty” getting insurance approval for patients. The rest answered “only a little difficulty” (35%) or “none” (34%).

About one-third of the hospital pharmacists (34%) reported either “a lot of difficulty” (7%) or “a moderate amount of difficulty” (27%) acquiring IVIG for patients who had appropriate insurance approval. The rest experienced either “only a little difficulty” (28%) or “none” (38%). Sixty-five percent of the respondents were able to answer this question.

## Hospitals Turning Away Patients Needing IVIG

Nearly one-third of hospitals that treat patients with IVIG (32%) had to turn away some patients needing the product during the first three-quarters of 2006 (Figure 16). This was more true at hospitals serving outpatients (34%) than those serving only inpatients (19%).

Figure 16: Has hospital turned away patients needing IVIG treatment?



Q50: Since the beginning of 2006, has your hospital had to turn away patients needing IVIG treatment? Base: All Hospitals (N=310)

Source: Immune Deficiency Foundation

In most cases, the reason hospital had to turn patients away was unavailability of the product: 94% of hospitals who had to turn away patients mentioned this reason (Figure 17). Far fewer attributed the cause to staffing or capacity (23%), inadequate insurance reimbursement (7%), or other reasons (4%).

Up to now, product availability has been the primary problem impacting patients needing IVIG. However, if the price - reimbursement disparity grows, more patients could encounter difficulties obtaining treatment for insurance related reasons unrelated to product availability.

## Conclusions

There is much evidence in this report to support the belief that IVIG has been more difficult to obtain than in the recent past, leading some hospitals to turn away patients needing infusions, although the number of patients unable to obtain hospital infusions is unknown. Demand for treatment at hospitals, however, is clearly up, due in part to an increased number of Medicare patients being shifted to outpatient facilities from private doctors' offices and other sites, which is often less desirable for PIDD patients because of the greater risk of infection. Prices for the product have increased for many hospitals, regardless of type of supplier. The new Medicare reimbursement formula means that a considerable number of hospitals are not being adequately compensated for IVIG purchases, in some cases, experiencing a large gap between purchase price and reimbursement. Many hospitals report that reimbursements from private insurers are also insufficient to cover their price. Should this situation continue, more patients will be at risk of missing or delaying potentially life-saving treatment. In light of these findings, Congress might wish to re-evaluate current law to allow the CMS to recalibrate its IVIG reimbursement formula, which should help ameliorate present conditions.

The findings of this survey are consistent with two earlier surveys of PIDD patients and physicians treating PIDD patients. More patients with PIDD are being shifted to hospitals for their IVIG treatment. The average price paid by hospitals for IVIG is higher than the Medicare reimbursement. Some hospitals admit turning patients away who needed IVIG since the beginning of 2006 because of inadequate insurance reimbursement. However, at this point most hospitals seem more concerned about the availability of IVIG than reimbursement rates.

However, an important limitation of this research must be acknowledged. Throughout, the report has referred to IVIG "unavailability" - a somewhat vague term that begs interpretation. What do hospital pharmacists mean by IVIG unavailability? Does it mean the products cannot be obtained from any source at any price? Or, does it mean that products cannot be obtained at prices that are reasonable and acceptable from a business standpoint. The analysis has exercised caution in not construing "IVIG unavailability" as solely a supply issue - simply a shortage of IVIG being produced - although temporary demand-supply disparities or distributional obstacles might be contributing to the problem. How much of IVIG "unavailability" should be attributed to these causes and how much to other factors, such as the difference between price and insurance reimbursement, cannot be quantified in a pharmacy survey. . A lingering question is how much of the IVIG needed by hospitals is unavailable at a reasonable price in terms of reimbursement, and how much is unavailable at *any* price? Despite the inability of this research to better untangle the IVIG availability puzzle, it has demonstrated that financial considerations - particularly the rate of Medicare reimbursement -- must be included in the solution.

## Appendix A: Hospitals Treating Indication/Condition in Past Four Weeks with IVIG and Average Number of Times IVIG Was Dispensed in Hospitals Where it Was Dispensed at Least Once (Total N=85)

<u>PIDD Indications</u>	%	Ave.
Agammaglobulinemia (XLA)	19	2.6
Common Variable Immunodeficiency (CVID)	32	4.2
Hyper IgM Syndrome	1	2.0
IgG Subclass Deficiency	8	1.7
Severe Combined Immunodeficiency (SCID)	16	6.6
Specific Antibody Deficiency	10	11.9
Any other PIDD	1	4.0
Any PIDD (net)	55	7.7

### Other On-Label Indications

Immune thrombocytopenic purpura (ITP)	42	2.3
Chronic lymphocytic leukemia	20	1.6
Kawasaki Disease	7	1.2
Bone marrow transplantation	6	1.4
Pediatric HIV infection	1	2.0
Any other On-Label	1	20.0
Any Other On-Label (net)	52	3.3

### Neurological Conditions

Guillain-Barré syndrome	15	1.7
Chronic demyelinating polyneuropathy	15	4.8
Multifocal motor neuropathy	5	1.3
IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy	2	1.0
Myasthenia gravis	24	2.1
Stiff-man syndrome (or Stiff-person syndrome)	1	1.0
Monoclonal gammopathy	0	
Multiple sclerosis	18	2.1
Intractable childhood epilepsy	1	1.0
Rasmussen's syndrome	0	
Acute disseminated encephalomyelitis	0	
HTLV-1-associated myelopathy	1	2.0
Cerebral infarctions with anti-phospholipid antibodies	1	1.0
Demyelinative brain stem encephalitis	0	
Lumbosacral or brachial plexitis	2	1.0
Paraproteinemic neuropathy	0	
Opsoclonus myoclonus	0	
Post-infectious cerebellar ataxia	0	
Acute idiopathic dysautonomia	0	
Demyelinating neuropathy associated with monoclonal IgM	5	1.0
Adrenoleukodystrophy	0	

Amyotrophic lateral sclerosis	1	4.0
POEMS syndrome	0	
Paraneoplastic cerebellar degeneration, sensory neuropathy or encephalopathy	0	
Other neurological conditions	0	
Any neurological (net)	45	4.7

## Appendix A (continued)

### Auto-Immune Conditions

Graves' ophthalmopathy	1	1.0
Dermatomyositis and polymyositis	7	1.0
Autoimmune uveitis	0	
Severe rheumatoid arthritis	11	1.8
Autoimmune diabetes mellitus	1	2.0
Post transfusion Purpura	1	1.0
Vasculitides and anti-neutrophil antibody syndromes	2	1.0
Autoimmune neutropenia	4	1.0
Autoimmune cytopenia	0	
Autoimmune hemophilia	4	1.3
Systemic lupus erythematosus	4	1.0
Fetomaternal alloimmune thrombocytopenia	1	1.0
Neonatal isoimmune hemolytic jaundice	1	1.0
Inclusion body myositis	0	
Antiphospholipid antibody syndrome in pregnancy	0	
Toxic epidermal necrolysis and Stevens-Johnson Syndrome	1	2.0
Severe persistent high dose steroid-dependent asthma	1	1.0
Prevention of acute humoral rejection in renal transplantation	1	1.0
Pediatric autoimmune neuropsychiatric disorders assoc'd w/ streptococcal infections (PANDAS)	0	
Delayed pressure urticaria	0	
Treatment of acute humoral rejection in renal transplantation	0	
Autoimmune Blistering skin diseases and manifestation of systemic diseases	0	
Chronic urticaria	1	1.0
Autoimmune liver disease	2	1.5
Acute Myocarditis	1	60.0
Prevention of spontaneous recurrent abortions	0	
Non steroid-dependent asthma	0	
Dilated Cardiomyopathy	0	
Atopic Dermatitis	0	
Other auto conditions (not specified)	2	3.0
Any auto-immune (net)	28	4.8

### Other Conditions

Acute rheumatic fever	1	1.0
Autistic disorders	0	
Chronic fatigue syndrome	2	1.0
Alzheimer's disease	0	
CMV pneumonitis in solid organ transplants	0	
Neonatal Sepsis	1	1.0
Prevention of neonatal sepsis	2	1.5
Rotaviral enterocolitis	0	
Bacterial infections in lymphoproliferative diseases	0	
Staphylococcal toxic shock	1	1.0

Enteroviral meningoencephalitis	0	
Postoperative sepsis	2	1.5
RSV lower respiratory tract infection	0	
Pseudomembraneous colitis	0	
Campylobacter enteritis	0	
Infertility	0	
Any other "other"	1	1.0
Any other (net)	7	2.0

**Appendices B1 and B2:  
Telephone Survey Questionnaire and  
Mailed Out Follow-Up Survey Form**

## Appendix B1: The 2006 IDF (CATI) Questionnaire

### Hospital Pharmacist Survey

S1. Hello, I'd like to speak with the pharmacy director or the person in charge of the hospital pharmacy. May I have his/her name and phone number.

- 01. Enter director's name and telephone number /overwrite original phone number
- 02. Call being automatically transferred to pharmacy
- 03. Disconnected/Hung up (schedule system callback)

#### **[Interviewer: When connected to pharmacy/pharmacy director]**

S2. Hello, my name is \_\_\_\_\_[use full name]. I'm calling on behalf of the Immune Deficiency Foundation. I would like to speak with the pharmacy director, are you this person?

- 01. Yes /Go to Survey Introduction/
- 02. No [Ask for and record director's name and phone number] /overwrite original phone number
- 03. Call being transferred to pharmacy director /Go to Survey Introduction/  
**[If you receive voicemail on first attempt, hang up and schedule callback] [If you receive voicemail on second attempt, leave scripted message including the masterid and toll-free call center phone number]**
- 04. No [Director unavailable. Ask for and record director name and phone number/overwrite original phone number. Ask for a good time to call back, then schedule callback]
- 05. Refused to transfer call or give director's name or number. /*schedule system callback next day/*

#### ***Survey Introduction:***

(WHEN CHIEF PHARMACIST IS REACHED:) Hello, my name is \_\_\_\_\_ **[use full name]**. I'm calling on behalf of the Immune Deficiency Foundation - the national non profit patient organization that advocates for patients with primary immune deficiency diseases. We are conducting a national survey about intravenous immunoglobulin (IVIG). The purpose of this research is to help identify changes in intravenous gamma globulin treatment.

We would like to interview the pharmacy director of the hospital pharmacy that serves the most patients getting IVIG at hospital infusion suites, chemo clinics, and other outpatient clinics or programs at your hospital. Is this the hospital pharmacy that serves this population?

- 01. Yes /go to Q1\_Intro/
- 02. No /go to S3/

S3. What is the name and phone number of the hospital pharmacy (located in the hospital) that serves this population?

Record name of pharmacy, pharmacy director and phone number. */Startover – overwrite old number/*

No other pharmacy in the hospital serving this population. *GO TO Q1\_Intro /Set flag??*

*/Help screen text/*

**[Interviewer: Use as needed]**

REFUSAL STATEMENT: We need your help to identify changes in intravenous gamma globulin treatment. The purpose of this important research is to help measure impact on patients' health and access to care related to IVIG supply and changes in Medicare reimbursement policies. If you have any questions about this survey, I will provide a telephone number for you to call to get more information. [list Reno phone number]. You can also visit the Immune Deficiency Foundation Website, located at: [www.primaryimmune.org](http://www.primaryimmune.org)

Q1\_Intro

Your answers will be confidential and neither your name nor the name of your pharmacy will be associated with your responses. Participation in the survey is voluntary and there are no foreseeable risks to you. Do you have 15 minutes now to help us with this important survey?

**[INTERVIEWER NOTE: IF NO: CAN YOU GIVE ME A CONVENIENT TIME FOR ME TO CALL BACK?]**

*(IF CALLBACK REQUESTED, ASK FOR TIME AND NAME AND RECORD BELOW.)*

- 01. Yes /go to Q1/
- 02. Enter callback time, verify name and phone number
- 99. Refused to take survey **[Go to REFUSAL STATEMENT]**

*(IF PHARMACIST SAYS THEY DO NOT DISPENSE INTRAVENOUS IMMUNOGLOBULIN –IVIG - RECORD Q1 AS "NO," AND ATTEMPT TO ASK Q2-4.)*

Does your pharmacy dispense intravenous immunoglobulin (IVIG)?

- 01. Yes → Go TO Q6
- 02. No
- 98. Don't know
- 99. Refused

1. Was IVIG dispensed by your pharmacy in the past?

- 01. Yes
- 02. No → Go to Q5a
- 98. Don't know → Go to Q5a
- 99. Refused → Go to Q5a

3. How about since the beginning of 2005?

- 01. Yes
- 02. No → Go to Q5a
- 98. Don't know → Go to Q5a
- 99. Refused → Go to Q5a

4. When, or in what year did your pharmacy stop dispensing IVIG? **[Interviewer: Probe, if necessary: Was it this year, last year (2005), or sometime before 2005?]**

- 01. Before 2005
- 02. 2005
- 03. 2006
- 98. Don't know/Not sure
- 99. Refused

5. Why is IVIG no longer dispensed by your pharmacy? **[Interviewer: Code all mentions – Probe persistently: Any other reasons? /MUL=6 [DO NOT READ]**

- 01. Medicare reimbursement rates too low
- 02. Private third party Insurance reimbursement rates too low
- 03. Reimbursement rates too low  
(unspecified or both Medicare and private).
- 04. Cost of product is too high
- 05. Cannot obtain product
- 66. Other (SPECIFY:) \_\_\_\_\_
- 98. Don't know/Not sure
- 99. Refused

5a. Is there another pharmacy in the hospital that dispenses IVIG ?

- 01. Yes→ [ASK WHICH OTHER PHARMACY DISPENSES IVIG. RECORD PHONE NUMBER AND PHARMACY DIRECTOR] /START OVER FROM BEGINNING/

- 02. No → [THANK AND TERMINATE]
- 98. Don't know → [ASK HOW TO REACH OTHER PHARMACY IN HOSPITAL]
- 99. Refused → [THANK AND TERMINATE]

Thank you for your time and participation in this survey. Have a nice afternoon/evening.

6. Does your pharmacy currently dispense IVIG in an inpatient setting, an outpatient setting or both?

- 01. Inpatient only
- 02. Outpatient only
- 03. Both settings
- 98. Don't know
- 99. Refused [THANK AND TERMINATE]

*/IF INPATIENT ONLY /If Q6 = 01, go to 6a.*

6a. Thank you for your time. At this point, we are only interested in speaking with pharmacists who also serve outpatients. Have a nice afternoon/evening. /Terminate

*/Please also add a "screened out: inpatient only" disposition, so we can track these terminates.*

7. In your hospital, is IVIG administered in ..... **[READ AND RECORD ANSWER FOR EACH ITEM]**

- 01. Yes
- 02. No
- 98. Don't know
- 99. Refused
  
- 7a. Infusion suites
- 7b. Clinics
- 7c. Outpatient department
- 7d. Patient rooms
- 7e. Anywhere else? (Specify:) \_\_\_\_\_

*/IF OUTPATIENT ONLY /If Q6 =02, go to Q11/*

8. In an average month, how much IVIG, in grams, does your pharmacy dispense for inpatient use? (*PROBE: Please make your best estimate.*)

**[Interviewer: If cannot estimate, mark DK]**

- 01. Less than 100 grams
- 02. 100 to 499 grams
- 03. 500 to 999 grams
- 04. 1,000+ grams
- 98. Don't know
- 99. Refused

9. Compared to 2005, has the average amount of IVIG dispensed per month for inpatient use: increased, stayed the same, or decreased?

- 01. Increased
- 02. Stayed the same → /Go to Q14
- 03. Decreased
- 98. Don't know → /Go to Q14
- 99. Refused → /Go to Q14

10. Why has inpatient IVIG use (increased/decreased) compared to 2005? (*PROBE: Any other reason?*) **[READ ALL AND RECORD ALL THAT APPLY]** /MUL=6/

- 01. Cost
- 02. Reimbursement
- 03. Availability
- 04. Patient mix, demand (decreased/increased)
- 05. Different supplier
- 66. Other (Specify:\_\_\_\_\_)
- 98. Don't know
- 99. Refused

*/IF INPATIENT ONLY – /If Q6=01, go to Q14/*

11. In an average month, how much IVIG does your pharmacy dispense [for outpatient use? (*PROBE: Please give me your best estimate. [Interviewer: IF CANNOT ESTIMATE, MARK DK]*)

- 01. Less than 100 grams
- 02. 100 to 499 grams
- 03. 500 to 999 grams
- 04. 1,000+ grams
- 98. Don't know
- 99. Refused

12. Compared to 2005, has the average amount of IVIG dispensed per month for outpatient use in 2006: increased, stayed the same, or decreased?

- 01. Increased
- 02. Stayed the same → GO TO Q14
- 03. Decreased
- 98. Don't know → GO TO Q14
- 99. Refused → GO TO Q14

13. Why has outpatient IVIG use (increased/decreased)? **[Interviewer: DO NOT READ LIST. MARK ALL MENTIONS.]**

- 01. Cost
- 02. Changes in Reimbursement
- 03. Availability
- 04. Patient mix, demand (decreased/increased)
- 05. Different supplier

- 97. Other (specify:) \_\_\_\_\_
- 98. Don't know
- 99. Refused

14. Is IVIG used at your hospital [in an outpatient setting] to treat Primary Immune Diseases such as Agammaglobulinemia (XLA), Common Variable Immunodeficiency (CVID), Hyper IgM Syndrome, IgG Subclass Deficiency, Severe Combined Immunodeficiency (SCID), Specific Antibody Deficiency, or other primary immune diseases?

**[NOTE: FOR THIS AND SUBSEQUENT QUESTIONS WHICH REFER TO OUTPATIENT SERVICES, /Programmer: FOR RESPONDENTS WHO SERVE INPATIENT ONLY – IF Q6 =01 /DELETE “OUTPATIENT”/ SO THE QUESTION REFERS TO GENERAL SERVICES.]**

- 01. Yes
- 02. No → *GO TO Q17*
- 98. Don't know → *GO TO Q17*
- 99. Refused

15. In the last 4 weeks, approximately how many times has your pharmacy dispensed IVIG for [out] patients with primary immune deficiency conditions? **[PROBE FOR BEST ESTIMATE]**

- 01. Record number of times **[Range 0-50]**
- 98. Don't know
- 99. Refused

16. About how many grams of IVIG were dispensed to treat these conditions in the last 4 weeks?  
**[PROBE FOR BEST ESTIMATE]**

- 01. Less than 50 grams
- 02. 50-99 grams
- 03. 100-499 grams
- 04. 500-999 grams
- 05. 1,000 or more grams
- 98. Don't know
- 99. Refused

17. Is IVIG used at your hospital [in an outpatient setting] for any of the following on-label indications including Immune thrombocytopenic purpura (ITP), Chronic lymphocytic leukemia, Kawasaki Disease, Bone marrow transplantation, Pediatric HIV infection, or other on-label indications?

- 01. Yes
- 02. No → *GO TO Q20*
- 98. Don't know → *GO TO Q20*
- 99. Refused

18. In the last 4 weeks, approximately how many times has your pharmacy dispensed IVIG for [out] patients with these non-PID on-label conditions? **[Interviewer: PROBE FOR BEST ESTIMATE]**

- 01. Record number of times **[Range 0-15]**
- 98. Don't know
- 99. Refused

19. About how many grams of IVIG were dispensed to treat these conditions in the last 4 weeks?  
**[PROBE FOR BEST ESTIMATE]**

- 01. Less than 50 grams
- 02. 50-99 grams
- 03. 100-499 grams
- 04. 500-999 grams
- 05. 1,000 or more grams
- 98. Don't know
- 99. Refused

20. Is IVIG used at your hospital **[in an outpatient setting]** to treat any other conditions not already mentioned including neurological, auto-immune, and other conditions?

- 01. Yes
- 02. No → *GO TO Q23*
- 98. Don't know → *GO TO Q23*
- 99. Refused

21. In the last 4 weeks, approximately how many times has your pharmacy dispensed IVIG for **[out]** patients with these other conditions? **[Interviewer: PROBE FOR BEST ESTIMATE]**

- 01. Record number of times **[Range 0-15]**
- 98. Don't know
- 99. Refused

22. About how many grams of IVIG were dispensed in the **last 4 weeks to treat these other conditions?** **[Interviewer: PROBE FOR BEST ESTIMATE]**

- 01. Less than 50 grams
- 02. 50-99 grams
- 03. 100-499 grams
- 04. 500-999 grams
- 05. 1,000 or more grams
- 98. Don't know
- 99. Refused

23. Compared to 2004, that is, to about two years ago – would you say that the amount of IVIG dispensed to treat *//INSERT ITEM A thru C/* has increased, stayed about the same, or decreased?

- 01. Increased
- 02. Stayed Same
- 03. Decreased
- 98. Don't Know
- 99. Refused

- 23a. Primary immune deficiency
- 23b. Other on-label indications
- 23c. All other conditions

24. Does your hospital have a P and T (Patient and Treatment) Committee that determines which patients will be treated with IVIG?

- 01. Yes
- 02. No
- 98. Don't know
- 99. Refused

25. Does your hospital have a priority protocol specifying which patients will be infused?

- 01. Yes
- 02. No → *GO TO Q28*
- 98. Don't know → *GO TO Q28*
- 99. Refused

26. What is the priority based upon? **[Interviewer: MARK ALL THAT APPLY]** (PROBE: Is it based on anything else?) **[Interviewer: Read categories 01 thru 97]**

- 01. Indications/conditions
- 02. Health status of patients
- 03. Supply
- 04. Insurance

- 97. Other (SPECIFY:)

---
- 98. Don't know
- 99. Refused

*/Ask if Q26=01/*

27. (IF INDICATIONS/CONDITIONS MENTIONED:) Which indications (conditions) have priority?  
**[Interviewer: PROBE: Any others?] [Interviewer: Read categories 01 thru 97**

- 01. Primary immune deficiency
- 02. Immune thrombocytopenic purpura
- 03. Chronic lymphocytic leukemia
- 04. Kawasaki Disease
- 05. Bone marrow transplantation
- 06. Pediatric HIV infection
- 07. All on-label uses
- 97. Other (Specify:)

---
- 98. Don't know
- 99. Refused

28. Do you have a contract to purchase IVIG from a GPO (group purchasing organization)?

- 01. Yes
- 02. No → *GO TO Q33*
- 98. Don't know → *GO TO Q33*
- 99. Refused → *GO TO Q33*

29. Are you currently under allocation with your GPO?

- 01. Yes
- 02. No. → *GO TO Q33*
- 98. Don't know/Not sure → *GO TO Q33*
- 99. Refused → *GO TO Q33*

30. Does your allocation meet all, most, some, few, or none of your recent needs?

- 01. All → GO TO Q32
- 02. Most
- 03. Some
- 04. Few
- 05. None
- 98. Don't know → GO TO Q32
- 99. Refused

31. About how much more IVIG product would you need, in grams per month, to meet your recent needs?

- 01. Record additional grams per month of IVG needed
- 98. Don't know/Not sure
- 99. Refused

32. About how long have you been purchasing IVIG from you current GPO?

- 01. Record number of years
- 02. Less than 1 year
- 98. Don't know/Not sure
- 99. Refused

33. I'm going to next read a list of various sources from which pharmacies may purchase IVIG, and I'd like you to tell me if your pharmacy has purchased any IVIG from that source since the beginning of 2006.

- 01. Yes
- 02. No
- 98. Don't Know
- 99. Refused

- 33a. From a GPO
- 33b. Directly from the manufacturer
- 33c. From a contractual (primary) distributor
- 33d. From a non-contractual (secondary) distributor
- 33e. From some other source not yet mentioned

*/IF ONLY ONE SOURCE PURCHASED FROM, ENTER 100% FOR THAT SOURCE BELOW, AND GO TO Q35/*

34. So your pharmacy has purchased IVIG from **[/Restore responses from Q33/REPEAT SOURCES PURCHASED FROM – Q33]**. Thinking about the total amount of IVIG your pharmacy has purchased since the beginning of 2006, I'd like you to estimate the proportion of that total which was purchased from each of those sources. What proportion was purchased from **[INSERT SOURCE]? (PROBE IF NECESSARY: Please give me your best estimate.) [INTERVIEWER: The total distribution should equal 100%. IF SUM OF PERCENTAGES DOES NOT EQUAL 100, ASK RESPONDENT TO RECONCILE.]**

- 01. \_ % Purchased from Source
- 98. Don't Know
- 99. Refused

- 34a. From your GPO \_\_\_\_\_
- 34b. Directly from the manufacturer \_\_\_\_\_
- 34c. From a contractual (primary) distributor \_\_\_\_\_
- 34d. From a non-contractual (secondary) distributor \_\_\_\_\_
- 34e. From some other source not yet mentioned \_\_\_\_\_

*/If one category from above = 100%, continue to Q36/*

*/Ask if 34=E > 0/*

35. OTHER. What other source was used to obtain IVIG? (*PROBE: Any others?*)

- 01. \_\_\_\_\_
- 02. \_\_\_\_\_
- 03. \_\_\_\_\_
- 98. Don't know
- 99. Refused

36. Since the beginning of 2006, has the price for IVIG from (*READ EACH SOURCE PURCHASED FROM –SEE Q33/Restore responses from Q33/*) gone down, stayed about the same, or gone up?

- 01. Gone Down
- 02. Stayed Same
- 03. Gone Up
- 98. Don't Know
- 99. Refused
  
- 36a. GPO
- 36b. Manufacturer
- 36c. Contractual (primary) distributor
- 36d. Non-contractual (secondary) distributor
- 36e. Other source

37. Since the beginning of 2006, has it become more difficult or less difficult to get the amount of IVIG that you need *from* (*READ EACH SOURCE PURCHASED FROM – SEE Q33 /Restore response from Q33/*), or has this been unchanged?

- 01. More Difficult
- 02. Less Difficult
- 03. Unchanged
- 04. Don't Know
- 99. Refused

- 37a. GPO
- 37b. Manufacturer
- 37c. Contractual (primary) distributor
- 37d. Non-contractual (secondary) distributor
- 37e. Other source

38. Since the beginning of 2006, have reimbursement rates for IVIG at your hospital gone down for none, only a few, some, most, almost all, or all of your third-party (private insurance) payers?

- 01. None
- 02. Only a few
- 03. Some
- 04. Most
- 05. Almost all
- 06. All
- 98. Don't know
- 99. Refused

39. Are you able to obtain one, two, or more than two brands of IVIG?

- 01. One
- 02. Two
- 03. More than two
- 98. Don't know
- 99. Refused → GO TO Q42

40. Which brand(s) do you currently use? (*PROBE IF NECESSARY: What are their names?*)

- 01. \_\_\_\_\_
- 02. \_\_\_\_\_
- 03. \_\_\_\_\_
- 98. Don't know → GO TO Q42
- 99. Refused → GO TO Q42

41. (*ASK FOR EACH BRAND LISTED ABOVE:/Display responses from Q40/*) Do you know the pedigree of **[INSERT BRAND]**?

**[INTERVIEWER NOTE: THE PEDIGREE OF A BRAND IS THE CHAIN OF CUSTODY OF A DRUG. IN OTHER WORDS, THE HISTORY OF ITS DISTRIBUTION – DO YOU KNOW WHERE IT CAME FROM?]**

- 01. Yes
- 02. No
- 98. Don't know
- 99. Refused

42. Moving on to a different topic, are you adequately reimbursed to purchase IVIG for patients who carry the following insurance coverage? **[Interviewer: Read A thru C]**

- 01. Yes
- 02. No
- 98. Don't Know
- 99. Refused

- 42a. Medicare
- 42b. Medicare with supplement
- 42c. Medicaid

43. Thinking of the **third-party insurers** (private insurance companies) with whom you've had some experience, how many of them would you say fail to provide adequate reimbursement for the purchase of IVIG? (*READ RESPONSES*). Would you say: none, some, about half, or more than half?

- 01. None
- 02. Some
- 03. About half
- 04. More than half
- 98. (*Don't read:*) Don't know
- 99. Refused

*/IF "NO" OR "DK" FOR MEDICARE IN Q42a, GO TO Q45/*

44. How much of your total cost, on average, to purchase IVIG is not covered by current reimbursement rates for Medicare? Is it about (*READ RESPONSES*)... 5% or less, 6 to 10%, 11 to 20%, 20 to 29%, 30% or more? **[Interviewer: PROBE IF NECESSARY: Please give me your best estimate.]**

- 01. 5% or less
- 02. 6 to 10%
- 03. 11 to 20%
- 04. 20 to 29%
- 05. 30% or more
- 98. Don't know **[Don't read]**
- 99. Refused

45. What is the average price you pay for 1g of liquid IVIG?

**[Interviewer: PROBE IF NECESSARY: Please give me your best estimate.]**

- 01. \$\_\_\_\_\_ /set range to \$6,000
- 98. Don't know
- 99. Refused

46. What is the average price you pay for 1g of lyophilized IVIG?

**[Interviewer: PROBE IF NECESSARY: Please give me your best estimate.]**

- 01. \$\_\_\_\_\_ /set range to \$3,000/
- 98. Don't know
- 99. Refused

47. How much difficulty have you had in the past 12 months in obtaining insurance approval for patients who require IVIG? Would you say: a lot, a moderate amount, only a little, or none?

- 01. A lot
- 02. Moderate amount
- 03. Only a little → GO TO Q49
- 04. None → GO TO Q49
- 98. Don't know → GO TO Q49
- 99. Refused → GO TO Q49

48. From which carriers have you had difficulty getting approval for IVIG? (*PROBE: Any others?*)

- 01. \_\_\_\_\_
- 02. \_\_\_\_\_
- 03. \_\_\_\_\_
- 98. Don't know
- 99. Refused

49. How much difficulty have you had since the beginning of 2006 in acquiring IVIG for patients who have had appropriate insurance approval? Would you say: a lot, a moderate amount, only a little, or none?

- 01. A lot
- 02. Moderate amount
- 03. Only a little
- 04. None
- 98. Don't know
- 99. Refused

50. Since the beginning of 2006, has your hospital had to turn away patients needing IVIG treatment?

- 01. Yes
- 02. No → GO TO Q52
- 98. Don't know → GO TO Q52
- 99. Refused → GO TO Q52

51. Did you have to turn away any patients because of ... **[INTERVIEWER: READ ITEMS A thru D]**

- 01. Yes
- 02. No
- 98. Don't Know
- 99. Refused

- 51a. Staffing or capacity shortage?
- 51b. Product availability?
- 51c. Inadequate insurance (reimbursement)?
- 51d. Any other reason(s) (Specify: \_\_\_\_\_ )

52. Given present IVIG reimbursement practices, do you feel that your hospital definitely will, probably will, probably will not, or definitely will not be able to continue to treat patients who require treatment, or are you uncertain?

- 01. Definitely will
- 02. Probably will
- 03. Probably will not
- 04. Definitely will not
- 98. Uncertain / Don't know
- 99. Refused

53. Thank you for your participation in this survey! Your answers have been very valuable. I have one last question: There is some additional information about specific IVIG treatment indications and conditions that we need for this study which would be difficult to obtain over the phone. We will pay you \$25 for your time. The information you provide will be confidential and neither your name nor the name of your pharmacy will be associated with the responses. May I fax or send you a form to fill out and return to us? *(ADD IF NECESSARY: It should take about 15-20 minutes to fill out this form.)*

- 01. Yes → Ask for or verify name and mailing address:
- 02. No (declines to do follow-up) → *(RECORD REASON BELOW.*

REASON: \_\_\_\_\_

*/If Q53=01*

53\_1a. Would you prefer to receive the form by fax or mail?

- 01. Fax
- 02. Mail
- 03. Either

*IF NO REASON GIVEN, /If Q53 = 02 AND NO REASON GIVEN -- ASK:*

53a. To help us fine-tune our research procedures, can you tell me why you choose not to complete this form?

Enter response: \_\_\_\_\_

*/If 53a = 01/*

You will receive this form in within the next few days.

Closing: Thanks again for your time and participation.

## Appendix B1: 2006 IDF Follow-Up Survey

### Immune Deficiency Foundation Hospital Pharmacist Survey

#### Follow-Up Questions to be Completed and Returned by Fax/Mail

Thank you again for agreeing to help with this important research study of intravenous immunoglobulin (IVIG). The information you provide will be confidential and neither your name nor the name of your pharmacy will be associated with your responses in the data files or study reports. You can call Jennifer Muncil at 1-800-639-1310 if you have any questions about the study.

Please answer as completely as possible and then return the form by fax or mail, following the instructions on the last page.

1. For which of the following primary immune deficiency (PID) indications has your pharmacy dispensed intravenous immunoglobulin (IVIG) in the past four (4) weeks? Please check either “No/Don’t Know (DK)” or “Yes” in column Q1 for *each* PID indication.
2. For *each* PID indication where “Yes” was marked, please estimate in column Q2 the number of times IVIG was dispensed for that condition in the past four weeks.

PID Indication	Q1		Q2 Times IVIG Dispensed
	No/DK	Yes→	
Agammaglobulinemia (XLA)	<input type="checkbox"/>	<input type="checkbox"/>	
Common Variable Immunodeficiency (CVID)	<input type="checkbox"/>	<input type="checkbox"/>	
Hyper IgM Syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
IgG Subclass Deficiency	<input type="checkbox"/>	<input type="checkbox"/>	
Severe Combined Immunodeficiency (SCID)	<input type="checkbox"/>	<input type="checkbox"/>	
Specific Antibody Deficiency	<input type="checkbox"/>	<input type="checkbox"/>	

Any other PID disease (Specify): \_\_\_\_\_

3. For which of the following on-label non-PID indications has your pharmacy dispensed IVIG in the past four (4) weeks? Please check either “No/Don’t Know (DK)” or “Yes” in column Q3 for *each* on-label non-PID indication.
4. For *each* on-label indication where “Yes” was marked, please estimate in column Q4 the number of times you have dispensed IVIG for that condition in the past four weeks.

On-Label Indication	Q3		Q4 Times IVIG Dispensed
	No/DK	Yes→	
Immune thrombocytopenic purpura (ITP)	<input type="checkbox"/>	<input type="checkbox"/>	
Chronic lymphocytic leukemia	<input type="checkbox"/>	<input type="checkbox"/>	

Kawasaki Disease	<input type="checkbox"/>	<input type="checkbox"/>	
Bone marrow transplantation	<input type="checkbox"/>	<input type="checkbox"/>	
Pediatric HIV infection	<input type="checkbox"/>	<input type="checkbox"/>	
Any other on-label use (Specify):			

- For which of the following neurological conditions has your pharmacy dispensed IVIG in the past four (4) weeks? Please check either “No/Don’t Know (DK)” or “Yes” in column Q5 for each neurological condition.
- For each neurological condition above where “Yes” was marked above, please estimate in column Q6 the number of times you have dispensed IVIG for that condition in the past four weeks.

Neurological Condition	Q5		Q6
	No/DK	Yes→	Times IVIG Dispensed
Guillain-Barré syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
Chronic demyelinating polyneuropathy	<input type="checkbox"/>	<input type="checkbox"/>	
Multifocal motor neuropathy	<input type="checkbox"/>	<input type="checkbox"/>	
IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy	<input type="checkbox"/>	<input type="checkbox"/>	
Myasthenia gravis	<input type="checkbox"/>	<input type="checkbox"/>	
Stiff-man syndrome (or Stiff-person syndrome)	<input type="checkbox"/>	<input type="checkbox"/>	
Monoclonal gammopathy	<input type="checkbox"/>	<input type="checkbox"/>	
Multiple sclerosis	<input type="checkbox"/>	<input type="checkbox"/>	
Intractable childhood epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	
Rasmussen’s syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
Acute disseminated encephalomyelitis	<input type="checkbox"/>	<input type="checkbox"/>	
HTLV-I-associated myelopathy	<input type="checkbox"/>	<input type="checkbox"/>	
Cerebral infarctions with anti-phospholipid antibodies	<input type="checkbox"/>	<input type="checkbox"/>	
Demyelinative brain stem encephalitis	<input type="checkbox"/>	<input type="checkbox"/>	
Lumbosacral or brachial plexitis	<input type="checkbox"/>	<input type="checkbox"/>	
Paraproteinemic neuropathy	<input type="checkbox"/>	<input type="checkbox"/>	
Opsoclonus myoclonus	<input type="checkbox"/>	<input type="checkbox"/>	
Post-infectious cerebellar ataxia	<input type="checkbox"/>	<input type="checkbox"/>	
Acute idiopathic dysautonomia	<input type="checkbox"/>	<input type="checkbox"/>	

Neurological Condition	Q5		Q6
	No/DK	Yes→	Times IVIG Dispensed
Demyelinating neuropathy associated with monoclonal IgM	<input type="checkbox"/>	<input type="checkbox"/>	
Adrenoleukodystrophy	<input type="checkbox"/>	<input type="checkbox"/>	
Amyotrophic lateral sclerosis	<input type="checkbox"/>	<input type="checkbox"/>	
POEMS syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
Paraneoplastic cerebellar degeneration, sensory neuropathy or encephalopathy	<input type="checkbox"/>	<input type="checkbox"/>	
Other neurological condition (Specify): _____			

- For which of the following auto-immune conditions has your pharmacy dispensed IVIG in the past four (4) weeks. Please check either “No/Don’t Know (DK)” or “Yes” in column Q7 for each Auto-Immune Condition.
- For *each* auto-immune condition above where “Yes” was marked above, please estimate in column Q8 the number of times you have dispensed IVIG for that condition in the past four weeks.

Auto-Immune Condition	Q7		Q8
	No/DK	Yes→	Times IVIG Dispensed
Graves’ ophthalmopathy	<input type="checkbox"/>	<input type="checkbox"/>	
Dermatomyositis and polymyositis	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune uveitis	<input type="checkbox"/>	<input type="checkbox"/>	
Severe rheumatoid arthritis	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune diabetes mellitus	<input type="checkbox"/>	<input type="checkbox"/>	
Post transfusion Purpura	<input type="checkbox"/>	<input type="checkbox"/>	
Vasculitides and anti-neutrophil antibody syndromes	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune neutropenia	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune cytopenia	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune hemophilia	<input type="checkbox"/>	<input type="checkbox"/>	
Systemic lupus erythematosus	<input type="checkbox"/>	<input type="checkbox"/>	
Fetomaternal alloimmune thrombocytopenia	<input type="checkbox"/>	<input type="checkbox"/>	
Neonatal isoimmune hemolytic jaundice	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion body myositis	<input type="checkbox"/>	<input type="checkbox"/>	
Antiphospholipid antibody syndrome in pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	

Auto-Immune Condition	Q7		Q8
	No/DK	Yes→	Times IVIG Dispensed
Toxic epidermal necrolysis and Stevens-Johnson Syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
Severe persistent high dose steroid-dependent asthma	<input type="checkbox"/>	<input type="checkbox"/>	
Prevention of acute humoral rejection in renal transplantation	<input type="checkbox"/>	<input type="checkbox"/>	
Pediatric autoimmune neuropsychiatric disorders assoc'd with streptococcal infections (PANDAS)	<input type="checkbox"/>	<input type="checkbox"/>	
Delayed pressure urticaria	<input type="checkbox"/>	<input type="checkbox"/>	
Treatment of acute humoral rejection in renal transplantation	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune Blistering skin diseases and manifestation of systemic diseases	<input type="checkbox"/>	<input type="checkbox"/>	
Chronic urticaria	<input type="checkbox"/>	<input type="checkbox"/>	
Autoimmune liver disease	<input type="checkbox"/>	<input type="checkbox"/>	
Acute Myocarditis	<input type="checkbox"/>	<input type="checkbox"/>	
Prevention of spontaneous recurrent abortions	<input type="checkbox"/>	<input type="checkbox"/>	
Non steroid-dependent asthma	<input type="checkbox"/>	<input type="checkbox"/>	
Dilated Cardiomyopathy	<input type="checkbox"/>	<input type="checkbox"/>	
Atopic Dermatitis	<input type="checkbox"/>	<input type="checkbox"/>	
Other auto-immune condition (Specify): _____			

9. For which of the following other conditions has your pharmacy dispensed IVIG in the past four (4) weeks? Please check either “No/Don’t Know (DK)” or “Yes” in column Q9 for each other condition.
10. For each “other” condition above where “Yes” was marked above, please estimate in column in Q10 the number of times you have dispensed IVIG for that condition in the past four weeks.

Other Conditions	Q9		Q10 Times IVIG Dispensed
	No/DK	Yes→	
Acute rheumatic fever	<input type="checkbox"/>	<input type="checkbox"/>	
Autistic disorders	<input type="checkbox"/>	<input type="checkbox"/>	
Chronic fatigue syndrome	<input type="checkbox"/>	<input type="checkbox"/>	
Alzheimer’s disease	<input type="checkbox"/>	<input type="checkbox"/>	
CMV pneumonitis in solid organ transplants	<input type="checkbox"/>	<input type="checkbox"/>	
Neonatal Sepsis	<input type="checkbox"/>	<input type="checkbox"/>	
Prevention of neonatal sepsis	<input type="checkbox"/>	<input type="checkbox"/>	
Rotaviral enterocolitis	<input type="checkbox"/>	<input type="checkbox"/>	
Bacterial infections in lymphoproliferative diseases	<input type="checkbox"/>	<input type="checkbox"/>	
Staphylococcal toxic shock	<input type="checkbox"/>	<input type="checkbox"/>	
Enteroviral meningoencephalitis	<input type="checkbox"/>	<input type="checkbox"/>	
Postoperative sepsis	<input type="checkbox"/>	<input type="checkbox"/>	
RSV lower respiratory tract infection	<input type="checkbox"/>	<input type="checkbox"/>	
Pseudomembraneous colitis	<input type="checkbox"/>	<input type="checkbox"/>	
Campylobacter enteritis	<input type="checkbox"/>	<input type="checkbox"/>	
Infertility	<input type="checkbox"/>	<input type="checkbox"/>	
Any other condition (Specify):	_____		_____

11. **In the last 4 weeks**, about how many grams of IVIG were dispensed to treat Primary Immune Diseases such as Agammaglobulinemia (XLA), Common Variable Immunodeficiency (CVID), Hyper IgM Syndrome, IgG Subclass Deficiency, Severe Combined Immunodeficiency (SCID), Specific Antibody Deficiency, or other primary immune diseases?

Please provide your best estimate for grams dispensed for **INPATIENT** and **OUTPATIENT** use separately. If you cannot distinguish between the two, please fill in the total grams dispensed in the total column.

	Inpatient	Outpatient	Total
# of grams dispensed			

12. **In the last 4 weeks**, about how many grams of IVIG were dispensed to treat non-PID on-label conditions indications including Immune thrombocytopenic purpura (ITP), Chronic lymphocytic leukemia, Kawasaki Disease, Bone marrow transplantation, Pediatric HIV infection, or other on-label indications?

Please provide your best estimate for grams dispensed for **INPATIENT** and **OUTPATIENT** use separately. If you cannot distinguish between the two, please fill in the total grams dispensed in the total column.

	Inpatient	Outpatient	Total
# of grams dispensed			

13. **In the last 4 weeks**, about how many grams of IVIG were dispensed to treat any other conditions not already mentioned including neurological, auto-immune, and other conditions?

Please provide your best estimate for grams dispensed for **INPATIENT** and **OUTPATIENT** use separately. If you cannot distinguish between the two, please fill in the total grams dispensed in the total column.

	Inpatient	Outpatient	Total
# of grams dispensed			

Thank you for your participation in this survey!

Please provide your name and mailing address so that we can send your \$25 money order. This information will be used solely for mailing you the money order.

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Return the completed survey by fax: 1-802-863-8974 or by mail:

IDF c/o ORC-Macro  
126 College Street  
Burlington, Vermont 05401

## Appendix C: Survey Response Data

Since there were two surveys needed to collect the data required for this study, response details are reported separately in tables C1 and C2:

<b>Table C1 Telephone Survey Response Data</b>				
	<u>Total</u>	<u>100-199 beds</u>	<u>200-299 beds</u>	<u>300+ beds</u>
A. Completed interviews:	<b>359</b>	189	82	88
A1. Dispenses IVIG	<b>310</b>	155	71	84
A2. Doesn't dispense IVIG	<b>49</b>	34	11	4
B. Dispenses to inpatients only (ineligible)	<b>26</b>	15	7	4
C. Refusals	<b>671</b>	348	133	190
D. Mid-survey terminates	<b>19</b>	10	3	6
E. Respondent unavailable	<b>2351</b>	917	577	857
F. No contact made	<b>117</b>	29	29	59
G. Incorrect or unworking number	<b>33</b>	16	8	9
Total numbers dialed at least once	<b>3576</b>	1524	839	1213

The cooperation rate for the total sample,  $A/(A+C+D) = 34\%$ . By bed size:

100-199 beds:	35%
200-299 beds:	38%
300+ beds:	31%

The overall survey response rate,  $A/(A+C+D+E)$  for the total sample = 11%. By bed size, the response rates are:

100-199 beds:	13%
200-299 beds:	10%
300+ beds:	8%

The survey response rates were negatively impacted by two factors: (1) use of a one-refusal protocol (refusal conversions not attempted, by design) and (2) interviewing ceased once the target number of completed interviews was reached. Because of a somewhat limited time schedule for fielding the survey, more sample numbers had to be dialed in order to complete the target number of interviews on time. This resulted in a large number of unresolved cases (especially "Respondent Unavailable"), depressing the response rate.

<b>Table C2</b>				
<b>Follow-Up Survey Response Data</b>				
	<u>Total</u>	<u>100-199</u> <u>beds</u>	<u>200-299</u> <u>beds</u>	<u>300+</u> <u>beds</u>
A. Potential completed forms	<b>310</b>	155	71	84
B. Agreed to participate (recruited at end of telephone interview)	<b>221</b>	111	52	58
C. Completed and returned the form	<b>85</b>	50	19	16

The follow-up survey completion rate for the total sample (C/A) = 27%. By bed size, the completion rates are:

100-199 beds:	32%
200-299 beds:	27%
300+ beds:	19%

The fact that only 85/221 = 38% of those agreeing to participate actually did so suggests that the task was perceived to be unduly burdensome by many who did not comply, once they saw the form. It is unclear why fewer large-hospital pharmacists complied with the follow-up survey.

