



Immune Deficiency Foundation

Presentation to the
Advisory Committee on Blood Safety and Availability

*Primary Immune Deficiency Diseases IVIG
Access Overview*

May 2007

Mission

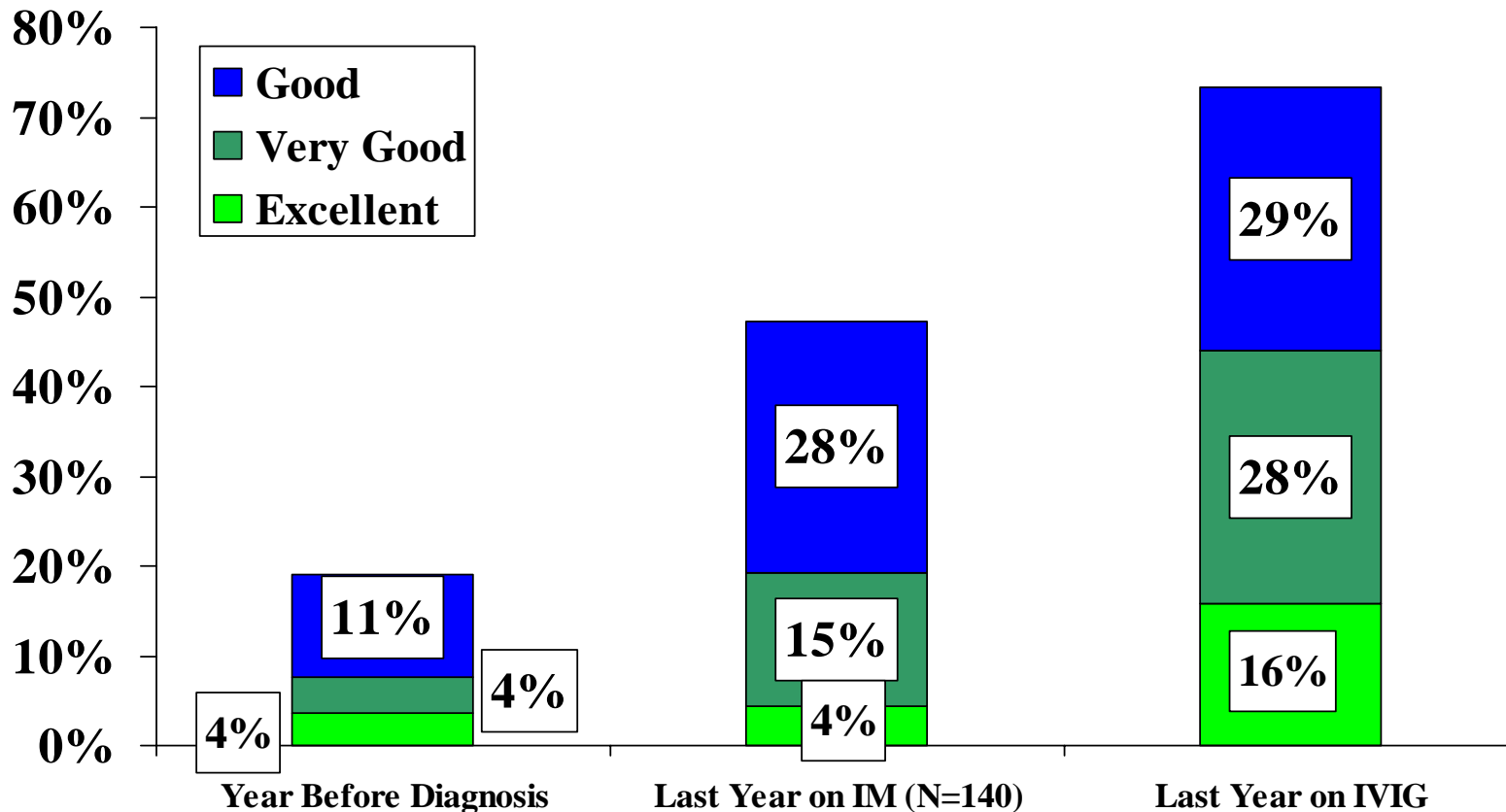
- The national patient organization in the U.S. dedicated to improving the diagnosis and treatment of primary immunodeficiency diseases through research, education and advocacy
- IDF is the first place to turn for help for patients and families



Primary Immunodeficiency Diseases

- According to IDF surveys, there are approximately 230,000 to 250,000 persons in the U.S. diagnosed with PIDD.
- Approximately two thirds of these diseases are antibody deficiencies, characterized by absent or deficient antibody productions.
- Immunoglobulin therapy is indicated as replacement therapy for many PIDD patients with antibody deficiencies.
- This is the ONLY clinically proven treatment, and is essential to prevent permanent harm from infectious disease, and/or premature death.
- However, we estimate that between 35,000 and 55,000 PIDD patients in the U.S. are currently using IVIG therapy.

Health Status: Before and After Treatment



Q6/Q60. Overall, how would you describe his or her health (in the year prior to diagnosis/during the last year (on IM/IVIG)?



Immune Deficiency Foundation

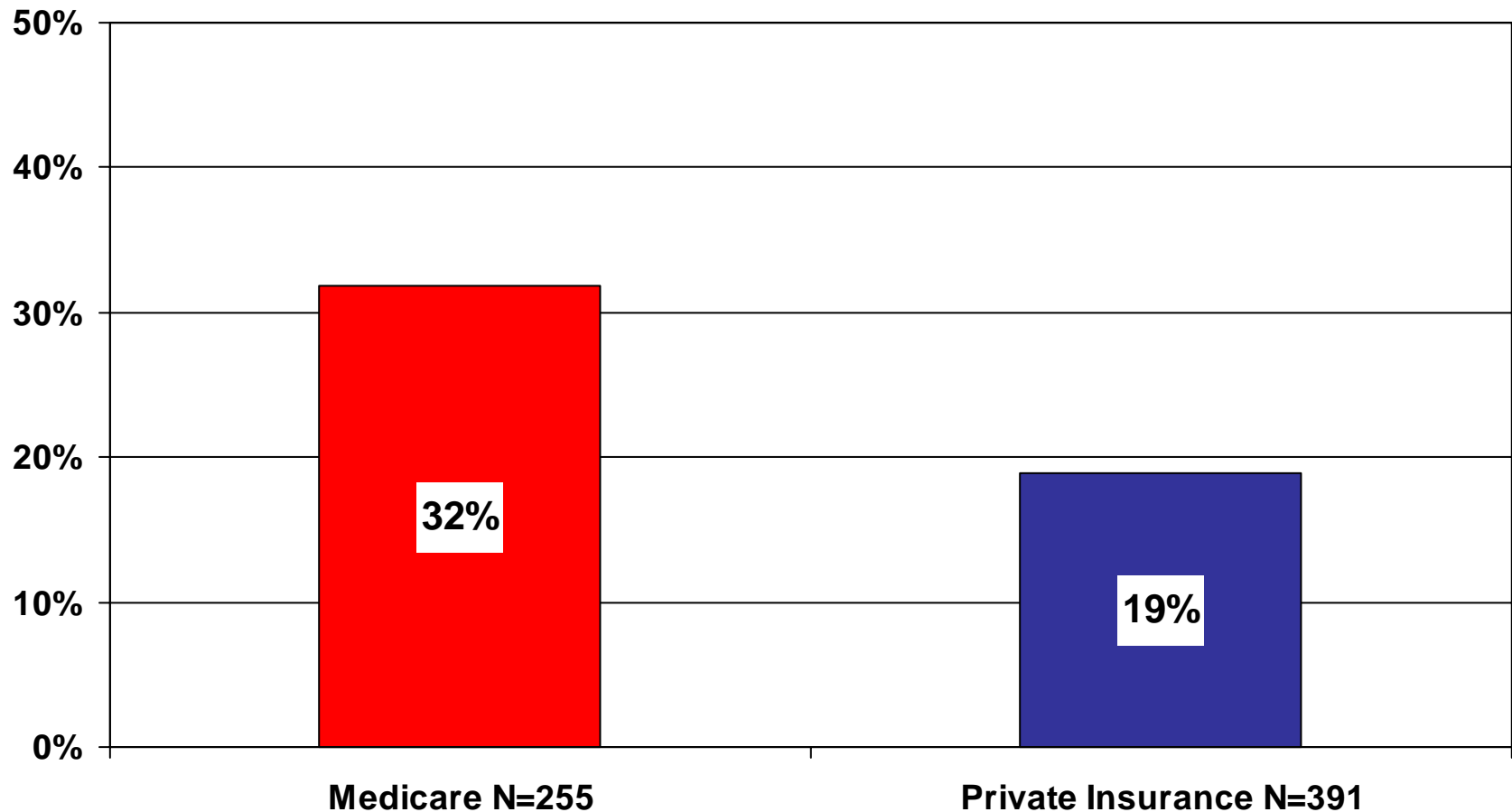
Survey of the Impact of Medicare
Reimbursement on Patients with Primary
Immune Deficiency Diseases using IVIG

Conducted between August – October 2006

Design: 2006 Patient Survey

- Mail survey of PID patient sample
- Completed PID interviews=1,009
- Cross-section (N=909)
 - Medicare=246
 - Non-Medicare=663
- Over-sample (N=100)
 - Medicare=90
 - Non-Medicare=10
- Total 2006 patient sample (N=1,009)
 - Medicare=336
 - Non-Medicare=673

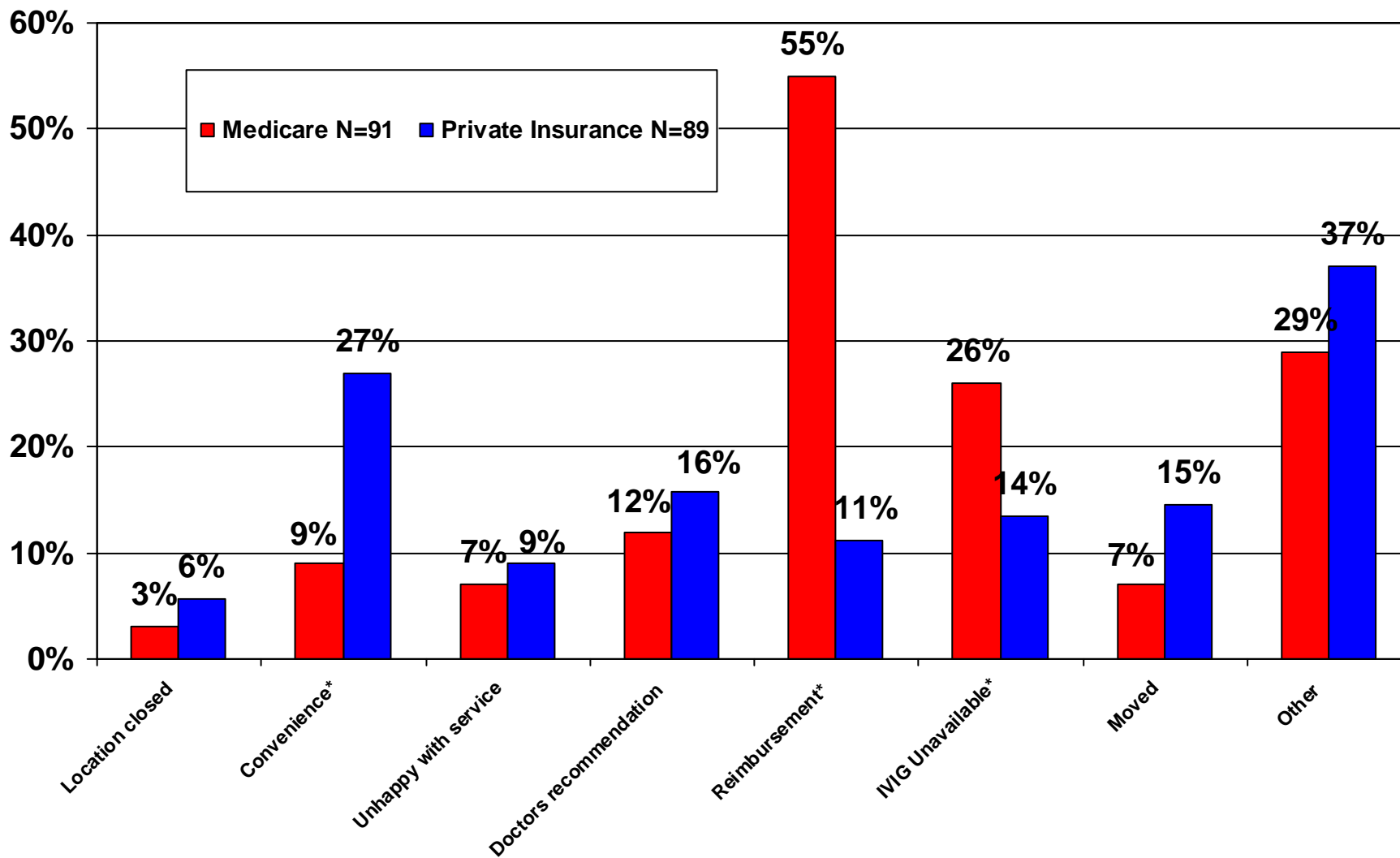
Different Treatment Location Since December 2004: IVIG Users



Q12. Is the patient now getting IVIG treatments at the same location as in December 2004 (or the same place they were given most recently before that time)? Base: Current IVIG use

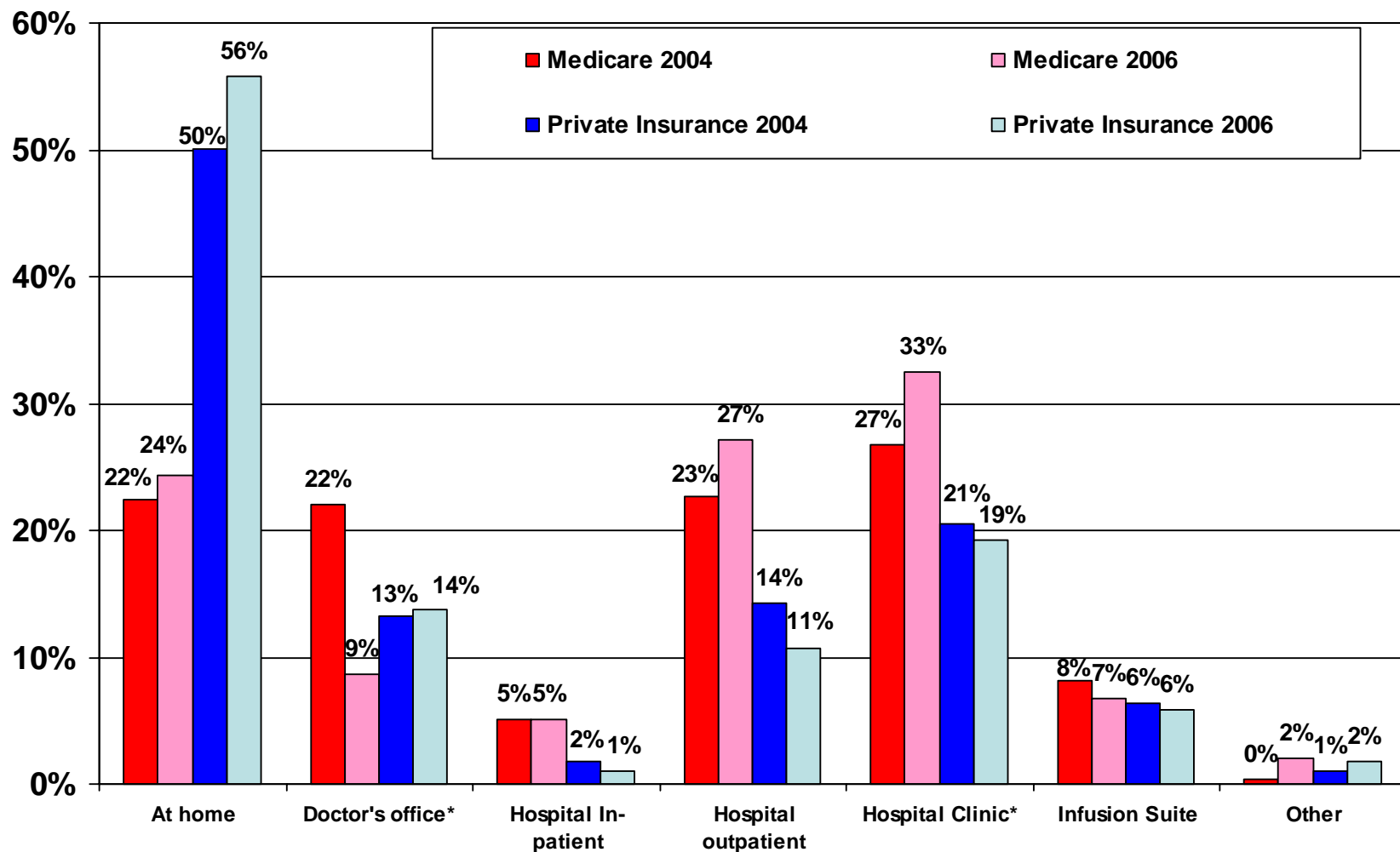
source: IDF 2006 Patient Survey

Reason Changed Locations



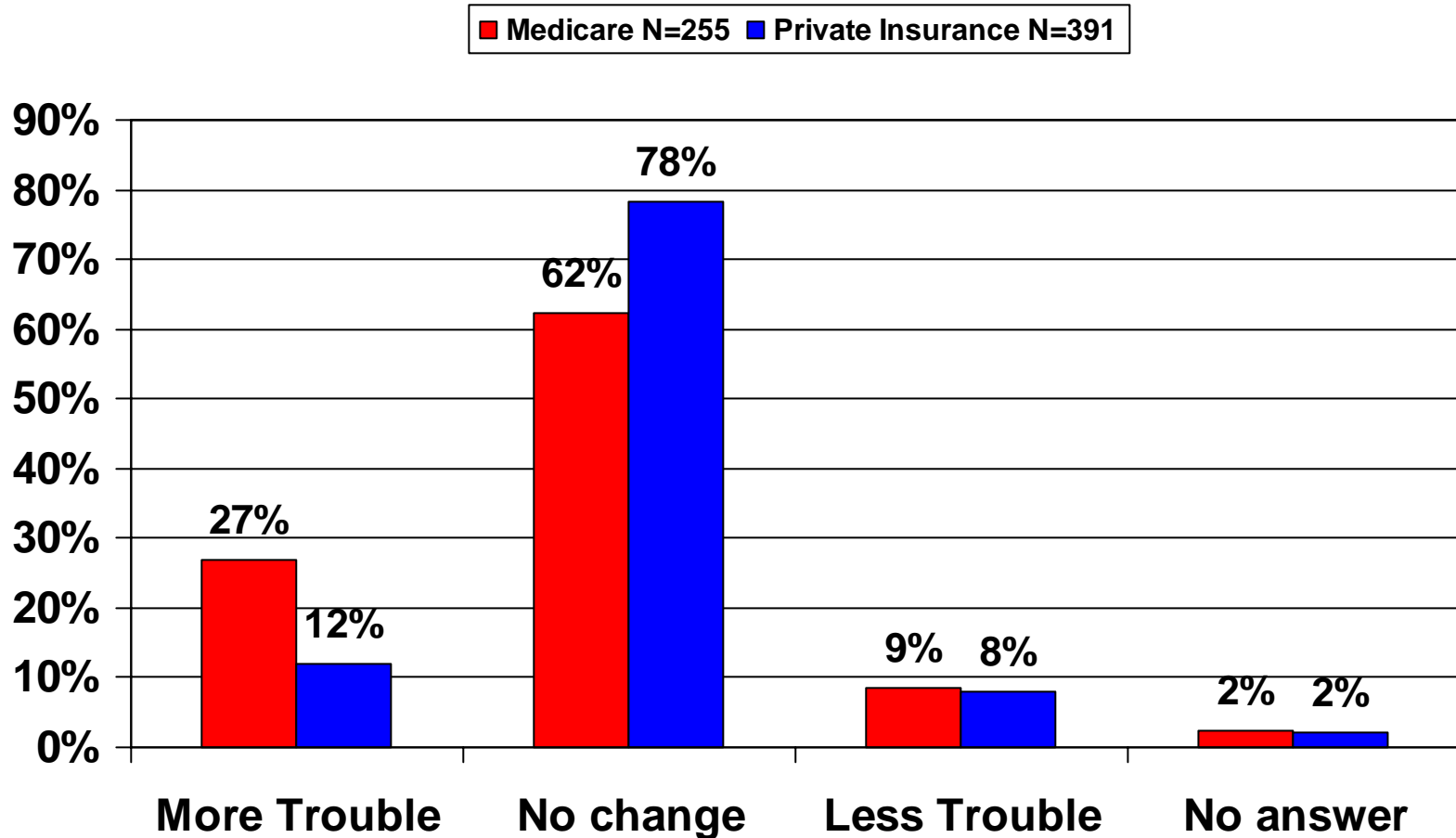
Q15. What was your understanding of the reason for the change? Base: Currently Using IVIG and now getting IVIG at different location than December 2004

Site of Infusion: December 2004 and Present



Q11. Immediately prior to 2005, where the IVIG treatments usually given? Q13. Where is the patient getting treatments now? Base: Currently using IVIG Medicare N=255 Private Insurance N=391

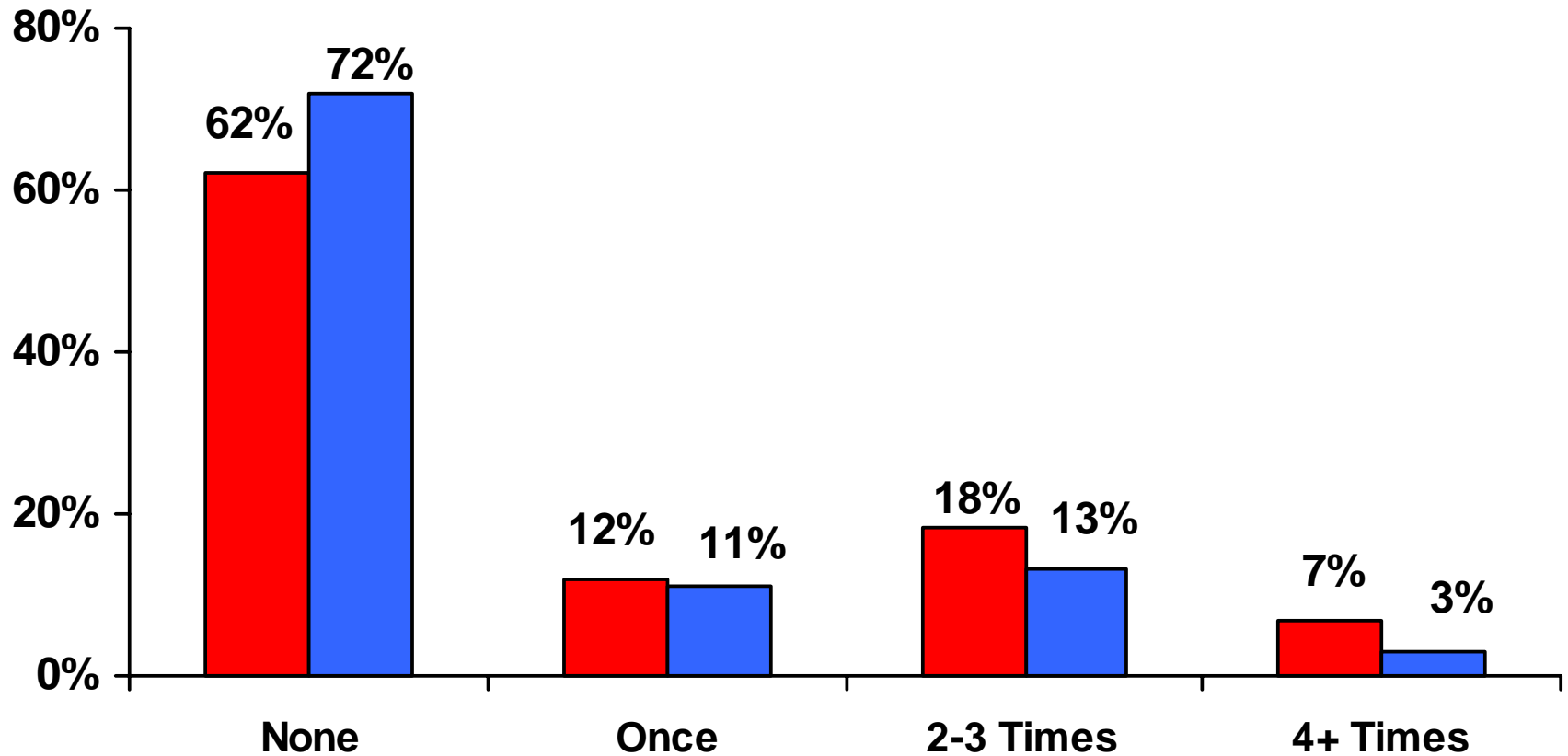
Trouble Getting IVIG Since January 2005



Q30. Overall, has the patient had less trouble or more trouble getting IVIG treatments since the beginning of 2005, or has this not changed? Base: Currently using IVIG

Number of Times Treatment Postponed Since January 2005

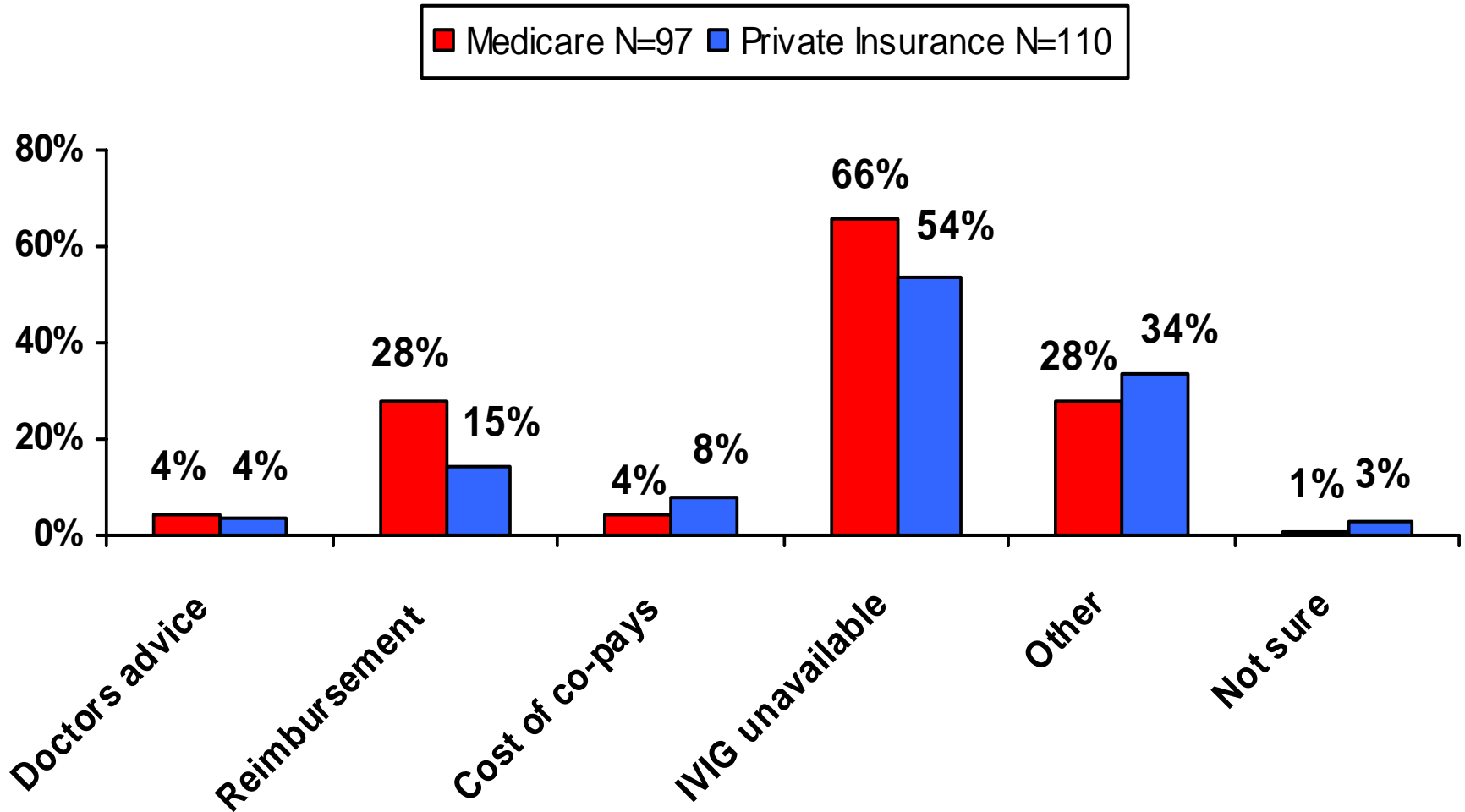
■ Medicare N=255 ■ Private Insurance N=391



Q16. Since the beginning of 2005, how many times have your MIG treatments been postponed?

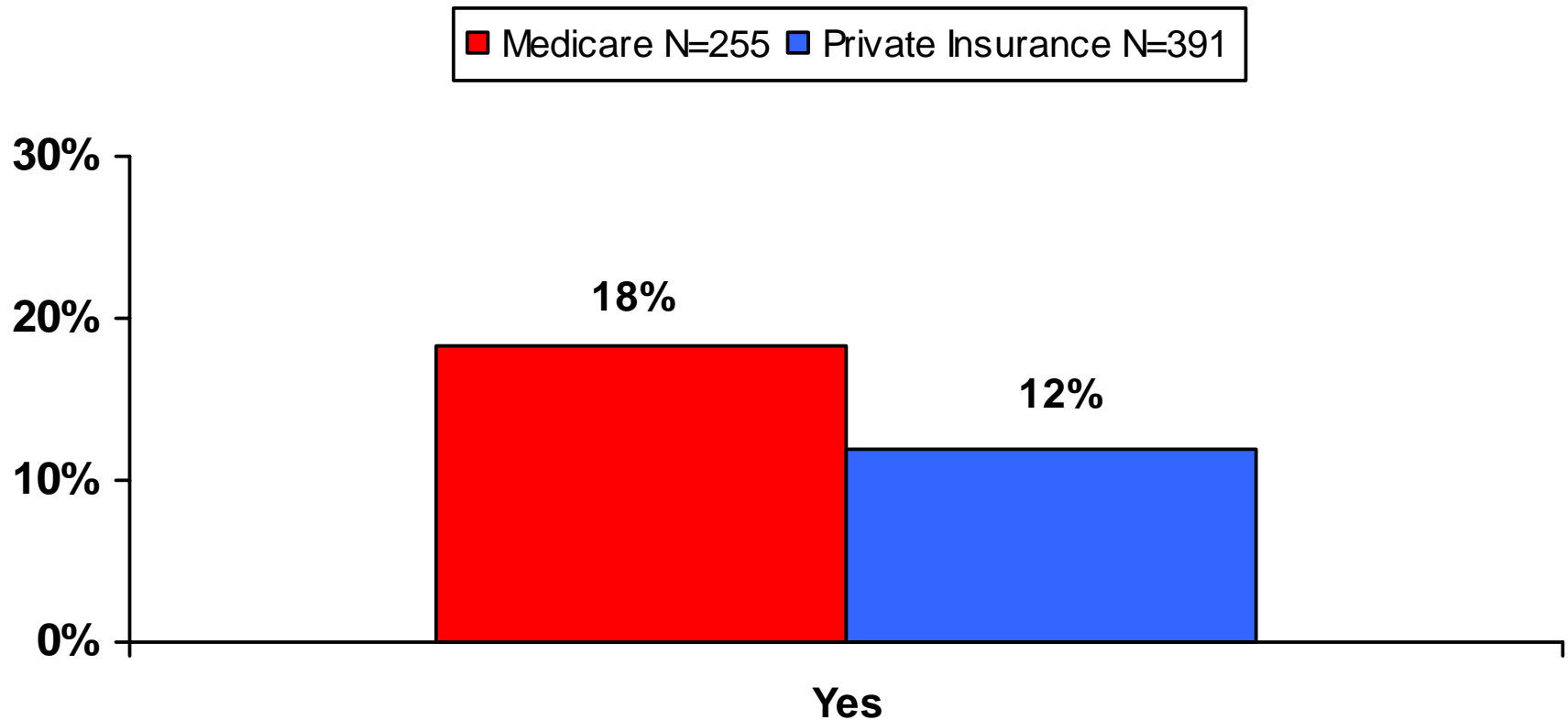
Base: Current MIG users whose treatments have been postponed since beginning of 2005 11

Reasons for Postponement of Treatment



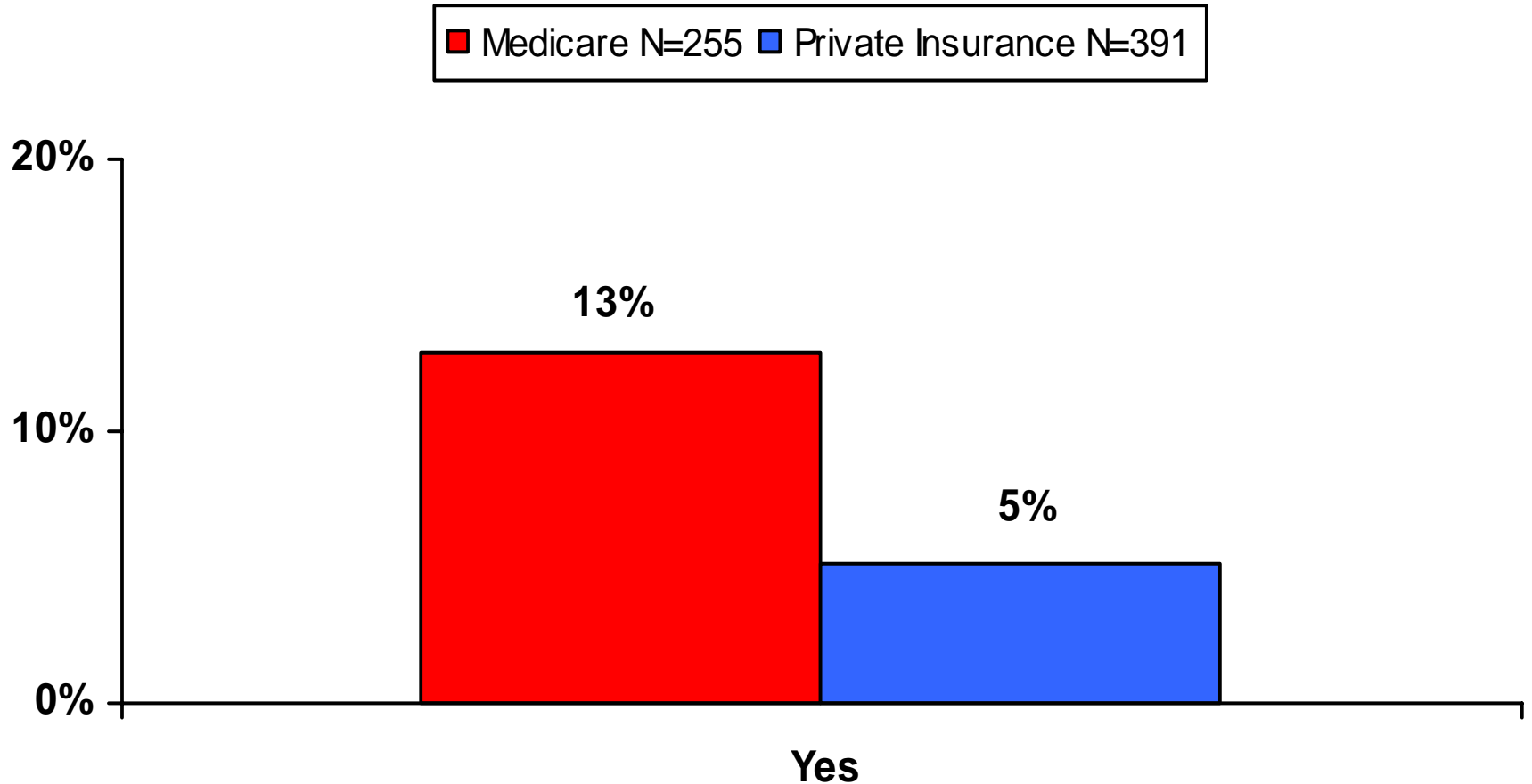
Q17. Why was treatment postponed? Base: Current IVIG users whose treatment was postponed since the beginning of 2005.

Patients Experiencing Increased Interval Between Treatments Since January 2005



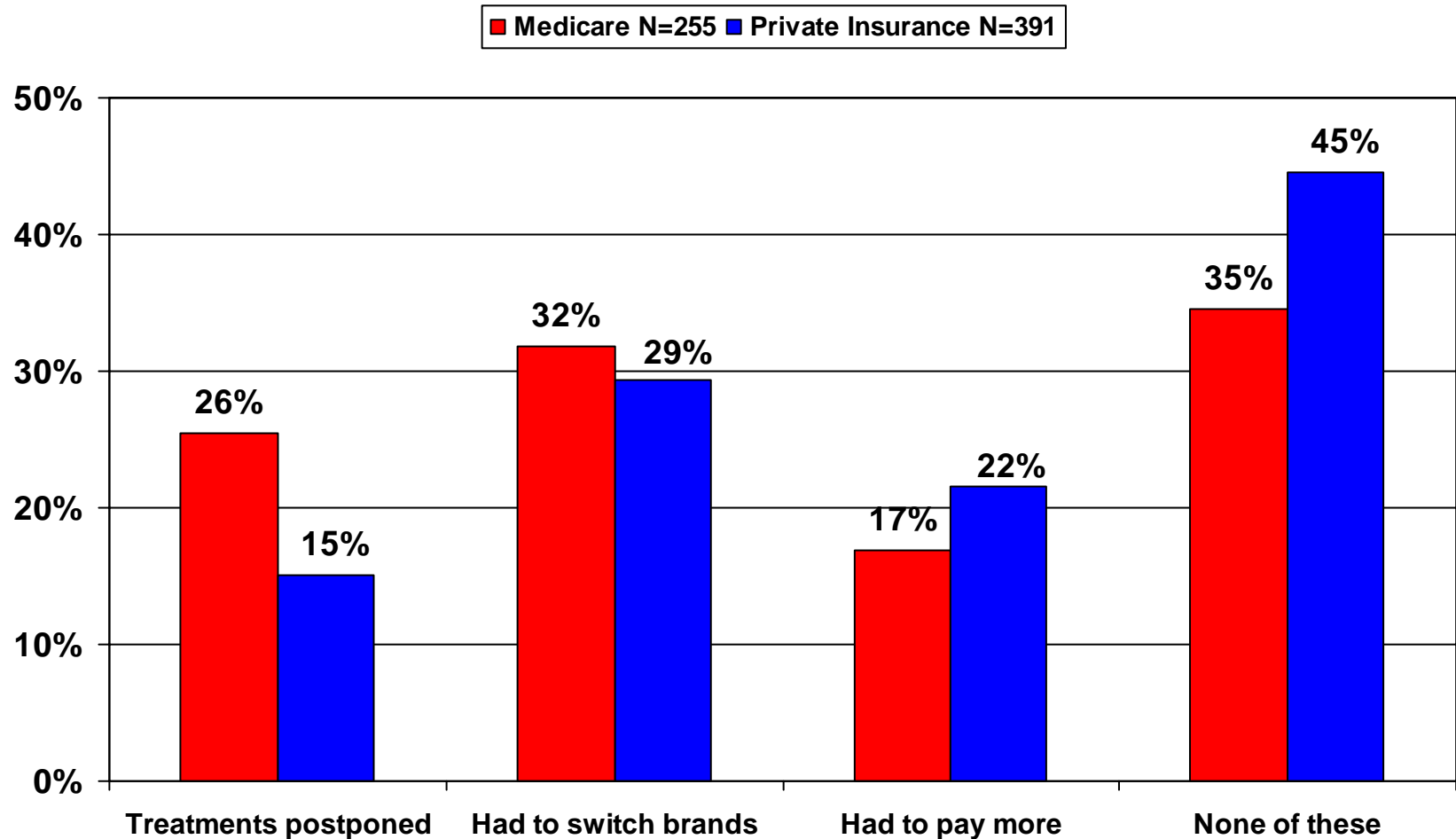
Q18. Has the time interval between IVIG infusions increased since the beginning of 2005
Base Current IVIG Users

Reduction in Dosage Since January 2005



Q21. Has the number of grams the patient receives been REDUCED since the beginning of 2005 for any reason? Base Current MIG Users

Treatment Problems Since January 2005

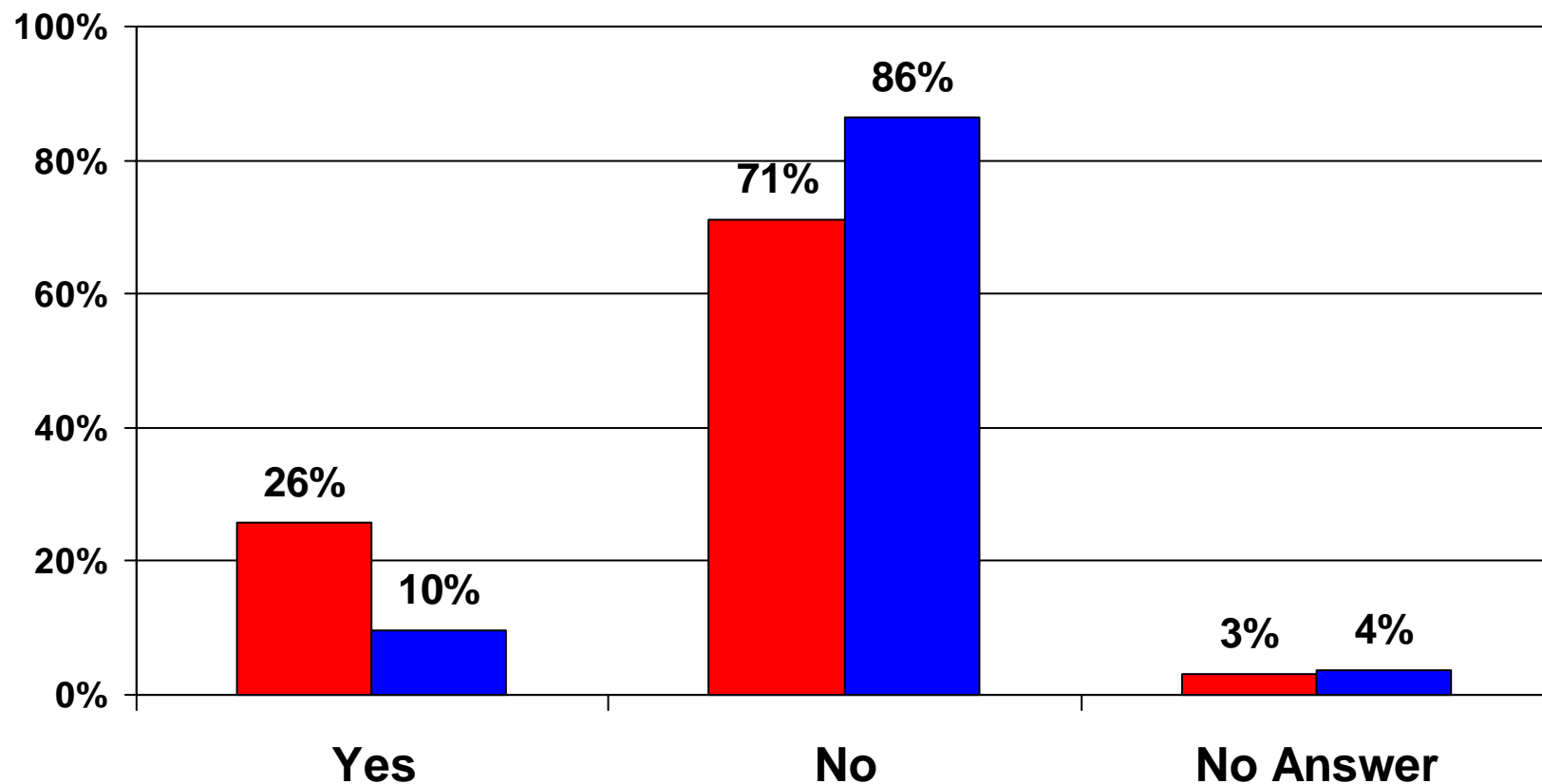


Q31. Which of the following problems, if any, has the patient experienced since the beginning of 2005?

Base: Currently using IVIG

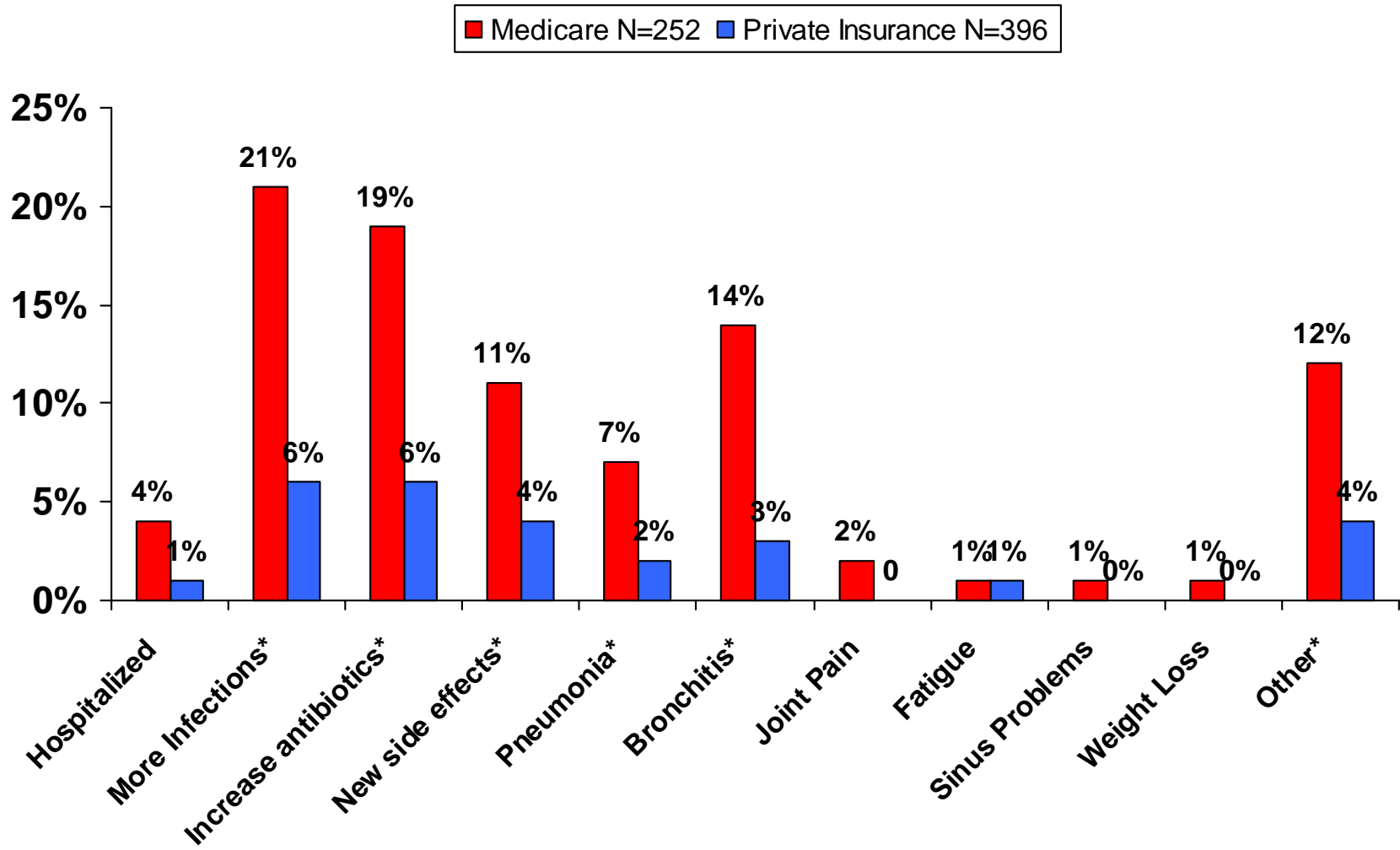
Negative Health Effects Related to Getting or Paying for IVIG Since January 2005

■ Medicare N=255 ■ Private Insurance N=391



Q32. Since the beginning of 2005 has the patient experienced any negative health effects as a result of problems in getting or paying for IVIG? Base: Currently using IVIG

Types of Negative Health Effects



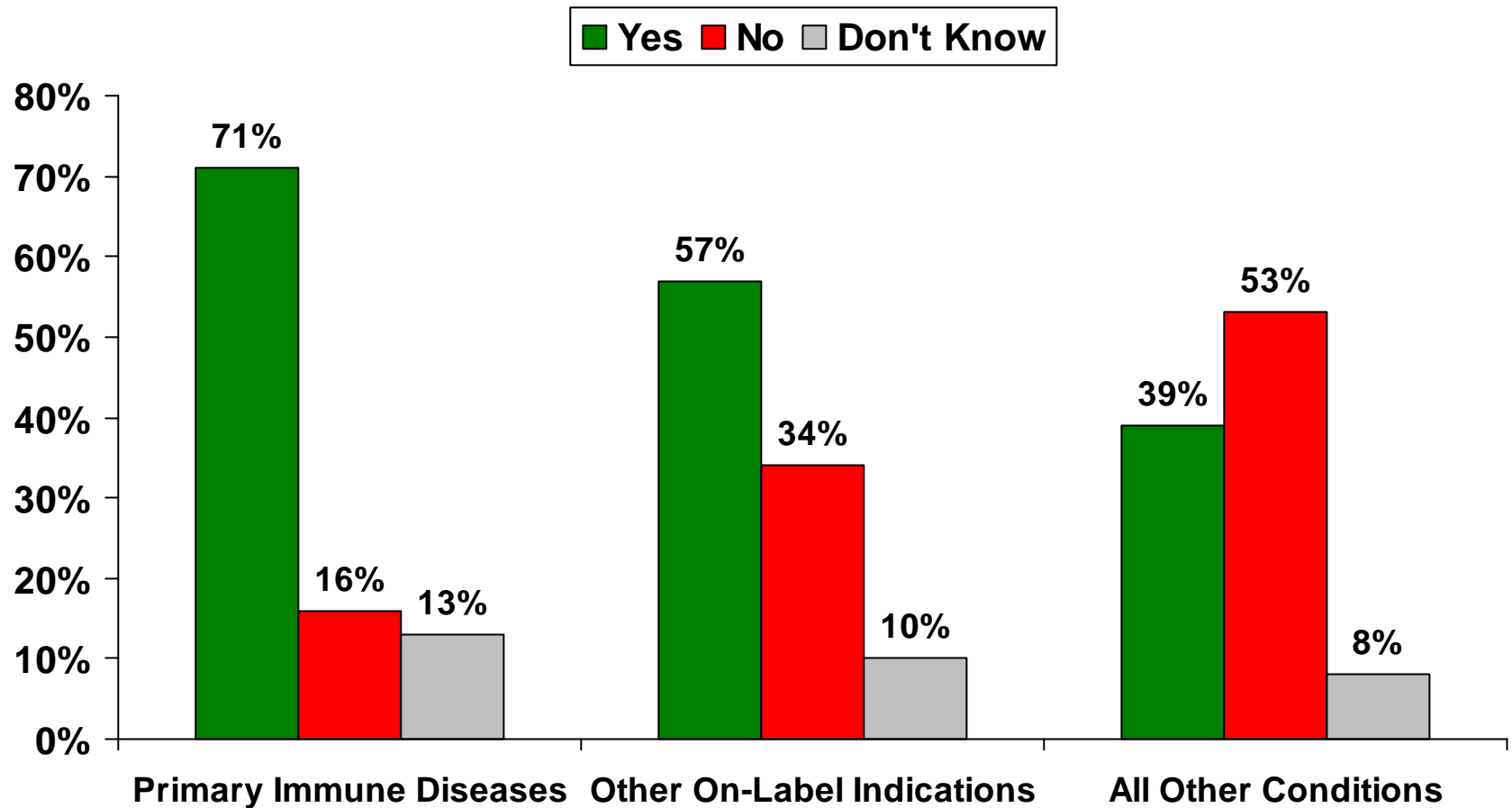
Q33. What kinds of health problems, if any, has the patient experienced since the beginning of 2005 as a result of problems in getting IVIG? Base: Current IVIG users



Immune Deficiency Foundation Survey of Hospital Pharmacists

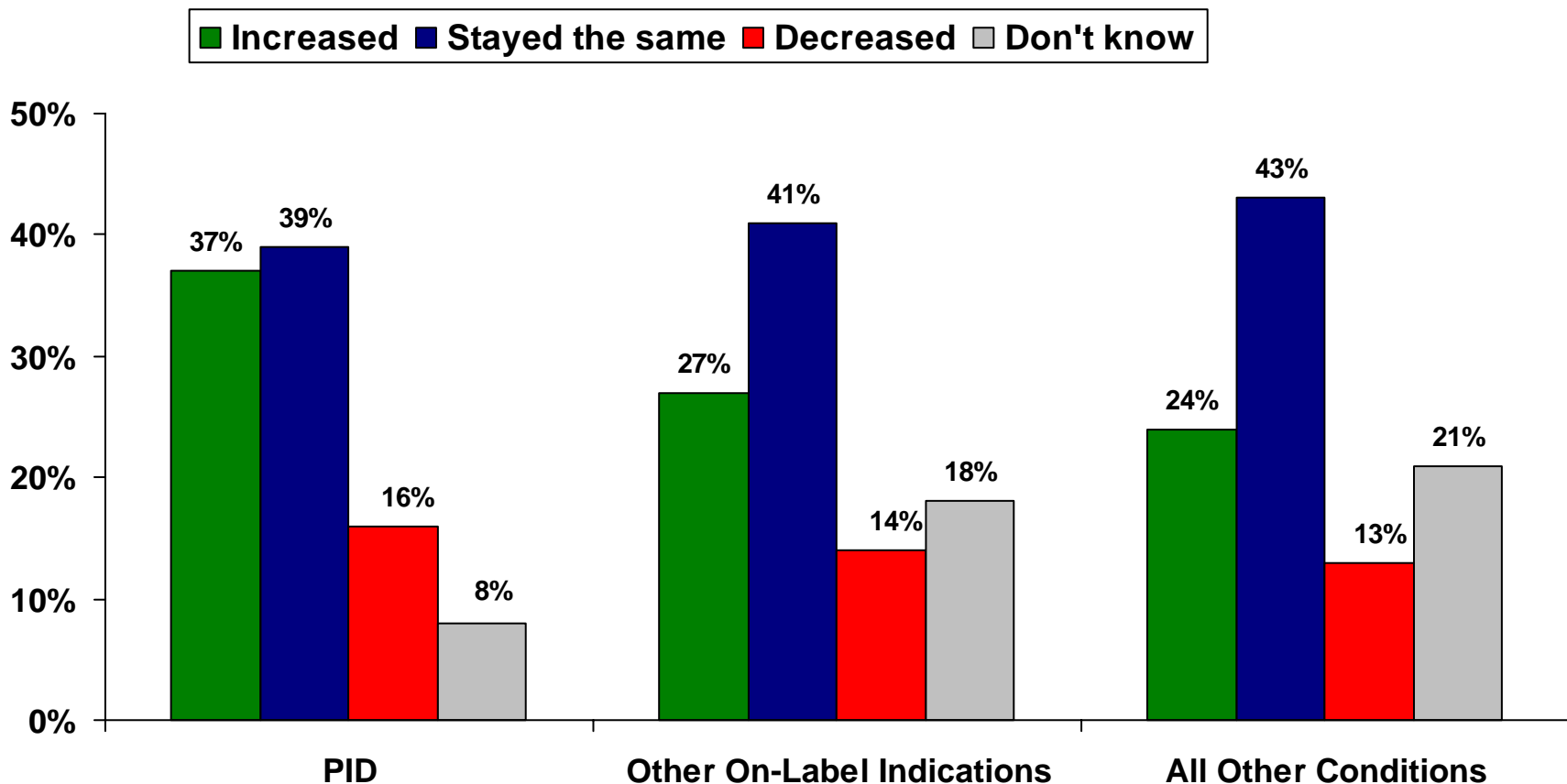
Telephone Survey of Hospital Pharmacists,
310 completed interviews
Conducted between Sept. 22-Oct. 30, 2006

Current Hospital Uses of IVIG



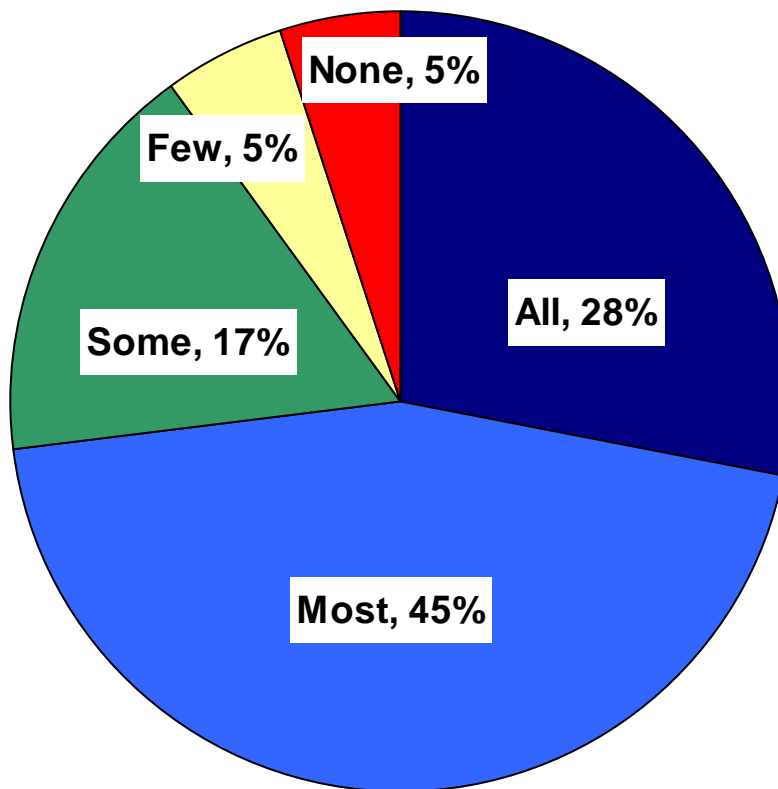
Q14/Q17/Q20: Is IVIG used in your hospital to treat [TYPE OF DISORDER]? Base: All hospitals (N=310)
(In hospitals treating outpatients, the question referred to outpatient use.)

Change in Amount of IVIG Dispensed by Type of Condition



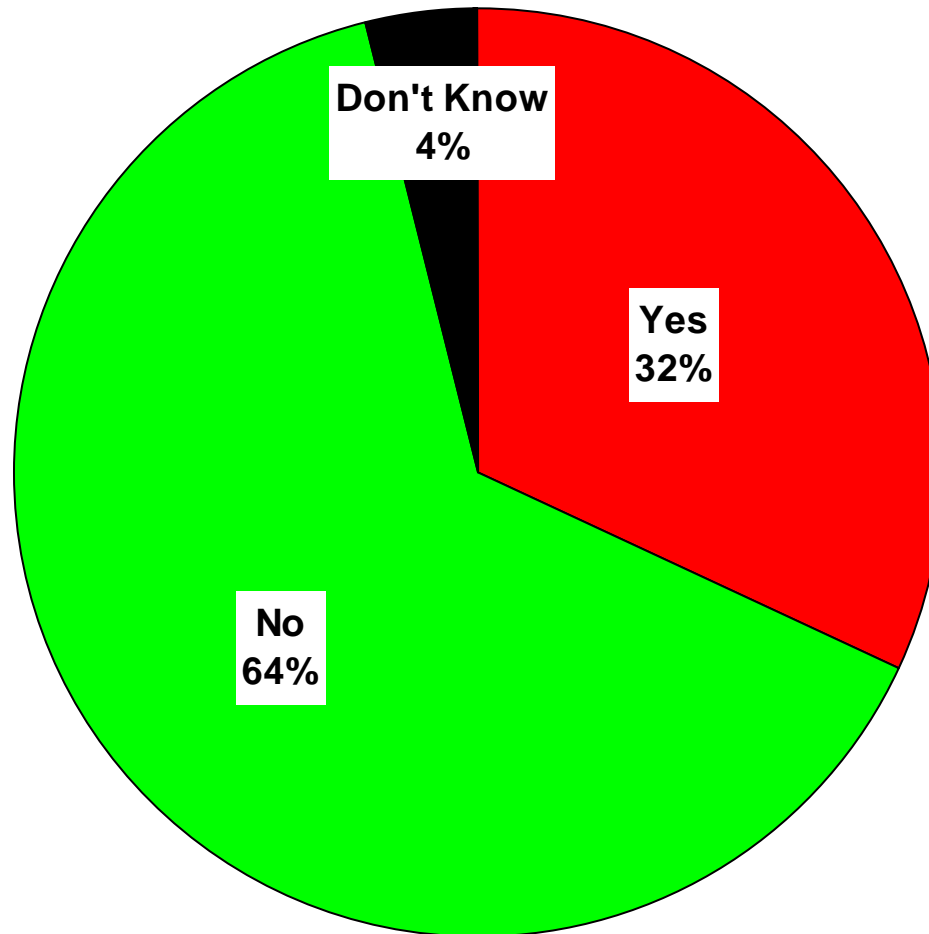
Q23a-c: Compared to 2004 - that is, to about two years ago – would you say that the amount of IVIG dispensed to treat [CONDITION] has increased, stayed the same, or decreased? Base: All hospitals (n=310)

Recent Needs Met by GPO Allocation



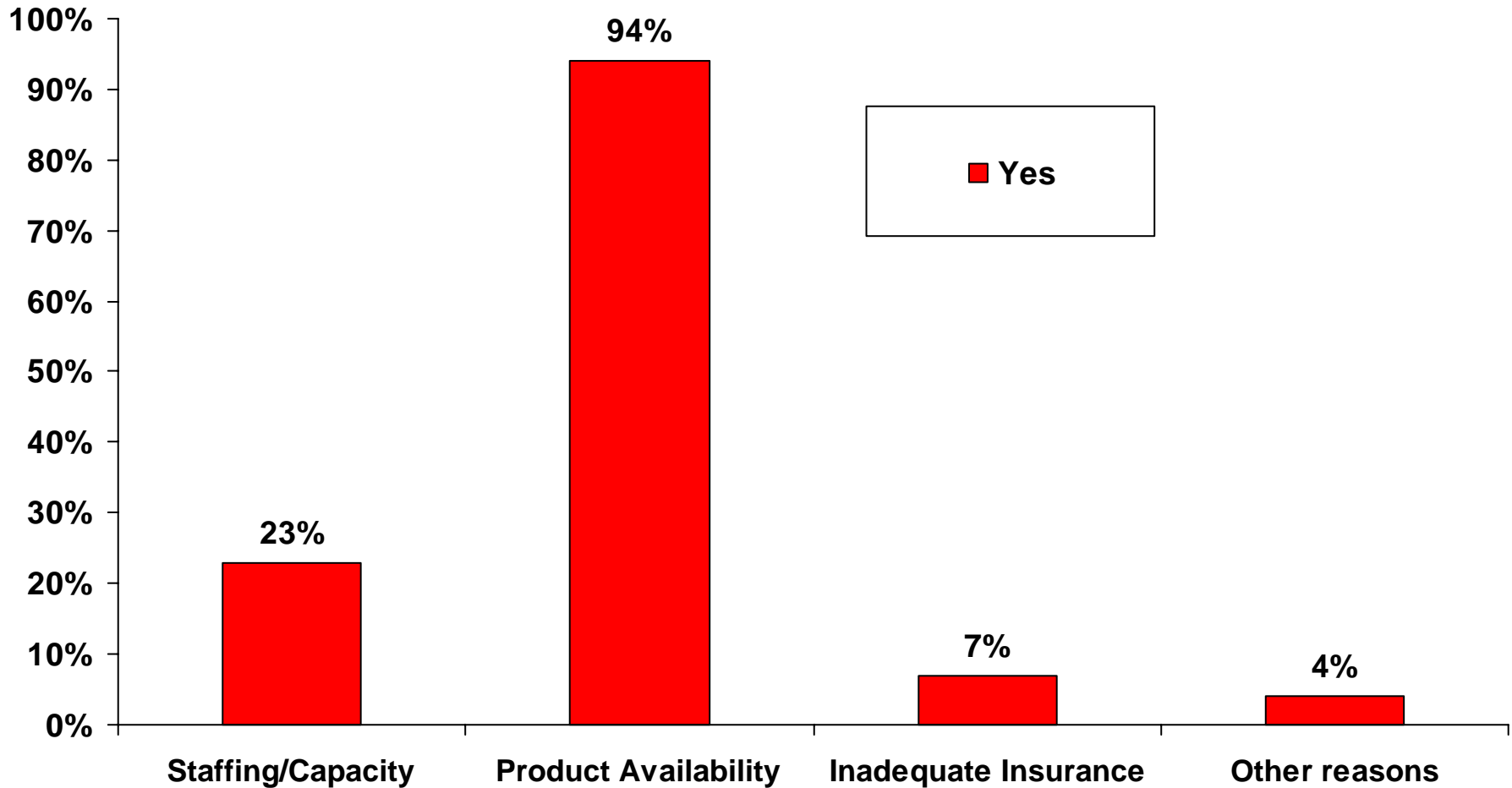
Q30: Does your allocation meet all, most, some, few, or none of your recent needs?
Base: Hospitals with GPO contract (N=241)

Turned Away Patients Needing IVIG



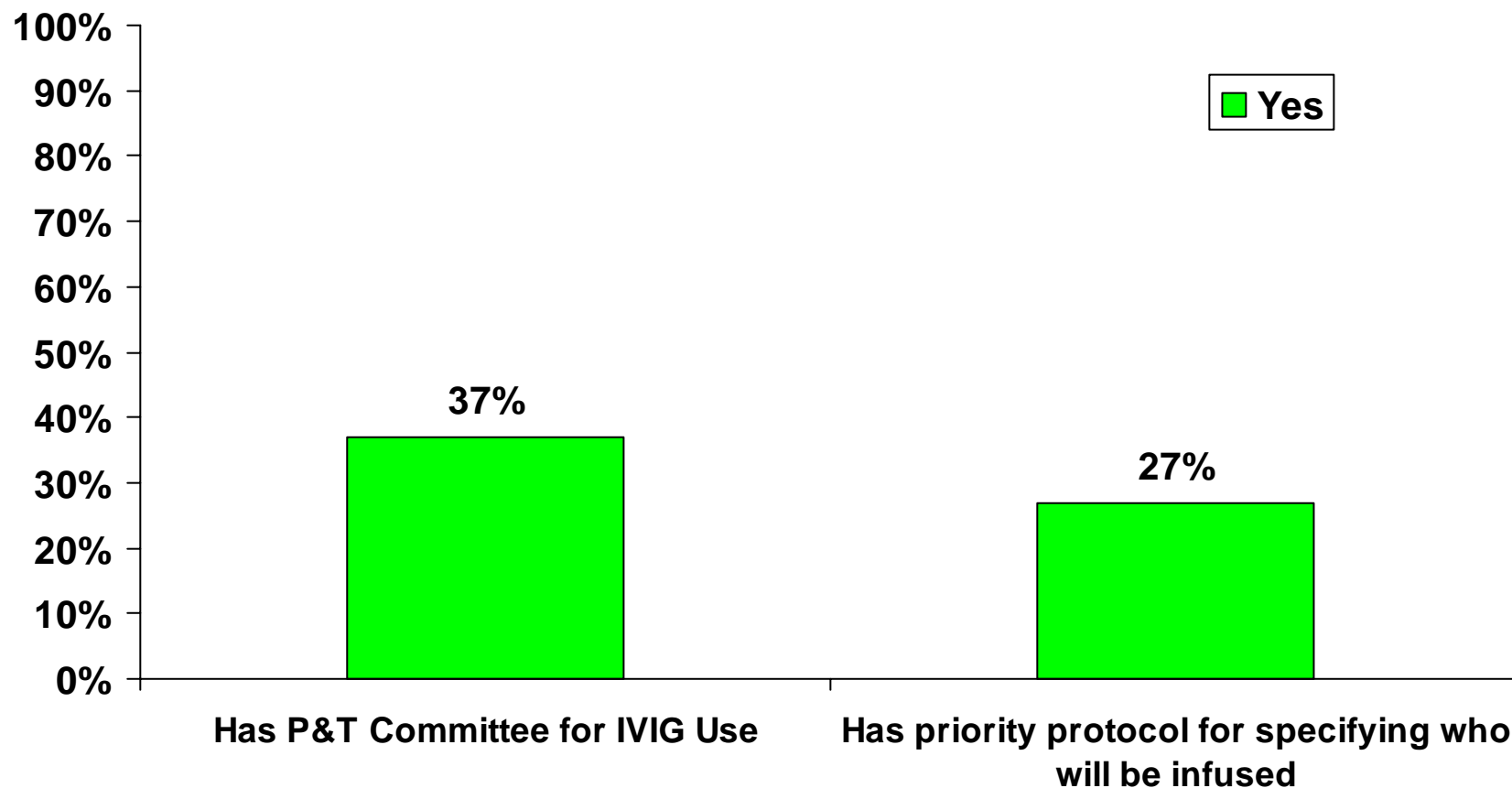
Q50: Since the beginning of 2006, has your hospital had to turn away patients needing IVIG treatment? Base: All Hospitals (N=310)

Reason(s) for Turning Away Patients



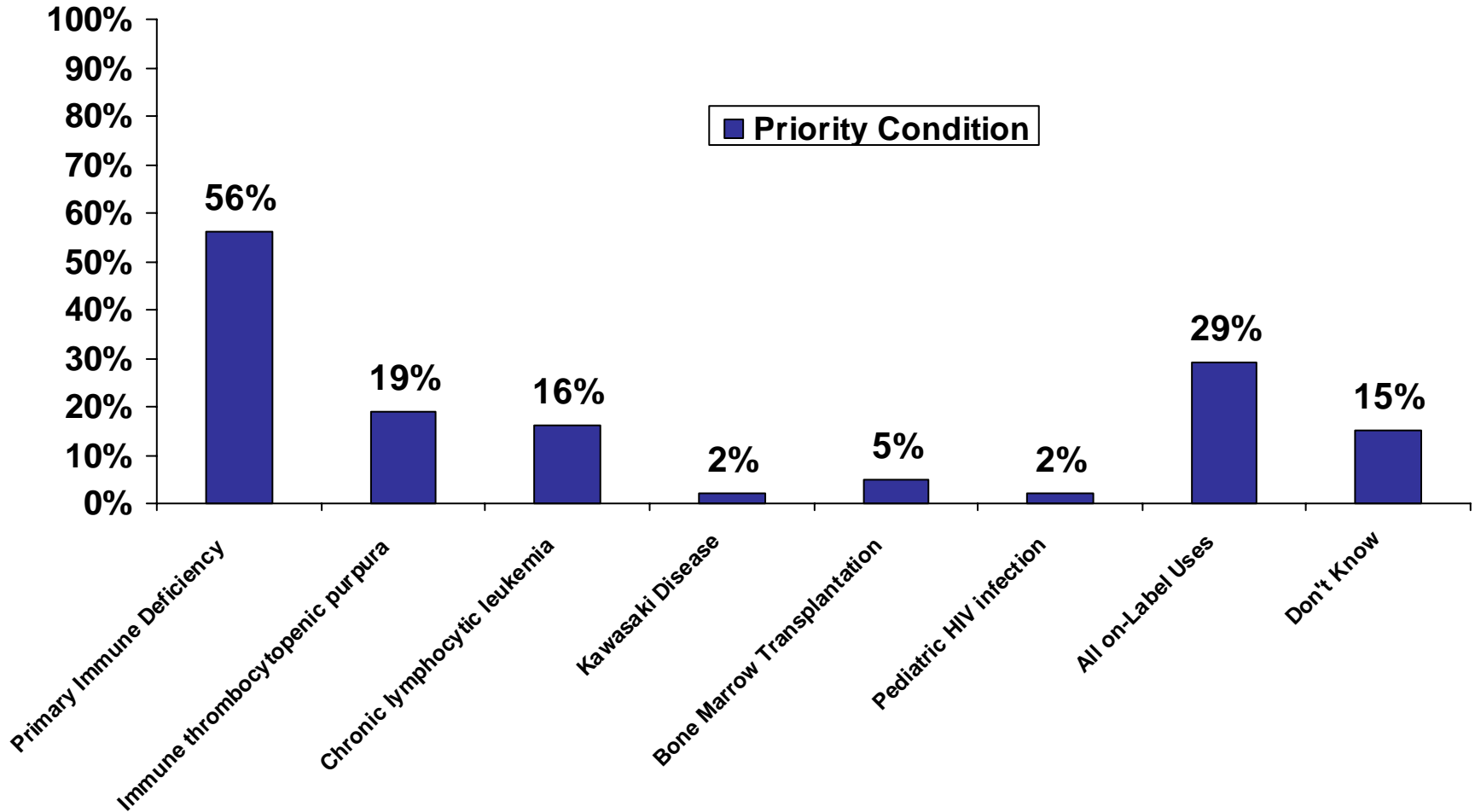
Q51a-d: Did you have to turn away any patients because of...
Base: Turned patients away needing IVIG since beginning of 2006 (n=98)
source: IDF 2006 Hospital Pharmacist Survey

Hospitals with Patient and Treatment Committees, Priority Protocols



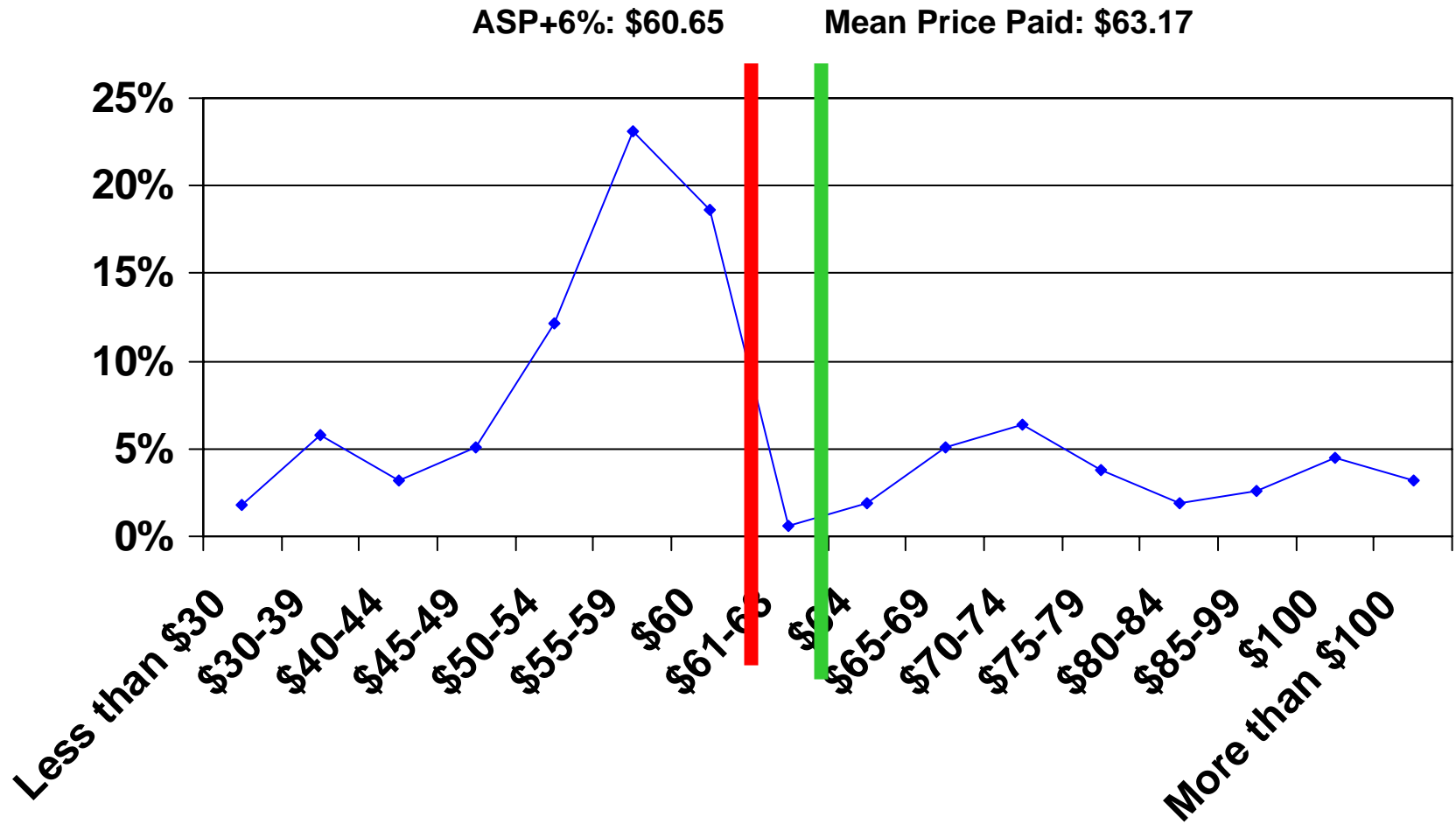
Q24: Does your hospital have a P and T (Patient and Treatment) Committee that determines which patients will be treated with IVIG? Q25: Does your hospital have a priority protocol specifying which patients will be infused? Base: All hospitals (n=310)

Priority Conditions for IVIG Infusions



Q27: Which indications (conditions) have priority? (N=62 hospitals basing their priority on indications/conditions)
(Percentages can sum to more than 100% because of multiple responses.)

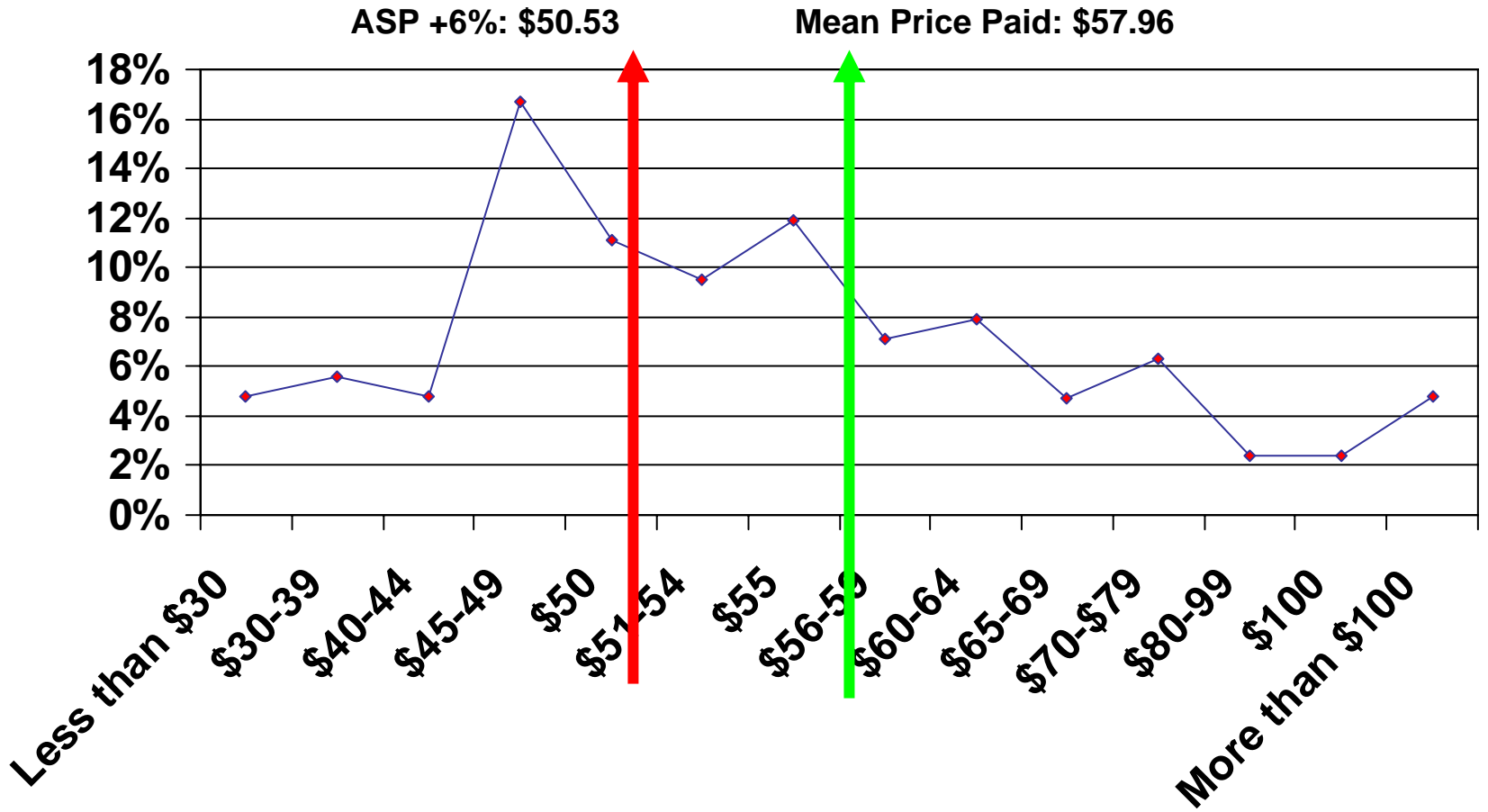
Average Price Paid for Liquid IVIG



Q45. What is the average price you pay for 1 gram of liquid IVIG?

Base: Hospitals who could answer N=156

Average Price Paid for Lyophilized IVIG



Q46. What is the average price you pay for 1 gram of lyophilized IVIG?

Base: Hospitals who could answer N=126

Cost Findings: 2006 IDF Pharmacist Survey

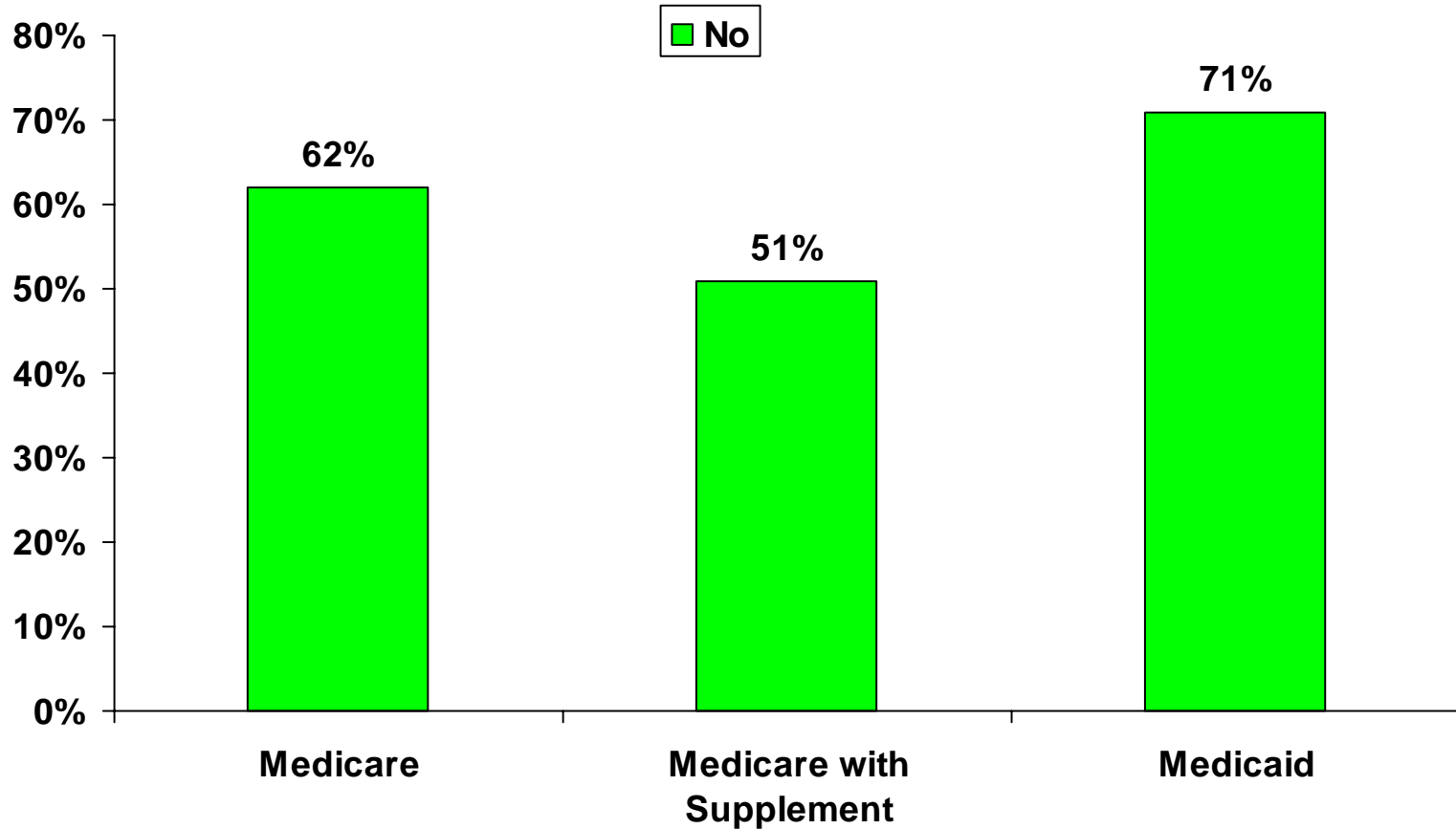
Liquid

Average price is **4% higher** than the reimbursement. **3 out of 10** hospitals pay more for product than they are reimbursed for product.

Lyophilized

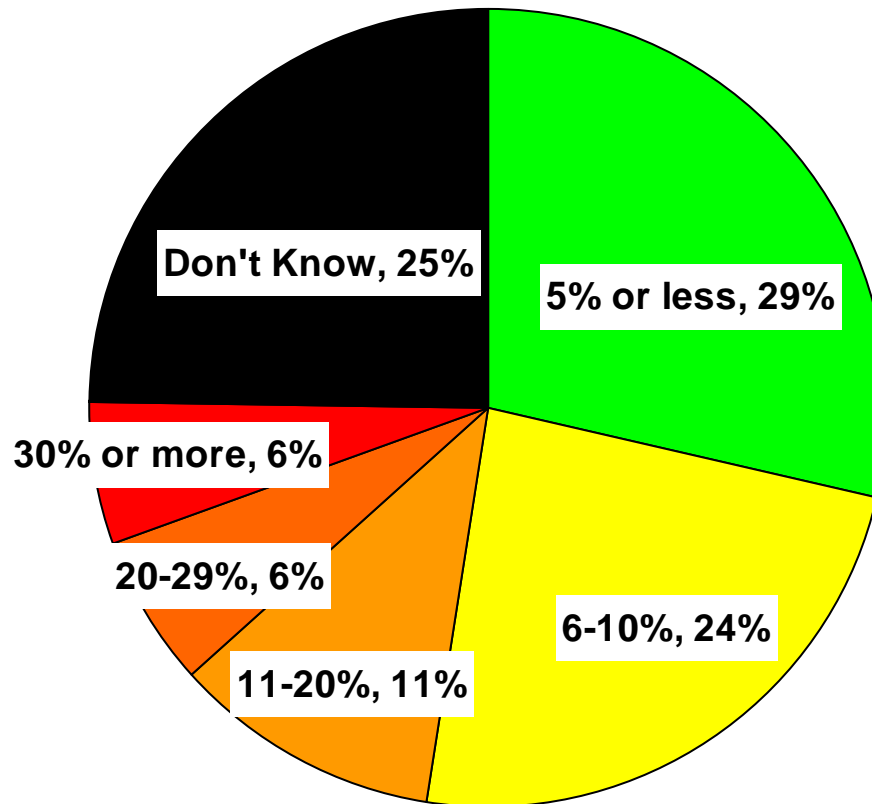
Average price is **15% higher** than reimbursement. **57%** pay more than they are reimbursed for product.

Adequacy of Reimbursement for IVIG by Type of Government Coverage



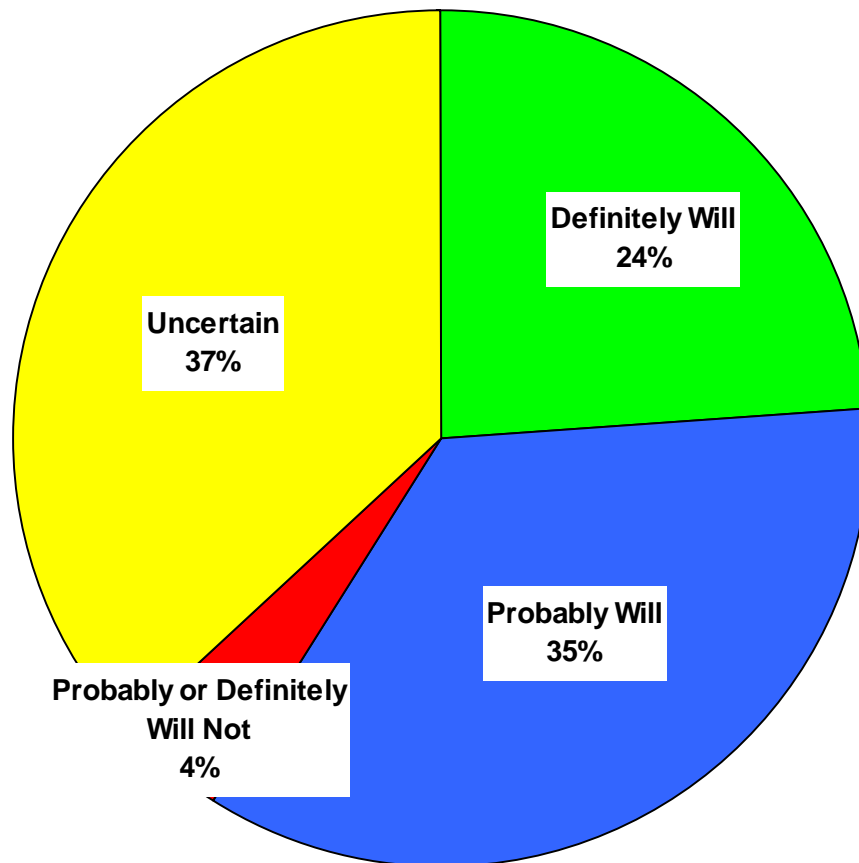
Q42a-c: Are you adequately reimbursed to purchase IVIG for patients who carry the following insurance coverage? Base: All hospitals (“Don’t Know” excluded from base)

Amount of IVIG Costs Not Covered When Medicare Reimbursement is “Adequate”



Q44: How much of your total cost, on average, to purchase IVIG is not covered by current reimbursement rates for Medicare? Base: Medicare adequate (n=72)

Expectation About Treating Patients in the Future Who Require 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)



IDF/American Academy of Asthma, Allergy & Immunology Survey of Physician Access to and Reimbursement for IVIG:

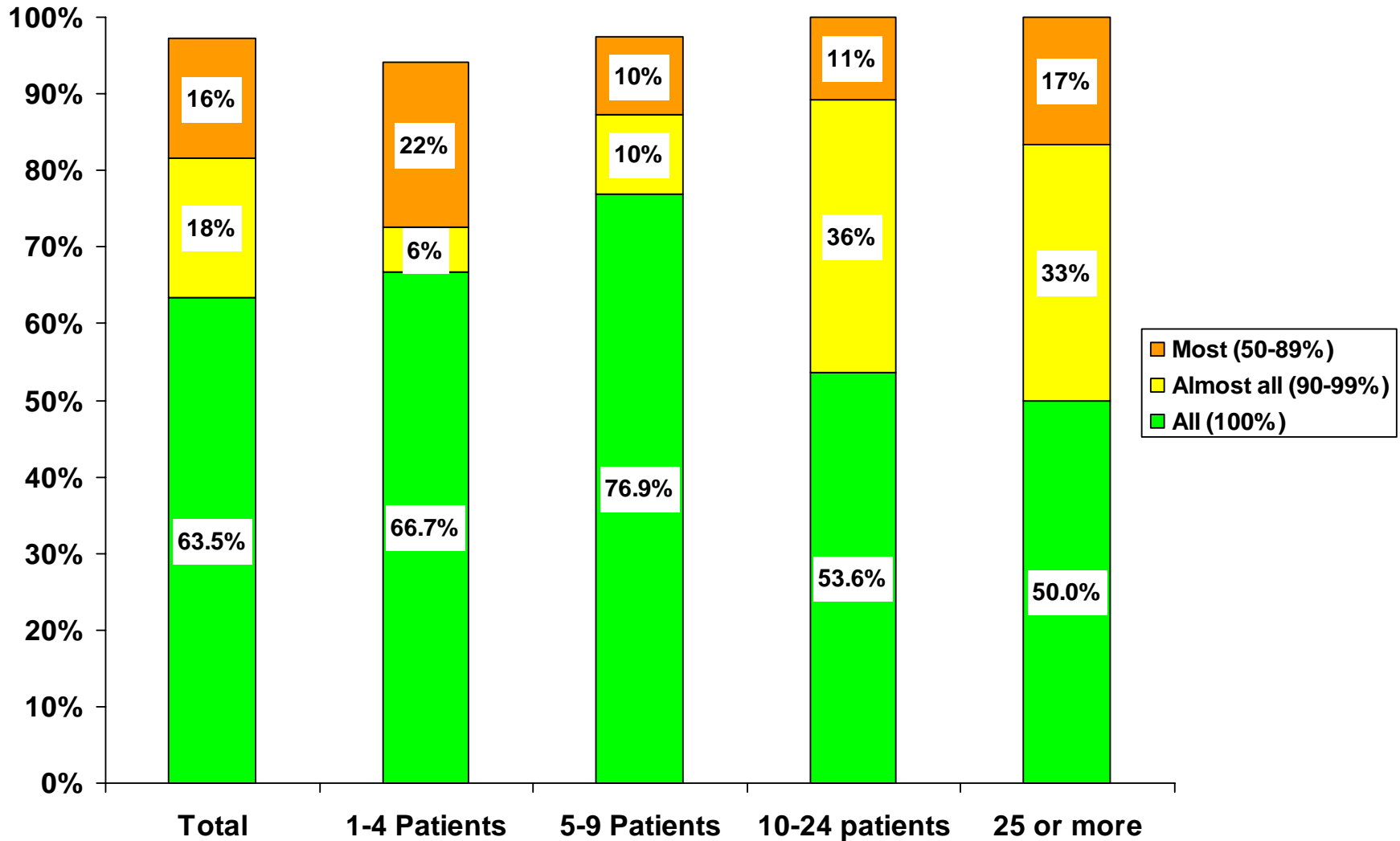
A 2006 Survey of the AAAAI membership

Web-based Survey

Conducted October 13, 2006 to November 17, 2006

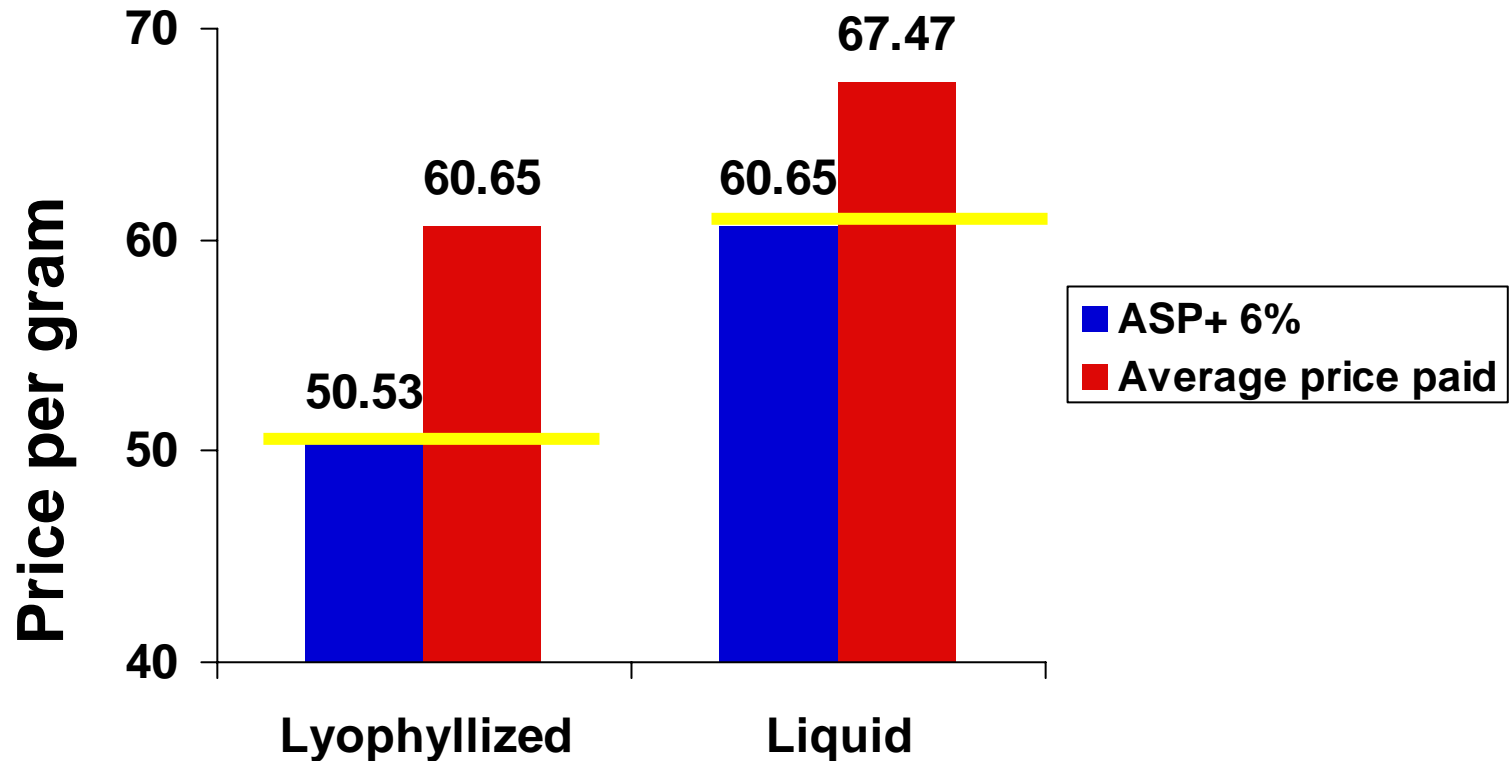
230 responses

Able to Obtain Amount of IVIG to Adequately Treat PID Patients



Q10. Thinking about the last 12 months, how many of your PID patients could you adequately treat with the amount of IVIG you were able to obtain – all, almost all, most, some or none? Base: Doctors with PID IVIG patients N=148 (excludes 4 no answers)

Price of IVIG



Median - 55.00-lyophilized, 60-liquid

Avg grams provided per physician is 568g/mo

Loss with ASP+6 for average physician is >1000.00/mo

Cost Findings: 2006 IDF Physician Survey

Liquid

Avg. price is **11% higher** than reimbursement.
44% of physicians pay more for the product than they are reimbursed.

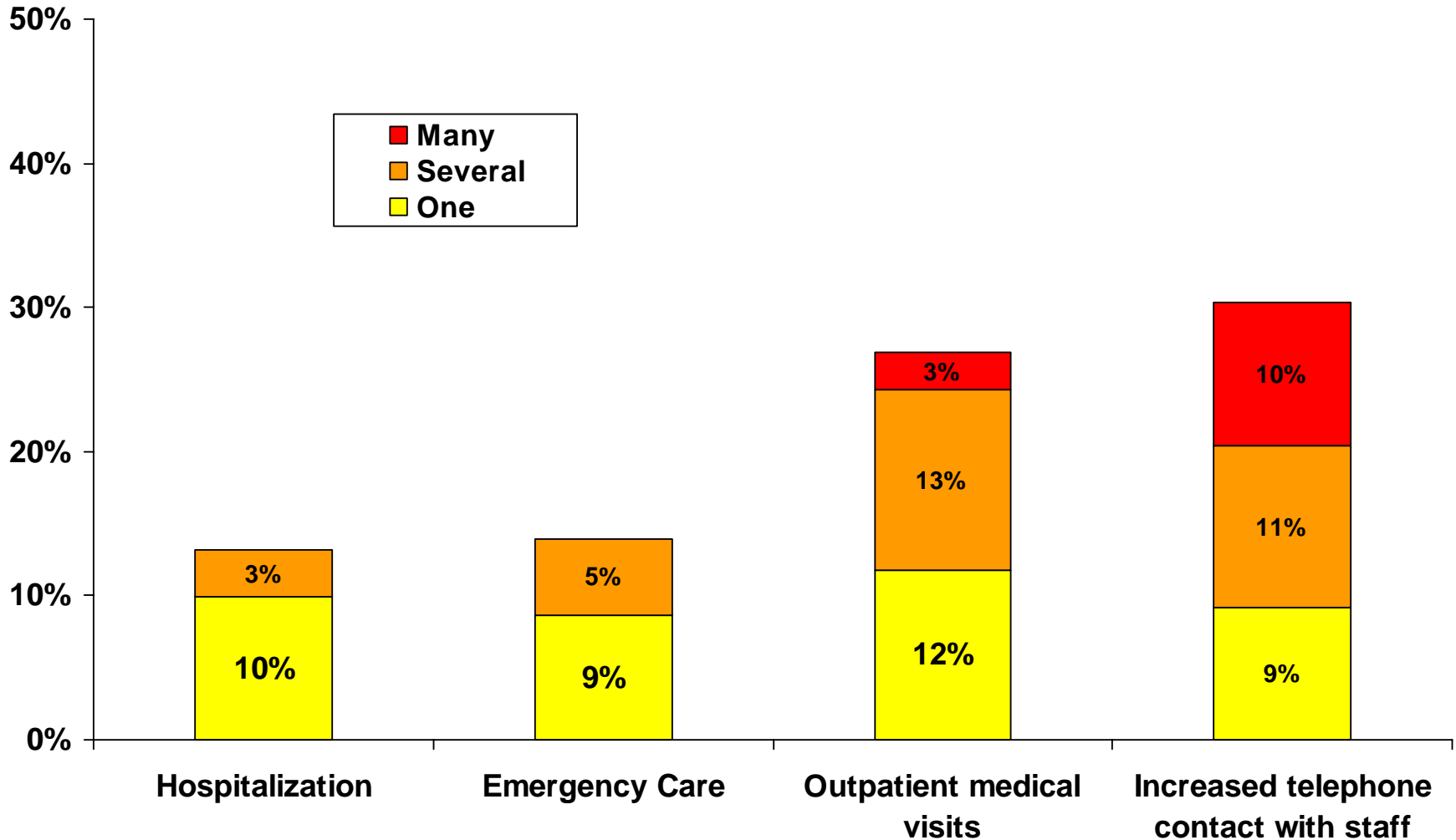
Lyophilized

Average price is **19% higher** than reimbursement. **81%** of physicians pay more than they are reimbursed.

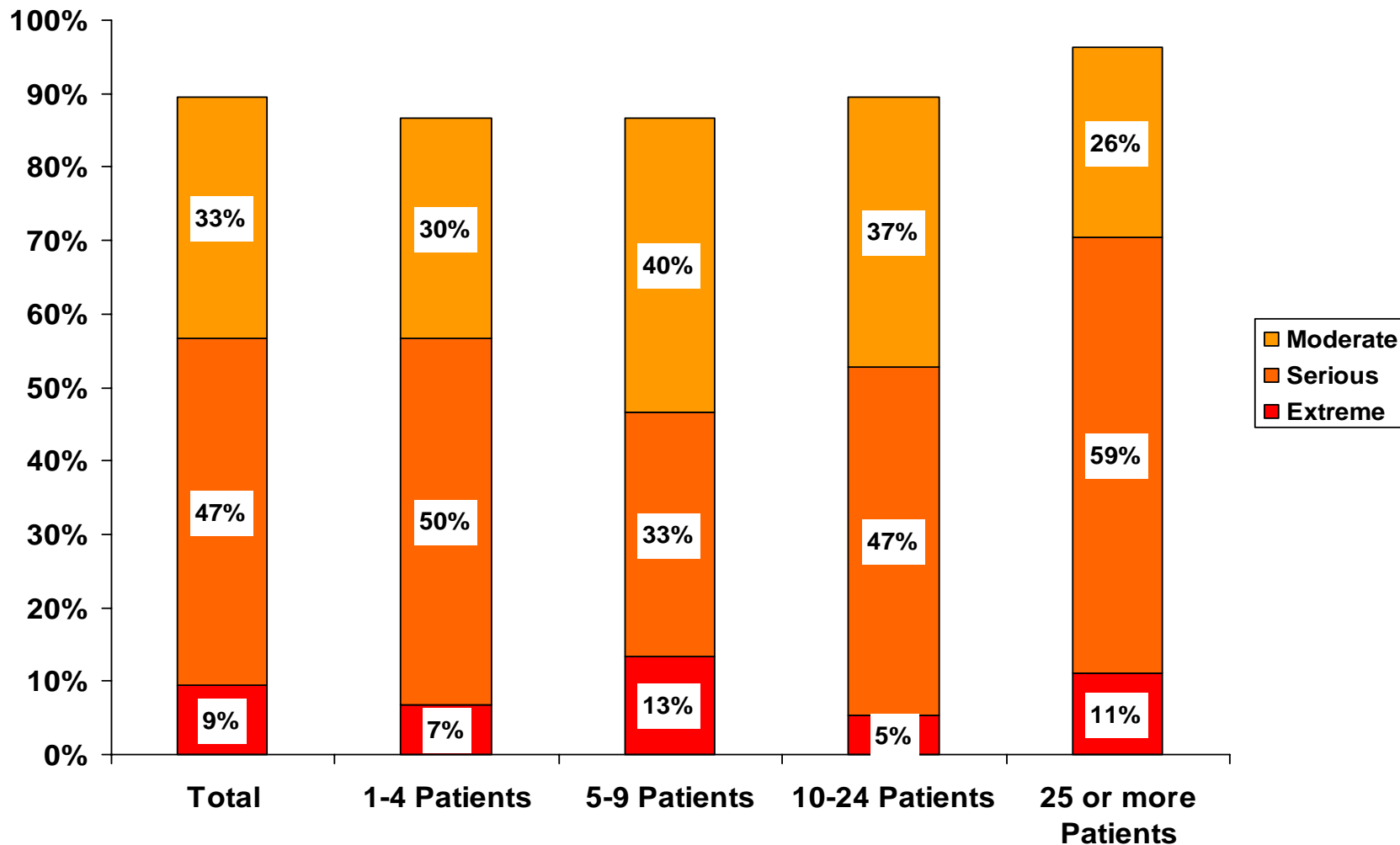
Effect of Medicare Reimbursement since 2005

- 51% have had patients change site of care because of reimbursement
- 36% of physicians have had to reduce frequency of infusion for patients
- 26% of physicians have had to reduce dosage for patients
- 36% have had patients who have experienced health problems because of reimbursement

Effect of Medicare Reimbursement on PID patients receiving IVIG (2005)

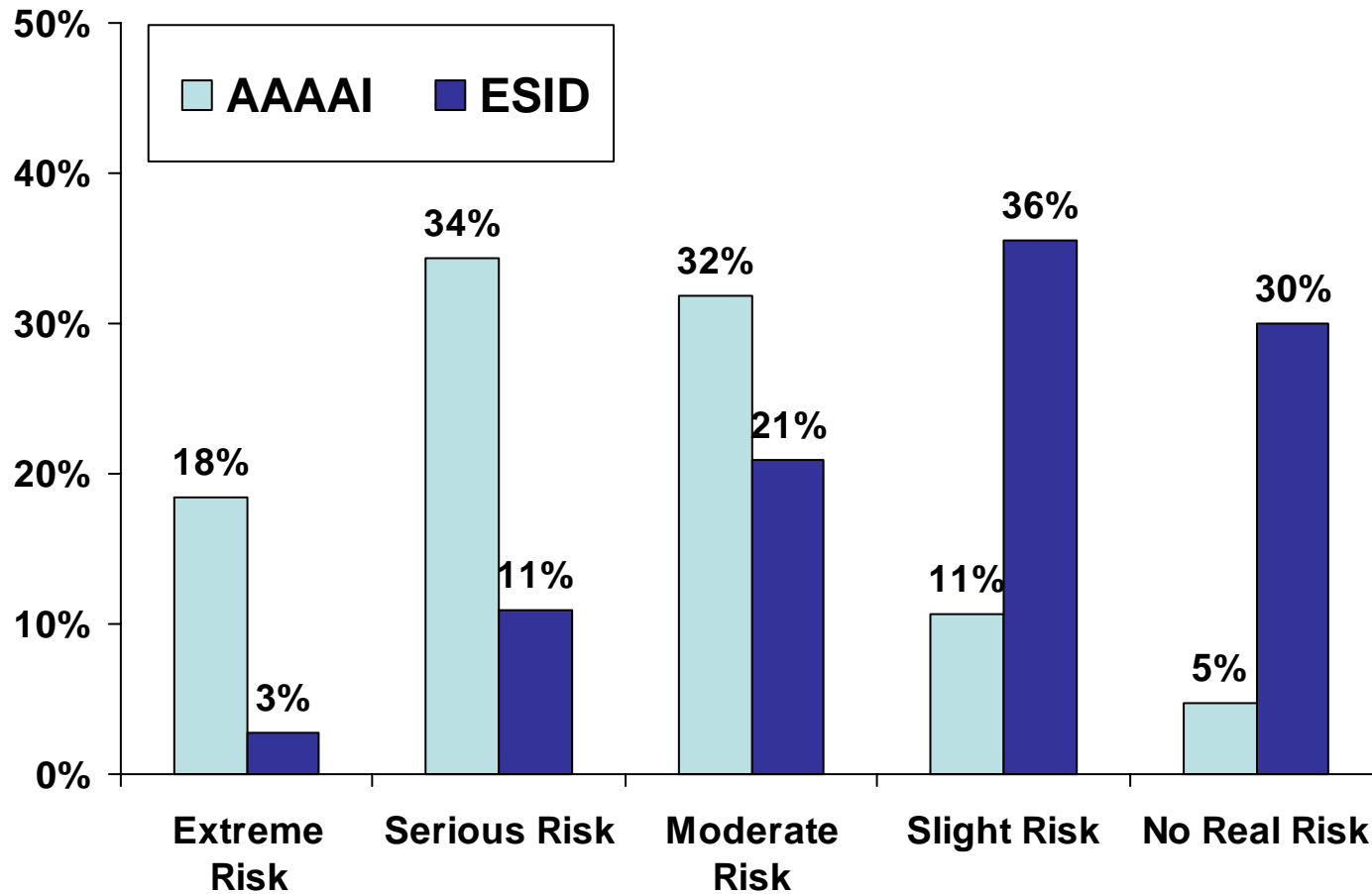


How Serious a Risk to Patients' Health are Current Reimbursement Standards



Q43. In your opinion, how much risk, if any, do current reimbursement standards for IVIG pose to the health of PID patients – extreme, serious, moderate, slight or no real risk? Base: Doctors with PID IVIG patients answering the question N=106

Reimbursement risk AAAAI vs ESID ...A uniquely American problem?



Thank you!