Intravenous Immune Globulin Treatment For Primary Immune Deficiency Diseases

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Advisory Committee on Blood Safety Availability
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IMMUNE DEFICIENCY FOUNDATION
The National Organization Dedicated to Research, Education and Advocacy for the Primary Immune Deficiency Diseases

Immune Deficiency Foundation

- Founded 1980
- Medical Advisory Committee
- Professional Staff
- Full-time Medical Director

- Mission: To improve the diagnosis and treatment of individuals affected by primary immune deficiency diseases through research, education and advocacy

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IDF Long Term Goals

- Improve access to state-of-the-art medical care
- Enhance early diagnosis
- Provide innovative life management programs
- Expand scientific and medical research
- Increase the strength and reach of IDF

Overview of Primary Immune Deficiency Diseases

- The World Health Organization recognizes over 140 primary immune deficiency diseases (PIDD), affecting approximately 50,000 people in the United States.
- The diseases are the result of genetic defects that involve the immune system and its responses.
- The exact genetic defect for each of the diseases is known for only a minority of the conditions.
- Primary immune deficiency diseases are characterized by an increased susceptibility to recurrent, poorly responsive, severe and unusual infections.

Overview of Primary Immune Deficiency Diseases (continued)

- Affected individuals have abnormalities of cells or proteins of the immune system.
- The cells include B-cells, cells producing antibodies; T-cells, cells that coordinate the immune system's responses; and leukocytes (white blood cells), cells that fight infections.
- Some of the proteins are immunoglobulins (gamma globulins), complement proteins, and blocking agents such as C1 Esterase Inhibitor.

List of the Most Common Primary Immune Deficiency Diseases

- X-Linked Agammaglobulinemia (Bruton's)
- Common Variable Immunodeficiency (CVID)
- Symptomatic IgA Deficiency
- IgG Subclass Deficiency
- Severe Combined Immunodeficiency (SCID)
- Wiskott-Aldrich Syndrome
- Ataxia-telangiectasia
- DiGeorge anomaly
- Hyper IgM Syndrome
- Chronic Granulomatous Disease
- Complement Deficiencies
- Hereditary Angioedema

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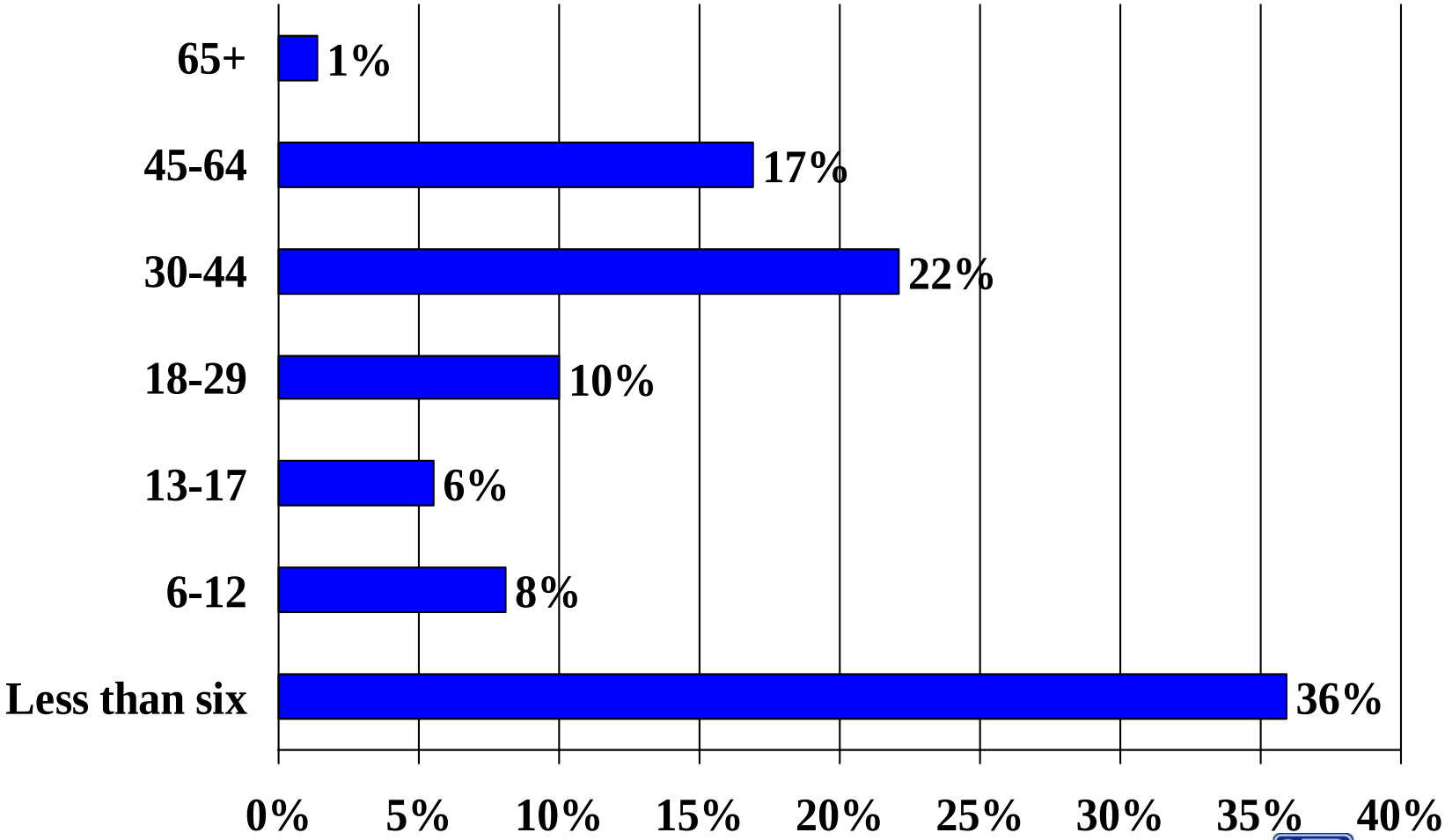
Background on PIDD Community and IVIG Use

- Survey of Primary Immune Deficiency Diseases in the United States: 2002
  - 1,526 respondents

- Treatment and Experiences and Preferences of Patients with Primary Immune Deficiency Diseases: First National Survey, 2002
  - 1,186 respondents

Patient Age at PIDD Diagnosis



At what age (in years) was that person first diagnosed with a primary immune deficiency disease? (Base: N=1,499 – excludes blank data)

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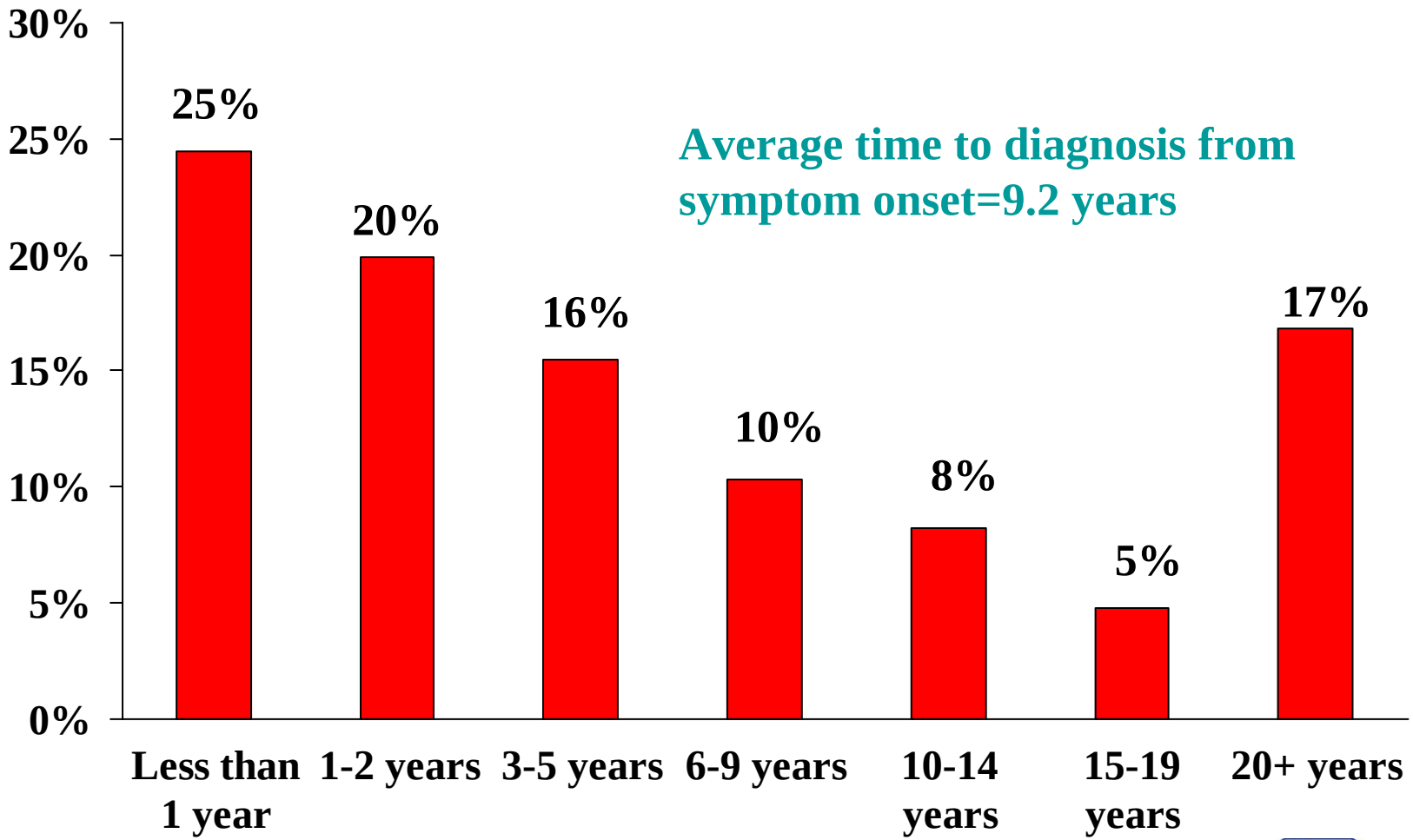
Time to Diagnosis After Symptom Onset



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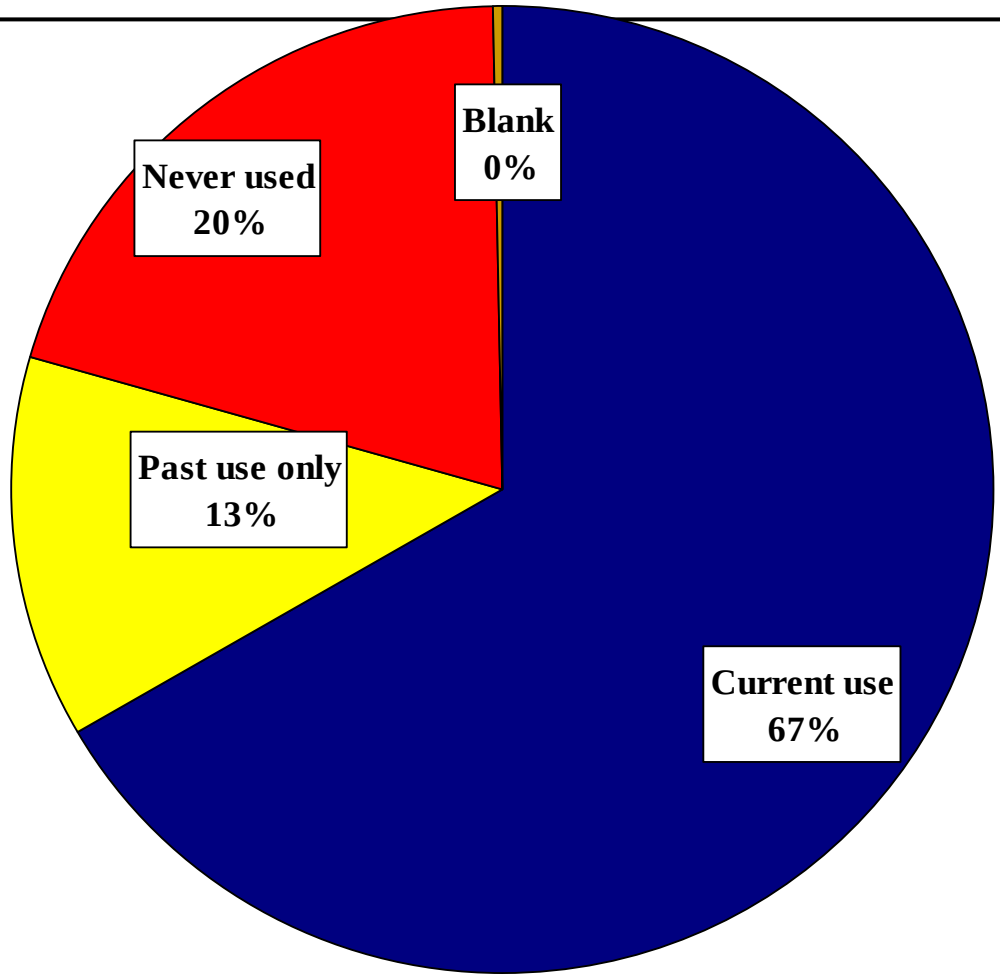
Use of IVIG Status



Has he/she ever been treated with intravenous gammaglobulin (IVIG) on a regular basis. Is he/she currently being treated with intravenous gammaglobulin (IVIG) for his/her immune deficiency disease? (Base: N=1,526)

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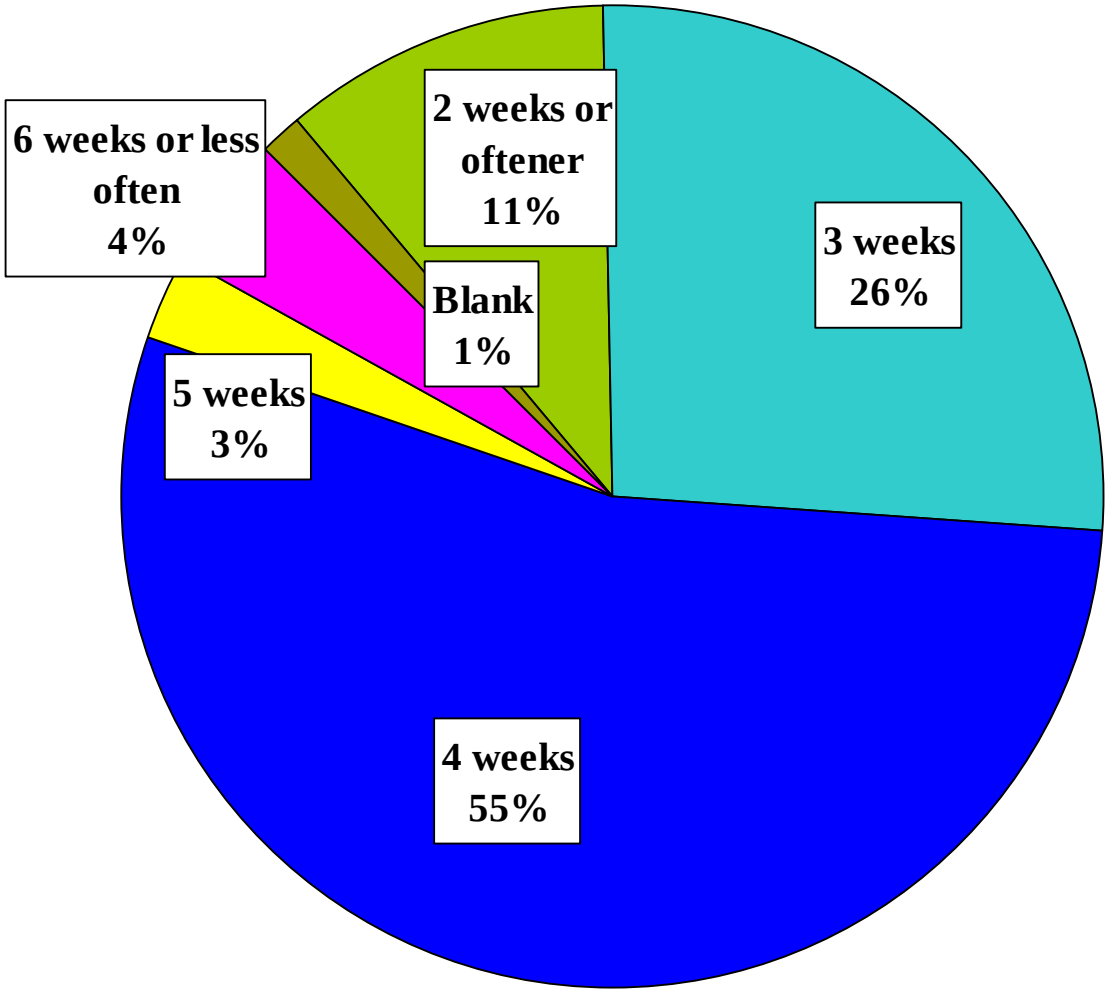
Frequency of IVIG Infusions



On average,how often does he/she get an infusion of IVIG? N=1,170

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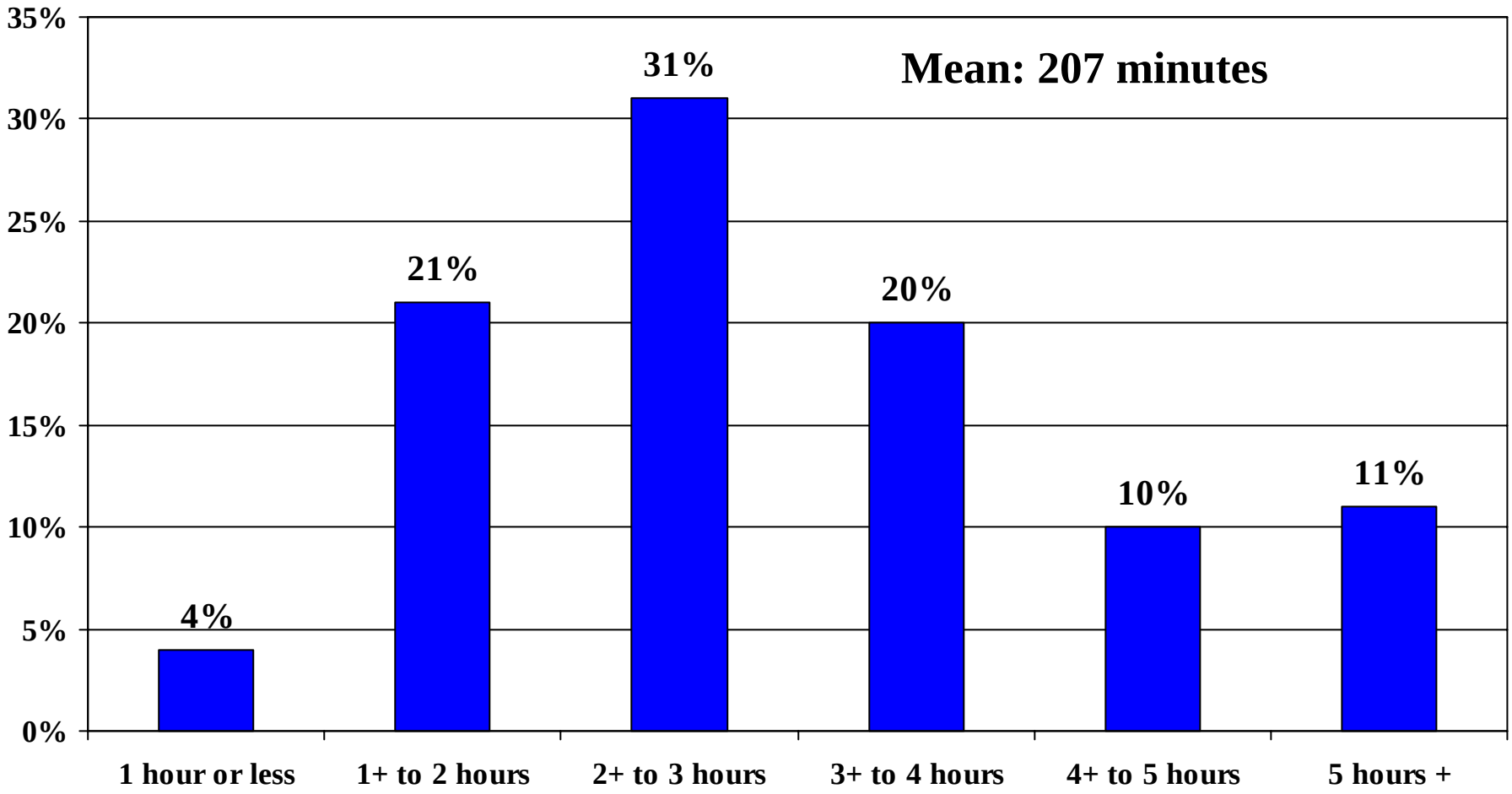
Length of Time for Infusion



How long does an infusion usually take (in minutes)? N=1170

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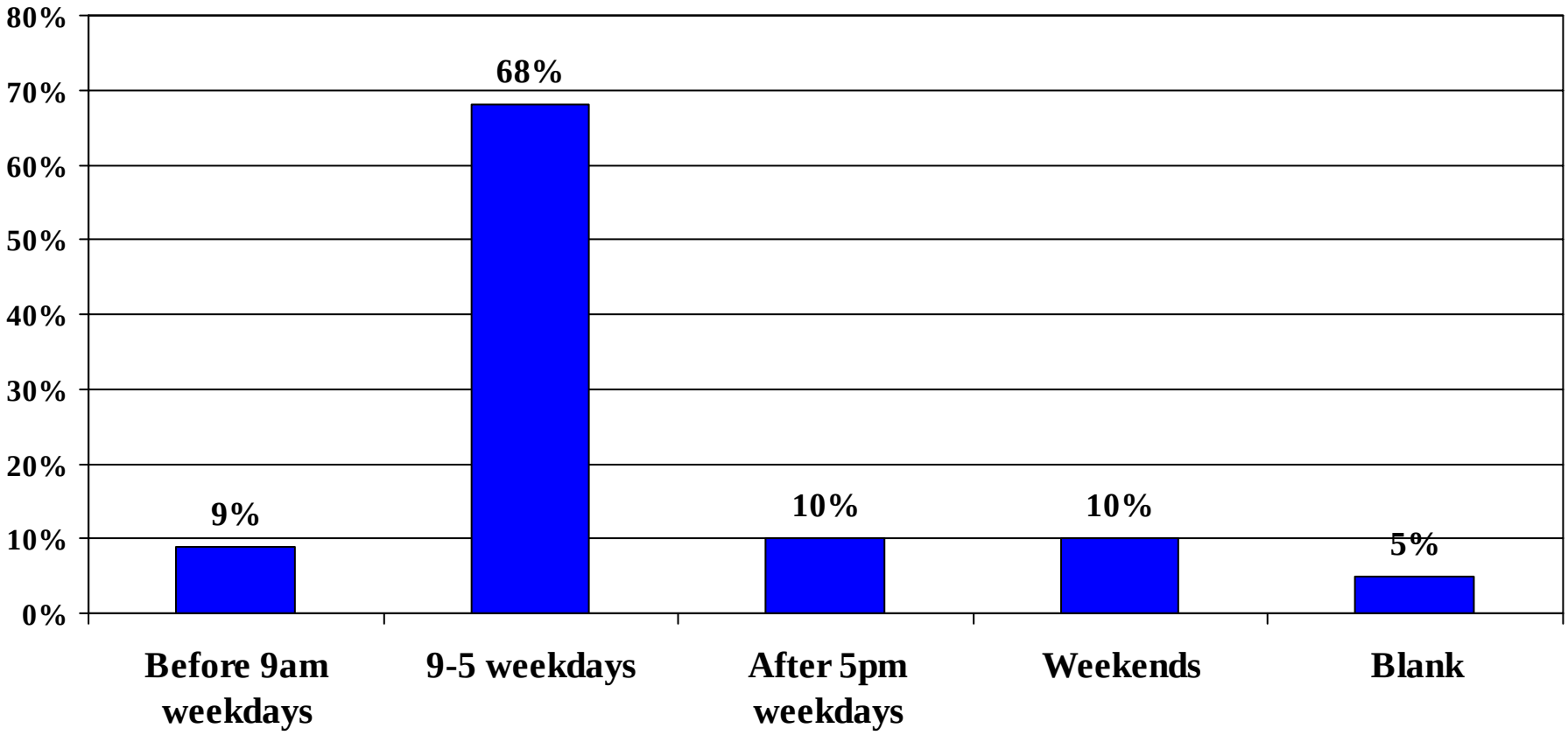
When does Patient receive Infusion?



When does the patient usually receive his/her infusions? N=100

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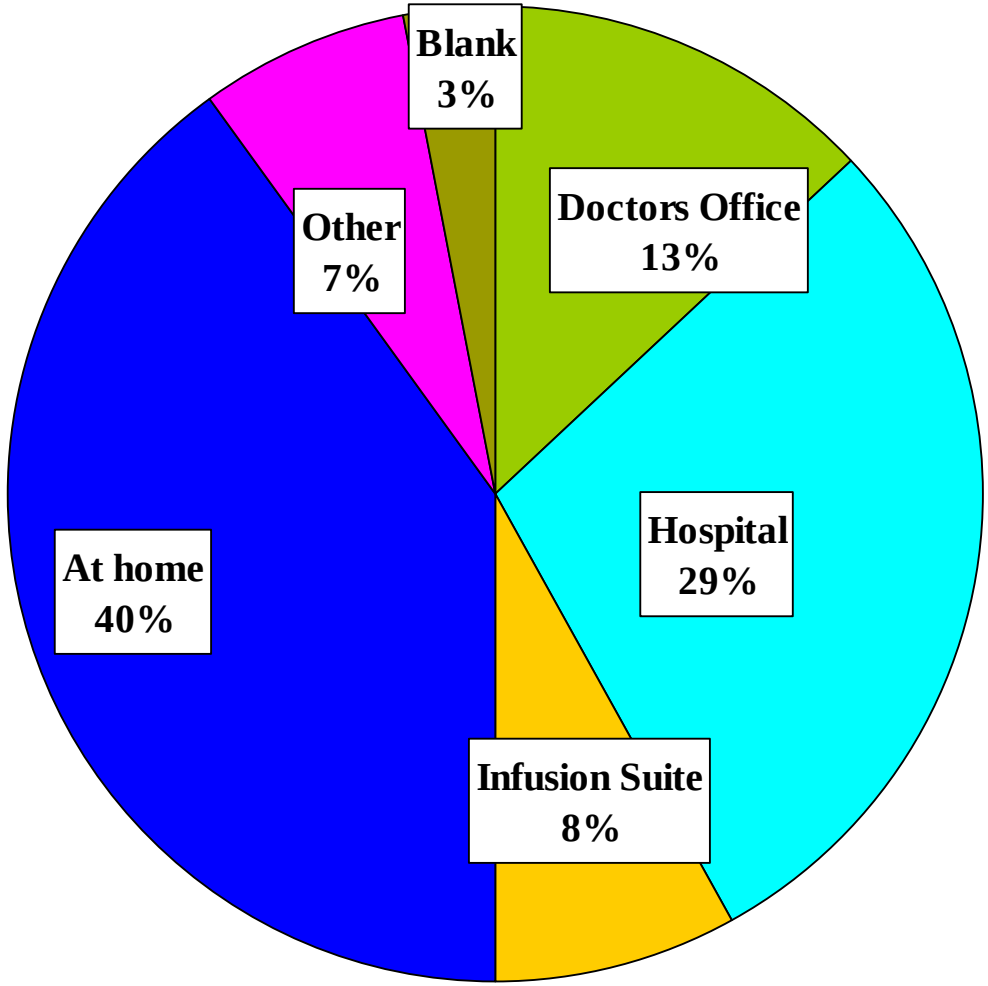
Where does Patient receive Infusion?



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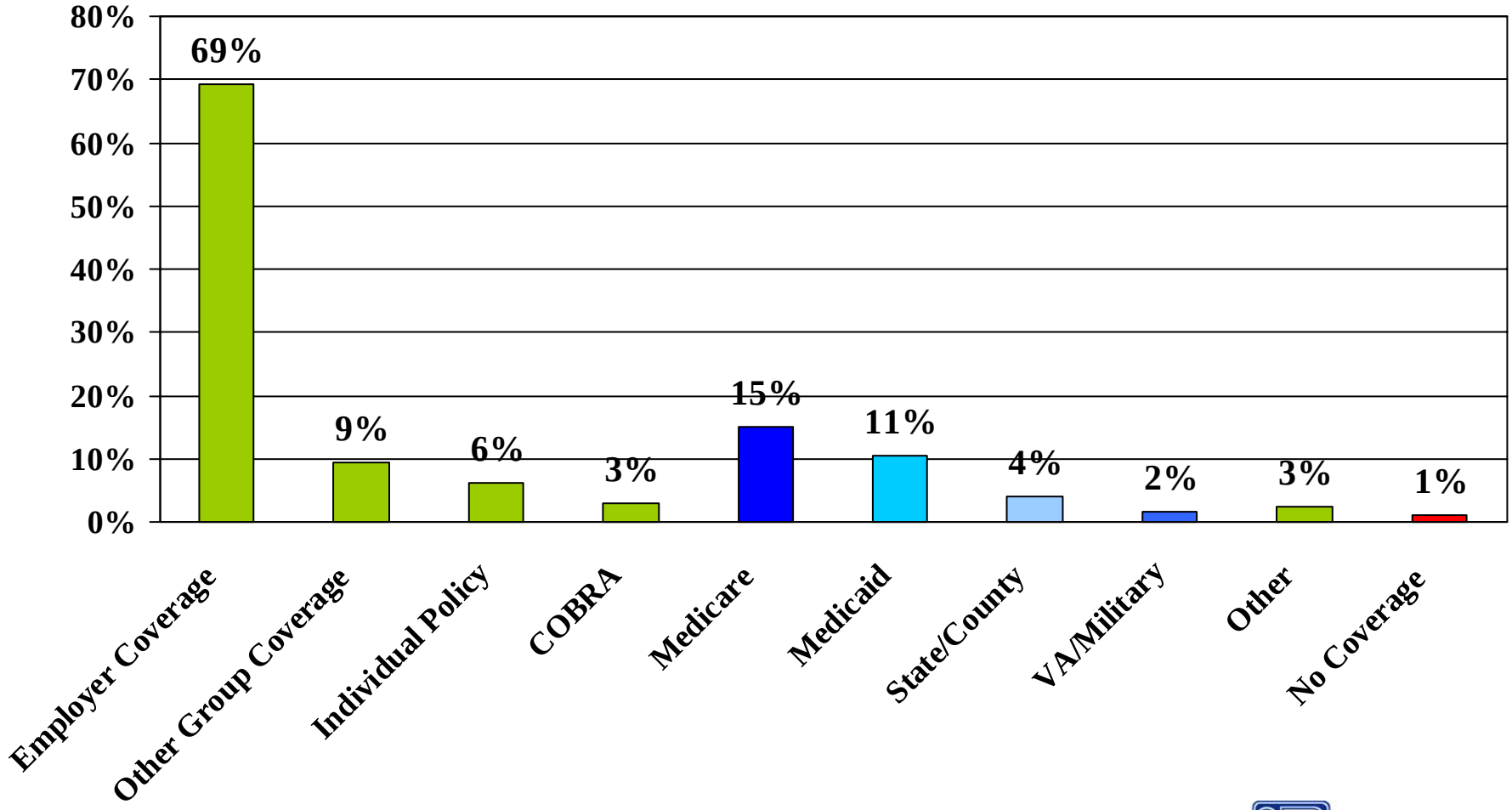
Source of Current Health Insurance



What is the current source(s) of the patient's health care coverage? (Base: N=1,526)

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Health Insurance Problems

64% of primary immune deficient patients have health insurance problems such as:

- Denial of coverage
- Exceeding lifetime caps
- Prior Authorization causing treatment delays
- IGIV not covered
- State's preferred drug lists/formularies
- Policy cancellation

Hospital Outpatient Prospective Payment System - 2004

PROBLEM:

- CMS Classified IVIG as a non-innovative multi-source therapy (generic).
  - **Reduced reimbursement to 46% of AWP - $37.95 per gram.**

NEGATIVE IMPACT:

- Patients denied access to life-saving treatment.
- Hospitals would not administer IVIG.
- Most Medicare patients received IVIG in the hospital outpatient setting

SOLUTION:

- **CMS Re-Classified IVIG as a sole source therapy.**
  - **Increased reimbursement to 88% of AWP or $72.60 per gram.**

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Hospital Outpatient Prospective Payment System - 2005

PROBLEM:

- CMS has proposed reimbursement of $68.48 per gram.

  A reduction of $4.12 per gram (5.67%)

- CMS does not classify IVIG as a "blood or blood product." This will become a significant problem in 2006 when CMS looks at acquisition costs.

RESULT:

- Patient access to care will be jeopardized
- IGIV is not protected under the dampening effect because it is not classified as a blood product

Hospital Outpatient Prospective Payment System - 2005

SOLUTION:

- Increase reimbursement of IVIG to at least the level of 2004.
- Reclassify IVIG as a “blood or blood product.”
  - IVIG is prepared solely from pooled human plasma by modification and refinements of the cold ethanol method of Cohn fractionation and other methods.
  - IVIG is fractionated from the same source material used to produce human derived clotting factors for the treatment of hemophilia, which is recognized as a “blood or blood product.”

Medicare Part B Prescription Drugs and Physician Fee Schedule (2004)

PROBLEM:

- In 2004, CMS classified IVIG as a generic drug.
  - Reimbursement reduced to 80% of AWP - $66.00 per gram.
  - Report language of the Medicare Bill reimbursed IVIG at 95% of AWP

NEGATIVE IMPACT:

- Patients denied access to life-saving treatment.
- Patients turned away from treatment sites

SOLUTION:

- CMS should reclassify IVIG as non-generic.
  - Increases reimbursement to 95% of AWP.

Medicare Part B Prescription Drugs and Physician Fee Schedule (2005)

PROBLEM:

- Medicare law will change reimbursement methodology from AWP to ASP +6%. Reimbursement of IVIG will be reduced.
- CPT codes and physician fees are chosen to offset reductions in reimbursement of drugs and biologics. However, AMA initially recommended classification of IVIG as a “low complexity administration procedure,” a category including saline and antibiotics. Last week, AMA reversed its decision.

NEGATIVE IMPACT:

- Providers have contacted IDF concerned that patients will no longer be able to be treated in physicians offices due to the reduction in reimbursement.

New IVIG Home Infusion Benefit (2004)

PROBLEM:

- **Although there is a new provision in the Medicare law to cover IVIG infusions in the home:**
  - **The benefit covers the drug only and not the administration of IVIG or use of DME.**
  - **Most home care companies are not accepting Medicare patients because the reimbursement is not adequate.**
    - **The home care companies that are accepting PIDD patients do so on a case-by-case basis. Patients lacking a secondary insurance plan, have to pay for nursing services.**
    - **If a patient is infused through an infusion pump, Medicare will not reimburse for IVIG deeming it medically unnecessary.**

IVIG Home Infusion Benefit (2004)

CONGRESSIONAL INTENT:

- It was the intent of Congress to cover IVIG home infusions for PIDD patients when doctors felt the home was the best site of service.
  - Congress had the Lewin Group conduct a study to ensure the safety of IVIG home infusion for PIDD patients.

SOLUTION:

- **CMS should publish a new program memorandum correcting the language included in the January 23, 2004 memorandum: "for coverage of IVIG under this benefit, it is not necessary for the derivative (IVIG) to be administered through a piece of durable medical equipment."**
- **Additionally, CMS needs to cover the administration of IVIG and DME in the new Home Infusion Benefit. This can be accomplished by increasing reimbursement for IVIG or adding an administration fee.**

Conclusions

- Primary immune deficiency diseases are chronic, life-threatening diseases. With the introduction of IVIG therapy, patients have been able to live productive and near normal lives.
- PIDD Medicare patients are currently being turned away from treatment sites, or are being shifted from one site to another depending on reimbursement of IVIG. We recommend that there be equal and adequate reimbursement for all sites of service.
- The new home infusion of IVIG site of service is greatly needed for our community. Most of our Medicare patients are on disability, and do not need to be exposed to additional infectious agents by visits to hospitals and doctors offices.

Conclusions (continued)

- IDF has recently met with MedPac, who is conducting a study on IVIG reimbursement for the primary immune deficiency community.
  - We stressed the importance of patients having access to this life-long, life-saving therapy in the best site of service for the patient determined by the patient and their physician; not based on reimbursement.
  - MedPac is also reviewing the need to separate the different IVIG products by giving each product its own HCPC code, so that CMS does not continue to classify IVIG as a generic.
  - IVIG should continue to be exempted from any competitive bidding model.