



# Effective Health Care

## Setting of Intravenous Immunoglobulin Therapy

### Nomination Summary Document

## Results of Topic Selection Process & Next Steps

- Setting of intravenous immunoglobulin therapy is not feasible for a full systematic review due to the limited data available for a review at this time.
- This topic could potentially be considered for new research in comparative effectiveness.

## Topic Description

**Nominator:** Individual

**Nomination Summary:** The nominator is interested in evidence supporting delivery of IVIG in the home for patients with common variable immune deficiency (CVID) to reduce nosocomial infection exposure and time missed from work/school.

### Staff-Generated PICO

**Population(s):** Patients with common variable immune deficiency (CVID); children with CVID are a possible subgroup of interest

**Intervention(s):** Intravenous immunoglobulin (IVIG) replacement therapy delivered in the home

**Comparator(s):** IVIG replacement therapy delivered in a hospital or other clinical setting

**Outcome(s):** Short-term outcomes include incidence of infection; long-term outcomes include complications of CVID, such as recurrent infections (e.g., chronic respiratory tract infection); development of inflammatory lung disease; development of autoimmune disease; malignancy; improved quality of life; patient satisfaction; time lost from work/school

**Key Questions from Nominator:**

1. For patients with common variable immune deficiency receiving intravenous immunoglobulin (IVIG) therapy, what is the difference in long-term outcomes for those who receive treatment in their homes vs. hospital or clinic?

## Considerations

- The topic meets Effective Health Care (EHC) Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)

- No studies have been conducted on the comparative effectiveness of IVIG delivered in the home compared to a hospital or other clinical setting. Very few observational studies on immunoglobulin replacement examine the impact of delivery setting on patient outcomes. Therefore, this topic is not feasible for a full systematic review due to the limited data available for a review at this time.
- The Medicare IVIG Access Act was introduced in May 2011 and is under consideration in the House and Senate. The Act is designed to address changes to coverage levels for supplies and services needed for home-based IVIG delivery. The act includes a demonstration project that would support evaluation of the benefits of providing payment for the items and services necessary for administration of IVIG in a home setting.

## Importance of New Research

- The setting of IVIG therapy is an important topic with a lack of primary evidence. Administration of IVIG therapy in the home has become popular with patients because it results in less time away from work or school. However, there is little exploration of optimal setting for IVIG delivery in existing systematic reviews or clinical practice guidelines on the topic of CVID management or IVIG delivery. New research on this topic could be used to establish the comparative effectiveness of home delivery of IVIG compared to delivery in clinical settings and could support patient preferences for delivery setting.

## Research Gaps

- 2010 clinical practice guidelines from the Canadian Blood Services and National Advisory Committee on Blood and Blood Products identify a comparison of subcutaneous immunoglobulin to IVIG delivered in the home as a focus for future research.
- Searches of the medical and nursing literature from 2008 forward found no controlled trials examining outcomes of IVIG therapy in patients with CVID or other primary immunodeficiencies by IVIG therapy setting (e.g., home vs. clinical). Eight observational studies that describe patient outcomes from home-based immunoglobulin delivery were identified, though most of these studies focus on subcutaneous immunoglobulin delivery. Outcomes examined in these studies include rate of infection, adverse events from treatment, health-related quality of life, and patient satisfaction.