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Is Norway's transfusion service ethical and sustainable?

PERSPECTIVES

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The use of immunoglobulins is increasing, but their administration is often not supported by robust scientific evidence. This creates ethical and supply-related challenges that require coordinated action at a national level.

Immunoglobulins are used both as replacement therapy for immunodeficiency and as immunomodulatory treatment in autoimmune and inflammatory disorders (1–3). They are classified as essential medicines by the World Health Organization (WHO) (4) and are life-saving for many patients.

Consumption has increased steadily and substantially since 2001 (5, 6). In 2024, immunoglobulin use in Norway reached 1.2 tonnes, which is nearly 18 times the amount consumed in 2001 (5). Meeting this demand requires over 300,000 litres of plasma.

Plasma shortage

Plasma can be obtained either by separation from whole blood donations or by automated plasmapheresis, in which blood cells are returned to the donor. A single whole blood donation yields 200–250 mL of plasma, whereas a plasmapheresis procedure produces more than twice that amount, typically 600–700 mL (7, 8).

Every year, approximately 50,000 litres of plasma are collected in Norway, with a slight decline in recent years. In 2024, around 46,000 litres were collected, of which roughly 40,000 litres were separated from whole blood donations, and the remainder were from 11,000 plasmapheresis procedures (9).

Plasma collected in Norway is sent to Austria under an agreement with the Norwegian Hospital Procurement Trust for fractionation into albumin, coagulation factors and immunoglobulins. Fractionation of Norwegian plasma produces approximately 200 kg of immunoglobulins; an amount that made Norway self-sufficient until 2007 (5). In 2024, Norwegian plasma production covered only about 15 % of domestic demand. The shortfall is met with roughly 400,000 plasmapheresis procedures (around 1800 per working day), mainly in the United States and some also in Central Europe (9–11).

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To meet Norway's 2024 immunoglobulin demand solely through domestic collection, national plasma production would have needed to increase more than 40-fold compared with current levels, which seems unrealistic.

Ethics and donor health

In Norway, blood donation is voluntary and unpaid, in line with recommendations from the World Health Organization (WHO) and the Council of Europe (12, 13). This provides reassurance for patients receiving plasma-derived medicines and protects donors from financial pressure. Plasmapheresis yields a larger volume of plasma per donation and allows for more frequent donations than whole blood collection. Norway's transfusion service guidelines recommend a minimum interval of two weeks between each plasma donation (14), but in reality, donors in Norway donate plasma far less frequently.

The most recent European guidelines allow up to one donation per week, equivalent to 52 plasmapheresis procedures per year (7). Evidence on the long-term effects of frequent plasma donation is limited (15), and it is essential that donation is safe for

donors both in the short and long term to ensure a sustainable supply of plasma-derived medicines.

Plasma donors in the United States and Central Europe receive payment. The exact amounts are not well documented, but USD 50–75 per donation is assumed to be typical in the United States, primarily for the most frequent donors (16). US donors can earn USD 5000–6000 per year, which for low-income families in a country without a welfare system can be critical for survival (17, 18). There are reports that some are able to donate more often than regulations permit because the data systems of various commercial operators are not coordinated (19). The plasma market relies on the exploitation of people in vulnerable situations and undermines the altruistic nature of blood donation (20, 21).

Collaborative body for blood banks in response to supply crisis

In 1983, the heads of Norway's five regional blood banks formed a collaborative body (*Regionblodbanksjefkollegiet*) to protect transfusion recipients from HIV transmission to the greatest extent possible. A haematologist and an anaesthesiologist subsequently joined this body. In 1985, it gained status as the Norwegian Directorate of Health's advisory committee for coordination of the transfusion service, and in 1986 it was renamed the Blood Bank Council (*Blodbankrådet*) (21). This national collaboration resulted in far fewer transfusion recipients being infected with HIV in Norway compared with most other industrialised countries (22).

Throughout the 1990s, control over transfusion-related infection risks improved steadily. National health authorities eventually concluded that the Blood Bank Council was no longer needed, and it was dissolved at the turn of 1998/99 (21). Norway's transfusion service may soon face a new supply crisis (5), and the Blood Bank Council should therefore be reinstated to coordinate efforts and prevent this.

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Sustainable and evidenced-based use

Despite increasing use, there are no national guidelines in Norway for the evidence-based use of immunoglobulins. Clinical evidence is strong for replacement therapy in congenital or acquired immunodeficiency and for immunomodulation in certain autoimmune conditions, such as immune thrombocytopenia (ITP) (2, 3, 6). In 2021, the Norwegian Institute of Public Health reported that most immunoglobulin use in Norway is related to haematological, neurological and immunological conditions, but that the evidence base for many immunomodulatory indications is limited. In addition,

they identified substantial variations in use across counties, with up to three times higher consumption per capita in Nordland, Troms and Finnmark compared with Trøndelag and Vestland (6).

A national working group led by Central Norway Regional Health Authority is currently drawing up guidelines for the use of immunoglobulins in secondary immunodeficiency, similar to those established by the Danish Medicines Council (23). The guidelines do not address immunomodulatory use, despite this being an area where evidence is weak and consumption is probably excessive.

As a first step towards more evidence-based use, it should be a requirement that all use not supported by clinical evidence takes place within the framework of an approved research protocol. This would help ensure rational use and reduce unnecessary consumption (24).

Focus on self-sufficiency in Europe

Europe is currently around 60 % self-sufficient in plasma for medicinal production (25). SUPPLY is an EU-funded project launched in 2022 with the aim of strengthening capacity for voluntary, unpaid plasma donation in Europe (26). In recent years, several European countries have intensified efforts to increase plasma collection and reduce dependence on imports. In 2024, the EU adopted a new regulation on blood, cells and tissues; *Substances of Human Origin*, with the objective of achieving strategic autonomy and sustainable access to plasma-derived medications (27).

Denmark has set a goal of full self-sufficiency in immunoglobulins and the establishment of dedicated plasma centres. It has also achieved an annual volume of more than 144,000 plasmapheresis procedures, sending over 140,000 kg of plasma for fractionation. Its rate of self-sufficiency in immunoglobulins has increased from 31 % to 49 % since 2014 (28).

Sweden has launched a national strategy where the emphasis is on preparedness and increased plasma collection, but has so far not proposed measures to reduce consumption (29). In 2019, a report by the Norwegian Directorate of Health identified the lack of plasma self-sufficiency as a challenge to national preparedness (30). The issue was to be followed up by the Directorate in collaboration with the Transfusion Council, but implementation of effective measures has been limited.

Where is our strategy?

The use of plasma for medications is complex, and is shaped by three key factors: supply, ethics and consumption. Efforts to reduce immunoglobulin use or expand plasma availability in Norway have so far yielded limited results. The ethical implications of current practice, whereby frequent plasma donations from paid, low-income donors in other countries are needed to meet domestic demand, have also not been adequately addressed. It is paradoxical that a shortfall of 85 % is met through

plasmapheresis performed on paid donors abroad, in contravention of the Council of Europe's and the World Health Organization's principles of voluntary, unpaid blood donation (12).

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Global consumption of immunoglobulins is expected to increase, driven by improved diagnostics, a growing incidence of secondary immunodeficiency, and widespread use without a robust evidence base. Norway's low level of self-sufficiency makes the country vulnerable from a preparedness perspective, and the absence of a national body for the production and use of blood- and plasma-derived products increases the risk of shortages of life-saving medicines. Ongoing international trade tensions make Norway's dependence on plasma produced in the United States even more precarious.

To address this challenge, Norway needs a national strategy, which should start by establishing a national body overseeing plasma supply and consumption. This body should draw up evidence-based guidelines for immunoglobulin use and devise a strategy to increase plasma collection, ideally through dedicated plasma centres. Stronger national agreements on fractionation and production must also be put in place.

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