

LIQUID GOLD: NEW ZEALAND'S NEED FOR COMPENSATED PLASMA COLLECTIONS

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Foreword

At the start of National Blood Donor Week, the New Zealand Blood Service warned that it will need more donors.

According to the Blood Service's Asume Burge, "If we can't meet demand, it means we are going to be forced to compete in the global market, for particularly plasma products. We don't want to do that."¹

The only surprising thing about the warning is that it has taken this long.

New Zealand relies on uncompensated blood and plasma donation. Compensation, in New Zealand, is prohibited.

Most countries that rely solely on uncompensated donation need to import plasma products to fill the gap. Because America allows compensation, its donors fill gaps in other countries' supplies.

Bioethicists sometimes worry about compensation for blood and plasma donation. But it seems strange, at best, to ban compensation here while relying on imported plasma from paid donors.

Worse, if New Zealand comes to rely more heavily on imported products, we will be contributing to a global problem. Countries without the resources to manufacture their own reliable blood plasma products rely on imports from countries like the United States. Failing to compensate donors here can mean fewer of these products are available in poorer countries.

Peter Jaworski is a global expert in the ethics and economics of blood plasma donation. He here provides a challenge to New Zealand. Should we maintain the status quo and rely ever more heavily on imported plasma products? Or should we follow the example set by places like Alberta, Canada?

In late 2020, Alberta repealed its ban on compensated donations. Since then, three commercial collection centres have opened. By 2024, Alberta is likely to be the only Canadian province approaching self-reliance, rather than importing product from elsewhere.

Banning compensation of plasma donors does not prevent compensation. It just changes where that compensation happens, while worsening global shortages of critical medical supplies.

New Zealand needs to rethink its prohibition.

Dr. Eric Crampton
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¹ " 'We need more people to donate' – NZ Blood Service." *Radio New Zealand* 11 June 2023. Available at <https://www.rnz.co.nz/news/national/491796/we-need-more-people-to-donate-nz-blood-service>

Executive Summary

Blood plasma, the straw-coloured part of our blood that is composed of a variety of essential proteins including immunoglobulins, is essential for meeting the medical and therapeutic needs of vulnerable patients. We collect blood and plasma in order to ensure that patients with immunodeficiencies, autoimmune disorders, a variety of neurodegenerative diseases, and rare blood disorders can have access to the therapies they need. But are we collecting enough plasma to ensure uninterrupted, safe, and sufficient access to those often life-saving therapies? Is the collection model to which New Zealand currently adheres the most efficient?

To answer that question, this paper compares the main models of plasma collection used around the world and examines the policies that have an impact on these models. One model is a non-commercial model – private or public – that does not compensate donors for their plasma. Another is a commercial model that does compensate donors. A third model, a public-private partnership with donor compensation, has also emerged recently.

Most countries, including the United Kingdom, New Zealand, Australia, 23 of the 27 EU countries, and Canada's most populous provinces, have adopted policies legally enshrining a single model – a domestic non-commercial model that does not compensate donors for plasma. However, a handful of countries – Germany, Austria, Hungary, the Czech Republic, and the United States – have at least a decade's worth of experience with policies that permit both models to operate within their borders. The difference in the outcomes of the two approaches is stark.

Every country that permits the commercial model to operate within its borders has *surplus* plasma. They collect more than enough plasma to meet the therapeutic needs of their own patient communities, and so help meet the therapeutic needs of patients outside of their borders. Every country that prohibits the commercial model or donor compensation has plasma collection *deficits* which have only grown over the past decade. There are no exceptions.

Germany, Austria, Hungary, the Czech Republic, and the United States provide close to 90 percent of the plasma used to manufacture therapies to meet the global needs of patients. The United States alone is home to more than 80 percent of the world's plasma collection centres and provides more than 70 percent of the plasma for the world's plasma therapies. All other countries combined – including Canada, Australia, New Zealand, the UK, many EU members, and others – manage to collect only enough plasma to meet 10 percent of the global need.

The figures represent an unacceptable imbalance in the global supply chain for plasma protein therapies. While the US could plausibly provide enough plasma to meet the growing global demand for therapies, both a precautionary approach and possible political and legal uncertainties recommend a greater regional balance in collections. For more than two decades national blood operators around the world have worried about the possibility of a plasma supply crisis. Despite the warnings, crises, and occasional shortages, most countries have either ignored the evidence or have failed to take action while not giving sufficient consideration to permitting at home what they all rely on from abroad.

To secure plasma, most countries look first to their own non-compensated donors. But apart from this method simply not producing the volumes needed, it is expensive to operate a non-commercial, non-compensated plasma collection system. Compared with the commercial alternative, non-compensated plasma collections typically cost between two to four times more according to a 2018 Health Canada expert panel. Using Canadian Blood Services' (CBS) own estimates and including only ongoing operational costs, the expected average collection cost of plasma is \$310 to \$413 per litre. Meanwhile, Canadian Plasma Resources, a Canadian commercial compensated plasma company, has offered (several times) to supply CBS with plasma at a cost of \$220 per litre, between 41 and 88 percent cheaper than the CBS alternative.

To collect enough plasma to meet the needs of Canadian patients in 2019 would have cost provincial governments \$1.7 billion in collection costs alone. Meanwhile, buying its plasma protein products from external sources where the donors are compensated cost Canada \$656 million between 2018 and 2019, according to the CBS. The question is obvious: why haven't Canada, or New Zealand, opted to permit domestic collections of commercial compensated plasma?

Governments worry that compensated plasma collections may adversely affect the collection of non-commercial, non-compensated whole blood. But studies have shown no apparent negative relationship between compensated plasma collections and non-compensated blood and plasma collections. In fact, one study found the introduction of compensated plasma donation opportunities in three cities in Canada and three cities in the US not only had no effect on non-compensated blood donations, but had a very small, positive effect on such donations.

At one time it was conceivable that non-compensated plasma collections could meet the needs of patients. But such a proposal has been unrealistic for years – not because people have become less willing to donate, but because the number of such donations necessary to meet the needs of patients has ballooned beyond what could be reasonably expected of even the most altruistic of countries.

New Zealand, and most other countries, need systems that collect enough plasma to ensure that every patient who needs a plasma therapy has access to it. Current policies are hypocritical. We don't permit commercial compensated plasma collections within our borders, but every country relies on them. If it is immoral to pay New Zealanders for plasma, why is it moral to pay Americans? It is time to steer away from the iceberg and to create a policy framework that permits rather than forbids commercial compensated plasma collections.

Introduction – The point of plasma collection

The primary point of collecting blood plasma is to meet the medical and therapeutic needs of patients. We collect blood and plasma in order to ensure that we can preserve and promote the health of current and future patients.

Blood plasma is the yellow or straw-coloured part of our blood. While it is mostly water, about 7 percent of it is made up of a variety of essential proteins like antibodies or immunoglobulins, albumin, a variety of coagulation or clotting factors, fibrinogen, and others. These proteins help us fight infections when we get sick, help our blood clot when we are injured, and many other things.

We collect blood plasma primarily to make medicine for the patients in our community who have rare diseases, like primary or secondary immunodeficiency, autoimmune disorders, a variety of neurodegenerative diseases like multifocal motor neuropathy, rare blood disorders like haemophilia or von Willebrand disease, and many others. The point of collecting blood plasma is to ensure that these patients and those of us who may become patients are given safe, secure, and reliable access to medicines that save and improve their lives.

Simply put, policy discussions should prioritise patients and the therapies they need. And the most important policy question is: Are we collecting enough plasma to ensure uninterrupted, safe, and sufficient access to quality-of-life-improving and often life-saving therapies for the current and future patients whose lives and health depend upon it?

Models of Plasma Collection

To answer that question, we need to compare the main models of plasma collection used around the world and the policies that impact which of these models emerge. One model is a non-commercial model, either private or public, that does not compensate donors for their plasma. The other model is a commercial model that does compensate donors.

Most countries have adopted policies that have legally enshrined a single model – a domestic non-commercial model that does not compensate donors for plasma. This includes the United Kingdom, New Zealand, Australia, and Canada's most populous provinces: Ontario, British Columbia, and Quebec. This also includes 23 of the 27 countries within the European Union (EU). A handful of countries – Germany, Austria, Hungary, the Czech Republic, and the United States – have at least a decade's worth of experience with policies that permit both models to operate within their borders.

The most important bottom line results are these:

- Every country that permits the commercial model to operate within its borders has *surplus* plasma collections. They collect more than enough plasma to meet the therapeutic needs of their own patient communities and so help meet the therapeutic needs of patients outside of their borders.

- Every country that prohibits the commercial model or donor compensation has plasma collection *deficits*. These deficits have grown over the past decade. These countries do not collect enough plasma to meet the therapeutic needs of their patient communities, and so to meet their patients' needs they rely on imports of therapies made from plasma collected using commercial, compensated plasma collections in the aforementioned handful of countries. Countries that ban the commercial model nevertheless are dependent upon it.

There are no exceptions.

We also now have more than two decades' worth of evidence demonstrating that permitting non-commercial, non-compensated blood and plasma collection to coexist with commercial, compensated plasma collection has ensured a safe, reliable, and sufficient quantity of plasma to meet the therapeutic needs of every patient.

The same cannot be said for countries that have banned commercial, compensated plasma collections. While the therapies produced through the non-commercial, non-compensated plasma collection model are equally safe, this model has been unreliable, expensive, and has failed to collect sufficient plasma everywhere it is in place. As Canadian Blood Services has said: "self-sufficiency is not operationally or economically feasible in a volunteer, unpaid model" (CBS 2015: 36).

The commercial model is effective and does not adversely affect non-compensated blood and plasma collections for transfusions. It has operated in countries without evidence of reducing nor undermining altruism or solidarity, harming donors, or wrongfully exploiting them.

This evidence has resulted in patient-centric policy changes in the province of Alberta and by Canadian Blood Services. These changes are promising. Australia, New Zealand, and the UK should take a similarly patient-centred approach and modernize their legal frameworks to permit commercial and non-commercial sectors to coexist.

Global supply

Germany, Austria, Hungary, the Czech Republic, and the United States provide close to 90 percent of the plasma used to manufacture plasma therapies to meet the global needs of patients. All other countries combined – including Canada, Australia, New Zealand, the UK, EU members, and others – manage to collect only enough plasma to meet 10 percent of the global need.

The United States is home to more than 80 percent of the world's plasma collection centres and provides more than 70 percent of the plasma used to manufacture plasma therapies for the world (Jaworski 2020). It is the 11th largest industry in the US, with exports of therapies or plasma representing about 1.9 percent of total US exports in 2019 (Greenberg 2019). Globally, the industry is valued at more than US\$30 billion, and is projected to reach over US\$45 billion by 2027 (BCC Research 2023).

The US supplies Canada with more than 80 percent of the plasma used to make therapies, about 15 percent of New Zealand's, and has provided nearly 100 percent of the plasma

needed to make therapies for the UK since 1998. Australia, which is home to CSL Behring, the second-largest plasma company in the world, does not allow CSL to collect plasma domestically so depends on CSL plasma collections in the US for nearly half of its therapies.

Approximately 300,000 patients rely on therapies made from plasma in the EU. The four countries that permit commercial compensated plasma collections supply more than a third (38 percent) of total EU plasma used to make therapies, while the remaining 23 countries together supply about a quarter (24 percent). The remaining deficit of more than a third (38 percent) is covered by donors in the United States. Table 1 provides an overview of the extent to which some European countries depend on imports.

Table 1: Extent of plasma self-reliance, by country, 2017-2020

Self-reliance	2017	2018	2019	2020
Germany	>100%	>100%	>100%	>100%
Austria	>100%	>100%	>100%	>100%
Hungary	>100%	>100%	>100%	>100%
Czech Republic	>100%	>100%	>100%	>100%
Italy	73%	76%	n/a	n/a
France	n/a	n/a	n/a	~50%
Denmark	30%	34%	n/a	n/a
Norway	0%	0%*	n/a	n/a
Belgium	n/a	n/a	~50%	n/a
Spain	44%	35%	33.5%	33.5%
Netherlands	n/a	n/a	n/a	45%

Sources: De Meester, Bourgeois, Devriese, and San Miguel 2020; WHO 2022; Ministerio de Sanidad (Spain) Various years; Canadian Blood Services Annual Reports; National Blood Authority Annual Reports; New Zealand Blood Services Annual Reports; NHS England National Immunoglobulin Database Annual Reports

Collections are anticipated to grow faster in the US than anywhere else, and so the proportion of plasma provided by the US to meet global therapy needs will rise. Over the next five years, US-supplied plasma is likely to rise to at least three-quarters of global collections. These absolute figures are even starker when we compare rates of plasma donation measured in litres per 1,000 residents. Within the EU, the four countries that permit commercial compensated plasma collections have rates that are at least twice that of countries that don't.

The Netherlands had the best-performing non-commercial, non-compensated plasma collection system in Europe in 2019 according to the available data, but it was still not collecting enough to meet the needs of its patient community. Collections in the

Netherlands stood at 18 litres per 1,000 residents that year, half that of Germany's 40 litres per 1,000 residents, and merely a third of the Czech Republic's 65 litres collected per 1,000 residents.

Australia has probably the best-performing non-commercial, non-compensated plasma collection system in the world. Red Cross Lifeblood managed to collect 29 litres per 1,000 people in 2019. But not only was that not enough to meet the needs of its patient community, it was also less than half the Czech Republic's and just a bit more than half of Germany's. Australia met only 48.4 percent of the needs of Australian patients that year.

New Zealand had the next best performing system among Canada, Australia, New Zealand, and the United Kingdom (CANZUK), but managed to collect only 14 litres per 1,000, relying on imports for 12.5 percent of its patient community needs in 2019. Canada's non-commercial blood operators (Canadian Blood Services and Héma-Québec) together collected 7.6 litres per 1,000 residents. That number rose to 10.3 litres per 1,000 if we include estimates for commercial plasma collections, and so Canada was more than 80 percent dependent on other countries for its plasma supplies (just under 80 percent when estimated commercial collections are included). The UK did not collect plasma for therapies in 2019, relying on imports for 100 percent of its patient needs.

The United States collected 163 litres per 1,000 residents in 2019 (130 and 149 litres per 1,000 in 2017 and 2018). This is more than twice the next-best performing country, the Czech Republic, and more than nine times that of the Netherlands. These collections backstop the poorly performing systems in most of the rest of the world. Tables 2 and 3 provide further information about plasma collection among these and other countries.

Table 2: Plasma self-reliance in Canada, Australia, New Zealand, the United Kingdom, and the US, 2017-2020

Self-reliance	2017	2018	2019	2020
Canada	18.2%	17%	15.8%	15.9%
Australia	56%	52.6%	48.4%	46%
New Zealand	88.5%	88.2%	87.5%	88.8%
UK	0	0	0	0
US	>100%	>100%	>100%	>100%

Source: Canadian Blood Services annual reports, National Blood Authority annual reports, New Zealand Blood Services annual reports, NHS England National Immunoglobulin Database Annual Reports

Table 3: Rate of plasma collection per 1,000 residents in the EU, 2017-2019

Plasma L/1,000	2017	2018	2019
Germany	36	38	40
Austria	59.4	53.8	53.3
Czech Republic	61	62	65
Netherlands	17	17	18
Finland	10	10	10
Denmark*	13.8	14.9	<i>n/a</i>
Norway	10	9	10
Sweden	11	11	10
Switzerland*	7.5	7.2	<i>n/a</i>
Italy	13	14	<i>n/a</i>
Spain	8	8	8

* WHO 2022.

Source: European Directorate for Quality Medicine Various years unless otherwise stated.

Table 4: Rate of plasma collection per 1000 in Canada, Australia, New Zealand, the United Kingdom, and the US, 2017-2019

Plasma L/1,000	2017	2018	2019
Canada*	8.8	9.7	10.3
Australia	26	27	29
New Zealand	14	14	14
UK	0	0	0
USA	130	149	163

*Includes author's estimates of plasma collection at commercial plasma centres.

Source: Canadian Blood Services annual reports, Héma-Québec annual reports, National Blood Authority annual reports, New Zealand Blood Services annual reports, NHS England National Immunoglobulin Database Annual Reports

Global imbalance

The plasma collection figures represent an unacceptable imbalance in the global supply chain for plasma protein therapies. While the US could plausibly provide enough plasma to meet the growing global demand for therapies, both a precautionary approach and possible political and legal uncertainties recommend a greater regional balance in collections.

The current pandemic provides just the latest example of the precarious situation facing patients when we are over reliant on American plasma collections. The pandemic reduced plasma collections in the US by around 20 percent. Separately, an unexpected decision by US Customs and Border Patrol to treat the donation of blood plasma as “employment” meant a further reduction in collections of approximately 10 percent as visitors to the country could no longer donate (Lind and Dodt 2021) – at least until September 2022, when the US District Court for the 9th Circuit granted a preliminary injunction preventing enforcement of this decision, thereby allowing visitors to again donate (Immune Deficiency Foundation 2022).

The reductions in the US led to a significant global reduction in the availability of plasma for plasma therapies, which reduced the availability of immunoglobulin. France and Italy both expressed concern about their ability to provide immunoglobulin replacement therapy for their patient communities, as did patients in Spain (Lluch 2021; Infosalus 2021). England limited the use of immunoglobulin in the face of this “critical situation.”

Immunoglobulin therapy was rationed in Canada for a time. Elsewhere in the world, some new patients were unable to access the therapy that would have been best for their specific condition. One immunologist from Sudan explained that of her nearly 100 patients with primary immunodeficiency, about a quarter died from lack of access to immunoglobulin.

For more than two decades national blood operators around the world have worried about the possibility of a crisis. Concerns in Canada about over-reliance on American plasma collections have been expressed since at least the founding of Canadian Blood Services in 1998. New Zealand Blood Services has been raising the alarm, as has the National Blood Authority in Australia, and NHS Blood and Transplant in the UK. The situation was described as “steaming towards an iceberg” in *Current Opinion in Allergy and Clinical Immunology* in 2020 (Prevot and Jolles 2020).

In June of 2020, an unnamed official at the European Directorate for the Quality of Medicines and Healthcare (EDQM) was quoted as saying, “This situation exposes European patients to the risk of sudden interruptions of plasma supplies from the U.S.” In 2019, when the world was facing an acute shortage of immunoglobulin, John Boyle, then-president of the US-based Immune Deficiency Foundation, wrote an article that was subtitled “The sky is not falling but the world needs more plasma” (Boyle 2019). The very same article could have been written every year for the past decade.

Rising demand, more indications

The European Union managed to collect 108 percent of the plasma it needed for its immunoglobulin use as recently as 2011, excluding the UK. However, growth in demand for immunoglobulin has seen the EU deficit grow from 16 percent in 2014, to 24 percent in 2017, to the current 38 percent (Bencharif 2022).

Australia was 100 percent self-reliant in plasma for plasma therapies in 2004. Since then, the country has seen a fairly steady decrease in self-reliance to a low of 46 percent in 2020, but rising to 57.8 percent in the latest annual report. In 2004, Australia used approximately

1.35 million grams of immunoglobulin, a rate of around 66 grams per 1,000 residents. By 2022, Australian patients used 8.05 million grams, or 310 grams per 1,000 residents.

Although Australia is amongst the highest users of immunoglobulin, its experience in steady and significant growth in immunoglobulin use is not unique. Over the last two decades, demand for immunoglobulin has been rising by 6 to 10 percent per year around the world. The EU saw 8.3 percent growth in demand from 2010 through 2019. Australia and Canada experienced many years of double-digit demand growth, with similar growth in demand in the UK. The latest annual report from New Zealand Blood Services (2021) puts the growth in that country's demand for immunoglobulin at 12 percent.

Experts have noted both the current growth in demand, which was even higher prior to two decades ago, and the anticipated ongoing demand growth. In a 2006 article for the *New Zealand Journal of Medicine*, David Hutchinson, Richard Charlewood, Peter Flanagan, and Terry Mitchell wrote:

The steady rise in demand for IVIG in NZ over the past decade matches the experience in other developed nations. Utilisation in Australia rose by an average of 14.8 percent per annum over the period 1995–2005, and in Canada it rose by an average of more than 15 percent per annum over the period 1992 to 2001. A continued rise in demand is inevitable with the improved management of antibody deficiency and the completion of new studies establishing the efficacy of IVIG in diverse inflammatory disorders. (Hutchinson, Charlewood, Flanagan, and Mitchell 2006).

Despite more than two decades of warnings, crises, and occasional shortages, and more than two decades' worth of evidence regarding the effectiveness of commercial, compensated plasma collections and the ineffectiveness of non-commercial, non-compensated plasma collections, most countries have either ignored the evidence or have failed to take action while not giving sufficient consideration to permitting at home what they all rely on from abroad.

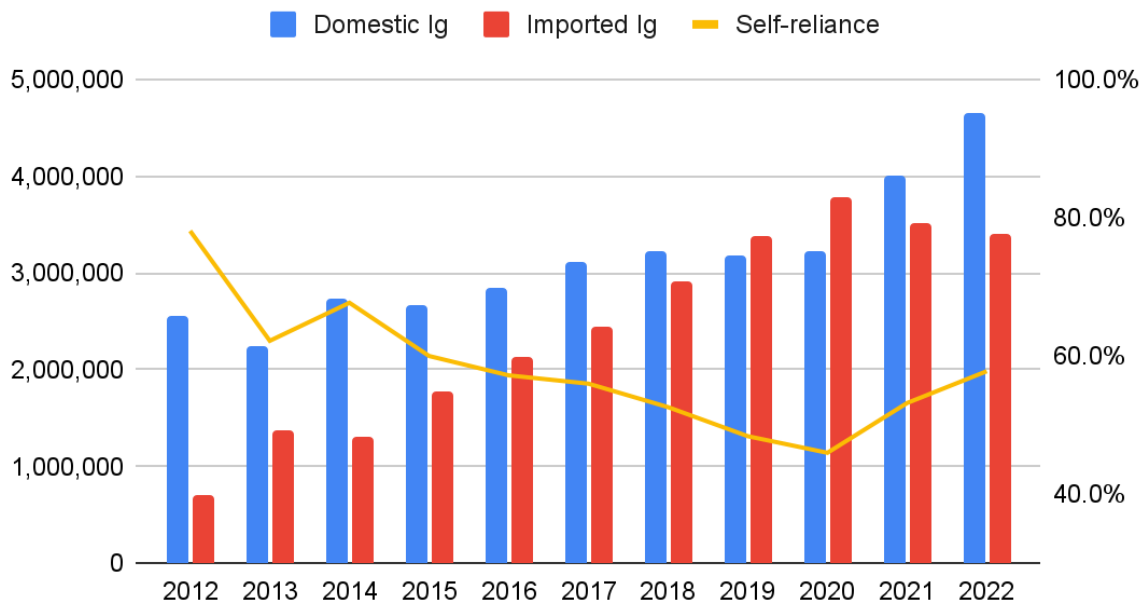
Canada, Australia, New Zealand, and the United Kingdom

Over the past 10 years, Canada, Australia, New Zealand, and the United Kingdom have become increasingly dependent on American plasma collections as a result of the steady increase in immunoglobulin use in each country. There was a temporary drop in dependence in 2022 as a consequence of the pandemic and the aforementioned drop in plasma donations in the United States. Of these countries, only Canada is likely to buck the trend in the next few years and see a significant reduction in this dependence.

As mentioned, Australia has the best performing non-commercial, non-compensated plasma collection system in the world. Australia was 14 percent dependent on the US in 2011, then 42.8 percent in 2016, and 46.8 percent in 2021 (Figure 1).

Figure 1: Australia's immunoglobulin self-reliance, 2012-2022

Australia immunoglobulin (Ig) self-reliance



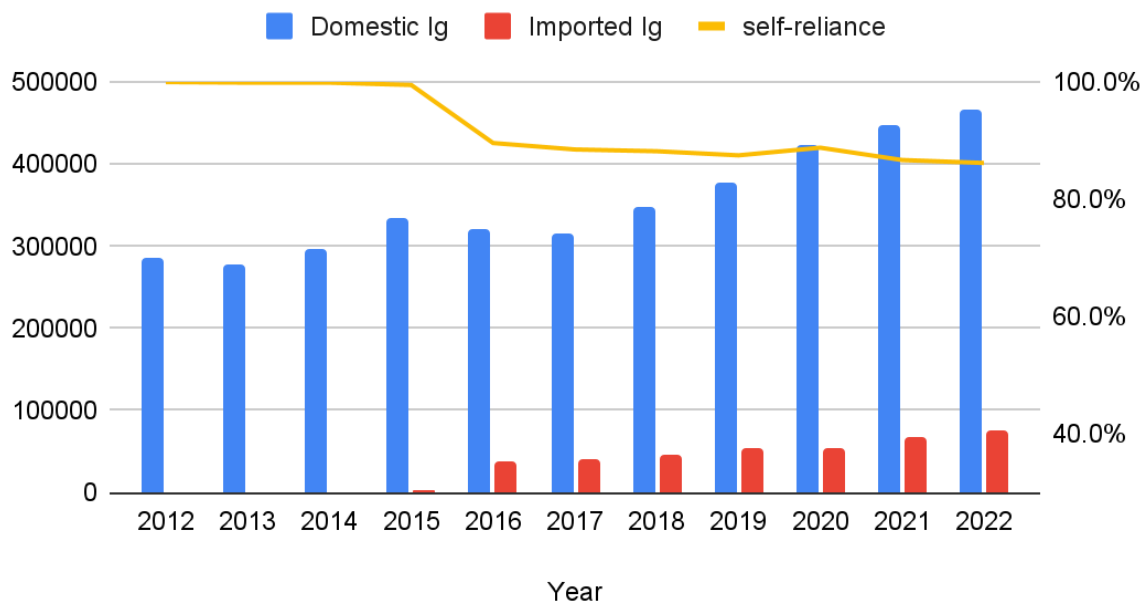
Source: National Blood Authority annual reports

New Zealand had the distinction of being exclusively reliant on domestic non-commercial, non-compensated plasma collections in 2012. This distinction is marred somewhat by the country's likely underuse of immunoglobulin. While neighbouring Australia was using 173 grams of immunoglobulin per 1,000, New Zealand was using only 66.2 grams per 1,000. (In 2021, Australia used 293 grams per 1,000, while New Zealand used 100.5 grams per 1,000.)

By 2015, however, despite the lower use, New Zealand's non-commercial, non-compensated plasma collection system began to show signs of inadequacy. New Zealand imported 1,828 grams of immunoglobulin, representing just 0.5 percent of patient needs that year. The hope that this was only temporary and New Zealand would soon be fully self-reliant again was in vain. Instead, New Zealand became just over 10 percent dependent on imports in 2016, and 13.3 percent dependent by 2021. The demand for immunoglobulin also spiked by 12 percent in 2022, auguring poorly for a return to self-sufficiency (Figure 2).

Figure 2: New Zealand's immunoglobulin self-reliance, 2012-2022

New Zealand immunoglobulin (Ig) self-reliance



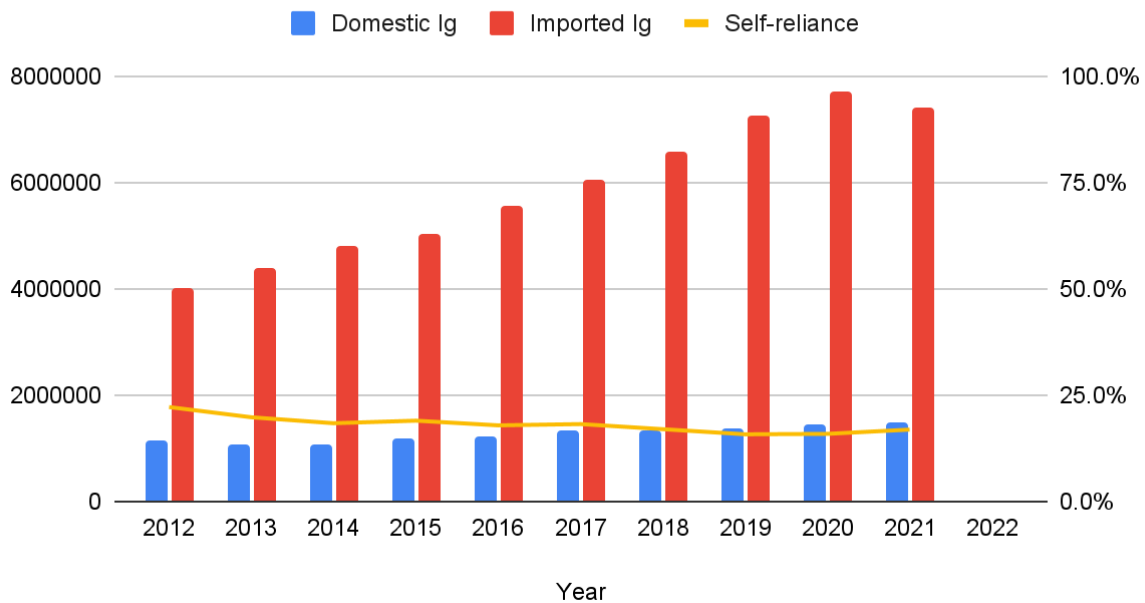
Source: New Zealand Blood Services annual reports

From 1998 until 2021, the UK did not collect plasma for therapies and so was entirely dependent on commercially-sourced therapies, overwhelmingly from the US. Use of immunoglobulin within the UK was also significantly lower than in Canada, Australia, or the United States, but the UK is slowly catching up as well. Since the ban on the manufacture of plasma therapies from domestic plasma collections, the UK has been discarding approximately 250,000 litres of recovered plasma for the past several years. They will now be able to use that plasma for the manufacture of therapies. Along with 11 new plasma collection centres, the UK is likely to be approximately 20 percent self-reliant by 2024, and may reach self-reliance levels as high as 30 percent by 2025. This is an improvement, but clearly inadequate.

In 2015, Canada was 81 percent dependent on US plasma collections. Six years later, in 2021 (the year for which we have the most recent data), that number had increased slightly to an 83.1 percent dependency on plasma collected in the US. However, if we include estimates for the three commercial plasma collection centres operating in Saskatoon, Winnipeg, and Moncton, the 2021 figure drops to 78.4 percent (Figure 3).

Figure 3: Canada's immunoglobulin self-reliance, 2012-2022

Canada immunoglobulin (Ig) self-reliance



Source: Canadian Blood Services Annual Reports

Expense

Apart from possibly asking too much of volunteer donors, an additional explanation for inadequate plasma collections is the expense involved in operating a non-commercial, non-compensated plasma collection system. Compared with the commercial alternative, non-compensated plasma collections typically cost between two to four times more according to a 2018 Health Canada expert panel (Health Canada 2018).

Australia releases more fine-grained data on costs than does Canada or New Zealand. In 2022, each gram of immunoglobulin from its non-commercial, non-compensated plasma collection system cost AUD\$118.99. That same year, imported immunoglobulin cost Australia AUD\$75.59 per gram, which indicates that the cost for non-commercial immunoglobulin included a 57 percent premium (Table 5). However, prior to 2022, a year with unusually high costs for commercial immunoglobulin, one non-commercial gram of immunoglobulin cost at least 2.25 times more than a commercially-sourced gram.

Table 5: Cost of domestic vs commercial immunoglobulin in Australia, 2019-2022

AUSTRALIA	2019	2020	2021	2022
Cost per gram Ig (domestic)	143.72	141.98	133.03	118.99
Cost per gram Ig (imported)	45.90	47.36	59.25	75.59
% Difference	3.131 times (213%) more expensive	2.998 times (199.8%) more expensive	2.245 times (124.5%) more expensive	1.574 times (57.4%) more expensive

Source: National Blood Authority Annual Reports

Hypothetically, if Australia were to source immunoglobulin entirely from the commercial sector, the total cost in 2022 would have been AUD\$608,576,073, as compared with the actual total cost of AUD\$810,400,000. The Australian health care system would have saved a little more than AUD\$200 million that year. Back in 2018 economist Robert Slonim also estimated the cost savings from using commercial immunoglobulin at “over AUD\$200 million” per year. According to Slonim, “Likely culprits for the higher domestic costs include the Red Cross Blood Service’s monopoly powers and not compensating donors. Since not offering compensation limits donations, it likely increases other costs, including recruiting donors” (Slonim 2018). Indeed, the primary driver of the higher cost is the lower volume of plasma collected at non-compensated centres compared with compensated centres which have similar annual operating costs.

The Australian data captures both the costs of collection as well as the costs of fractionation, or producing the medicine. In Canada, we have evidence about the collection costs specifically. Hoping to open and operate 40 non-compensated plasma collection centres, Canadian Blood Services (CBS) requested from the federal government \$855 million dollars over seven years in 2017, with an ongoing annual operating budget of \$248 million each year thereafter; its goal was to reach 50 percent self-reliance (Grant 2017). These figures translate into an annual ongoing operating cost of \$6.2 million per centre, with expected collections of 15,000 to 20,000 litres per centre, for a total of about 600,000 to 800,000 litres collected per year. Using CBS’s own estimates and ignoring all costs other than ongoing operational costs, this works out to an effective average collection cost of \$310 to \$413 per litre.

That same year Canadian Plasma Resources (CPR), a Canadian commercial compensated plasma company, made its third offer to supply CBS with plasma at a cost of \$220 per litre. This price would have been 41 percent cheaper than the lowest cost estimate, or 88 percent cheaper than the higher estimate. If Canada were to rely entirely on commercial compensated plasma collections the cost would be \$176 million per year compared with \$248 million if it were to rely entirely on CBS non-compensated collections. The annual operational cost savings amount to at least \$72 million.

CBS has not accepted any of CPR's offers. Being the only entity legally permitted to purchase plasma in the country outside of Quebec, CBS's decision has forced CPR to find other buyers for its plasma, which it did in the form of Biotest in Germany. CBS initially explained that the volumes CPR was offering were too small. But this explanation ceased to be relevant in CPR's subsequent offers, which promised to supply the exact volumes CBS was hoping to achieve with its own plasma collection plan.

To collect enough plasma to meet the needs of Canadian patients in 2019 would have cost provincial governments \$1.7 billion in collection costs alone. Canada would still need to pay for fractionation. Meanwhile, the cost of the plasma protein products Canada used between 2018 and 2019 was \$656 million, according to the CBS annual report (CBS 2019). It is easy to see why provincial governments declined the budgetary request, offering enough funds to open just 11 plasma collection centres.

If the costs cited above are accurate, and if the global situation is as described, why haven't Canada, Australia, and New Zealand opted to permit domestic collections of commercial compensated plasma?

“Encroachment” or “Crowding out”

The most important reason is the theoretical concern of “encroachment,” or what is sometimes called “crowding out.” The worry for governments is that compensated plasma collections, used to manufacture therapies, may adversely affect non-commercial, non-compensated blood collections used for transfusions. This worry dates to at least the publication of Richard Titmuss' *The Gift Relationship* in 1970.

The European Blood Alliance insists: “Payments to blood and plasma donors by commercial suppliers erode the current community-based, non-remunerated, donor population... In countries with dual systems (where unpaid and paid collection coexist), blood establishments who collect components for transfusion encounter increasing difficulties in recruiting and retaining unpaid donors” (EBA 2016). Bernardo Rodrigues, an advocacy officer with the European Blood Alliance, has said that when people are drawn by the cash incentive to give plasma instead of blood, “it's what we call crowding out” (Bencharif 2022).

It is hard to see the basis of the European Blood Alliance's claim. Over a span of 60 years, we still have no studies demonstrating encroachment or “crowding out” from the presence of commercial compensated plasma collections. There is no study showing this in any of the countries that permit a parallel commercial, compensated plasma collection system.

The European Directorate for the Quality of Medicines and Healthcare (EDQM) reports discussed earlier do not show that countries that permit commercial, compensated plasma collections have markedly fewer non-compensated donors (Table 6). They do not appear to show any negative relationship between compensated plasma collections and non-compensated blood and plasma collections.

Table 6: Number of whole blood donors per 1,000 residents in selected EU countries, 2017-2019

Donors per 1,000 residents	2017	2018	2019
Austria	36	34	35
Czech Republic	25	25	26
Germany	28	28	28
Hungary	39	26	n/a
Netherlands	19	20	21
Finland	22	22	21
Norway	19	18	18
Sweden	21	20	20
Italy	28	28	28
Spain	25	25	25
Greece	48	48	38

Source: European Directorate for Quality Medicine. Various years.

Consider the specific case of the Czech Republic. Following the introduction of commercial compensated plasma collections in late 2007 there was no decrease in non-compensated collections. Over a 10-year period from 2006 through 2016, plasma sent for fractionation went from 82,900 litres (8.05 litres per 1,000 residents) to 613,600 litres (58 litres per 1,000). Despite that more than seven-fold increase in collections, there was no corresponding change in the rate of whole blood collections. While Germany contributes the highest volume of plasma for fractionation in the EU, the most recent EDQM report shows the Czech Republic leading all of Europe in the rate of plasma collection at 65 litres per 1,000 residents in 2019.

The Czech Republic also follows the general EU standard of permitting one plasma donation every two weeks, up to 34 times per year. Austria permits 50 donations per year (once every three days, up to twice a week and up to three times every two weeks), while Germany allows up to 60 donations a year (once every two days). The United States, Canada, and Egypt permit twice weekly donations, with at least 48 hours between donations, up to 104 donations per year. However, only 0.3 percent of donors donate the maximum amount, with 49 percent of donors donating 10 or fewer times in 12 months. The average number of donations was 21.4 in a 12-month period (Schreiber and Kimber 2017).

Amongst the countries that allow parallel commercial plasma collections, the Czech Republic had the lowest proportion of whole blood donors at 26 per 1,000 in 2019, but that rate is nevertheless higher than Finland, Sweden, Norway, and the Netherlands. It was also

higher than the median rate of 22 donors per 1,000 residents within the EU, and only slightly lower than Italy's rate of 28 per 1,000.

At the aggregate level, there is no evidence of "encroachment" or "crowding out" in the Czech Republic. There is also no such evidence at the aggregate level in Austria. There are no systematic studies showing a negative impact from compensated plasma collections on whole blood collections in either of these countries.

Germany and Hungary are more complicated because, in the case of the former, there are compensated blood collections running in parallel with non-compensated collections, while in the latter there are laws requiring a once-yearly whole blood donation prior to being permitted to donate plasma. However, the German Red Cross, which does not compensate donors, continues to be the largest whole blood collector despite the presence of not only compensated plasma collections, but also compensated blood collections. And at least some in Germany deny that there has been a negative effect on whole blood donations after the introduction of compensated plasma collections. According to Dr. Franz Weinauer of the Bavarian Red Cross, for example, they hadn't witnessed encroachment from compensated plasma collections: "blood and plasma donors are not part of the same donor population," with older people giving non-compensated blood and younger people giving compensated plasma (Wetzel 2018).

When Canadian Blood Services asked its counterparts in Germany, Austria, Hungary, and the Czech Republic if they had witnessed "encroachment," the conclusion was: "no evidence of VNRBD [Voluntary Non-Remunerated Blood Donation] being tangibly impacted by remunerated source plasma operations" (Bédard 2020).

The aggregate data in the EU and the evidence available so far suggests that "encroachment" or "crowding out" is an interesting theoretical concern without much empirical support. There is not much support for such a concern in Canada or the United States either. In a study I conducted with my colleague, William English, we found the introduction of compensated plasma donation opportunities in three cities in Canada and three cities in the US had no effect on non-compensated blood donations (English and Jaworski 2020). On the contrary, there was a very small, positive effect on blood donations, more pronounced in Canada than the US.

Our explanation of the results is as follows.

First, there may be an advertising spillover effect from the introduction of a plasma collection centre. The more centres that collect blood or plasma in a jurisdiction, the more aware people will be of the need for both. Second, different populations are attracted to these opportunities for different reasons. Some people are not interested in opportunities to give plasma for compensation, while others are not interested in donating either blood or plasma unless it is compensated. Others may wish to donate, but the costs associated with donation are too high, which are made up for by the compensation. Some are motivated by image or reputational considerations – they wish to do something that is perceived as altruistic to appear to be altruistic.

Finally, the overlap in the population, the place where we do anticipate competition, is with people who are motivated by the lives they might save. Both non-compensated blood donations and compensated plasma donations save lives and help patients. So genuinely authentically altruistic people who are less interested in how their behaviour is perceived will be attracted to both opportunities.

In combination, these explanations suggest that we should anticipate increases in both blood and plasma donations from the parallel operation of compensated plasma collections, up to a certain threshold point of saturation.

To illustrate, suppose that there are 100 people with the following desires and motivations: 60 will not donate, either because they are unable for medical or other reasons, or they are not interested. Of the remaining addressable market of 40 potential donors, 15 will do it for compensation (potential dedicated plasma donors), 15 will do it for the sake of saving lives (open to being either blood or plasma donors), and 10 will do it out of image motivation (potential dedicated blood donors).

With perfect awareness of the opportunities, at least 10 will be dedicated blood donors, and at least 15 will be dedicated plasma donors. Of the remaining 15, some will donate blood while others will donate plasma, and they may switch sometimes.

With imperfect awareness, it is possible that a blood centre is currently only attracting eight of their potential dedicated 10 donors. A new plasma centre may increase general awareness, and so a blood centre may see one or more additional dedicated blood donors when a plasma centre opens. Advertising for a plasma centre may function as a reminder to those who are aware of both opportunities, and so may spur some of the 10 potential dedicated blood donors to make a blood donation.

In this population, encroachment could happen if there were perfect awareness and sufficient opportunities to donate in convenient ways. A blood centre would draw all 10 of the dedicated blood donors, plus some from the 15 who are motivated by saving lives. At the limit, they would have 25 blood donors. A new plasma centre may draw some of the 15 from the blood centre, and so lower blood donations in the jurisdiction.

We suspect that most jurisdictions are not like the hypothetical jurisdiction with perfect awareness and sufficiently convenient donation options, and so we think that it is more reasonable to expect not encroachment but enlargement of the donor population at both blood and plasma centres.

Alberta bound

At the end of 2020 Alberta chose to repeal the 2017 Voluntary Blood Donations Act that had prevented commercial compensated collections in order to preserve a monopoly on blood and plasma collections by public sector unions. Since the Act's repeal, three commercial centres have opened in the province, one in Calgary (2021), one in Edmonton (2021), and one in Red Deer (2022), with plans for a fourth in Lethbridge (2023). Together, these centres will contribute approximately 250,000 litres of plasma from commercial collections by 2024 (at maturity these four centres should collect closer to 300,000 litres per year).

The CBS's non-compensated plasma collection centre in Lethbridge is expected to collect 15,000 litres, while recovered plasma from whole blood donations in Calgary, Edmonton, and Red Deer should result in an additional 15,000 litres. Thus, the total amount of plasma collected should be approximately 285,000 litres in 2024, or a rate of 60.4 litres per 1,000 in a population of about 4.7 million people. Collections would be nearly twice Germany's, and comparable to the Czech Republic's (although still less than half of that in the United States).

Meanwhile, assuming 4.7 grams per litre, these collections would yield 1.34 million grams of immunoglobulin. In 2022, Alberta had the highest rate of immunoglobulin use in Canada at 293 grams per 1,000 residents, or 1.33 million grams.

By 2024, Alberta is likely to be the only jurisdiction in Canada that will be collecting enough plasma to make it very nearly 100 percent self-reliant. It will collect more plasma than any other province, including Quebec or Ontario, which have two and three times Alberta's population, respectively. Alberta will also be the only jurisdiction within CANZUK to reach this objective. Despite a smaller population, Alberta's collection volumes will outpace all of New Zealand's. Were New Zealand to follow Alberta's example, it, too, would be in a position to return to self-sufficiency quickly and cost-effectively.

Just four years after the repeal of a law that favoured unions and their jobs over patients and their therapies, Alberta is likely to exceed total plasma collections in the rest of Canada *combined*. This should raise questions about what would have happened in Canada had provincial governments listened to patients rather than public sector unions and so never enacted the Voluntary Blood Donations Act in Ontario (2014), then Alberta (2017), and finally in British Columbia (2018). One very likely possibility is that Canada would now be a net contributor to the global supply of plasma, like the Czech Republic, rather than a net drain on that supply.

In the wake of Alberta's decision to repeal the Voluntary Blood Donations Act, the publication of two separate reports — the Health Canada Expert Panel report (2018) and the Ontario Auditor General's report (2020) — both of which urged increased domestic plasma collection, and an unwillingness on the part of provincial governments to fund 40 plasma collection centres, Canadian Blood Services has decided to create a partnership with Grifols. The partnership will see Grifols open and operate several commercial compensated plasma collection centres as an "agent" of Canadian Blood Services. As an agent, all plasma collected by Grifols will be collected exclusively for CBS and CBS retains the right to veto any collection centre location decision by Grifols. Both organizations expect that the Voluntary Blood Donations Act in Ontario and British Columbia will not prevent Grifols from operating there on the grounds that, as an agent of CBS, Grifols will enjoy the exemption written into those laws for Canadian Blood Services. The partnership should result in significant increases in plasma collection, and so Canada's dependence on the US for plasma should decrease quickly.

Conclusion

On June 11, 2009, the World Health Organization issued "the Melbourne Declaration," a report formally entitled *100% Voluntary Non-Remunerated Donation of Blood and Blood*

Components. The WHO declared a commitment by 2020 to achieve global reliance on exclusively “non-remunerated” blood and blood components, including plasma therapies. Australia, New Zealand, the UK, and Canada each approved of the declaration.

It is now well past 2020, and there are no countries that have met the goal. Instead, since 2009, reliance on compensated or remunerated plasma collections has only increased to the current level of more than 80 percent.

Clearly, once upon a time it was conceivable that non-compensated plasma collections could succeed at meeting the needs of patients. But such a proposal was unrealistic by 2009 – not because people became less willing to donate plasma, but because the number of such donations necessary to meet the needs of patients had ballooned beyond what could be reasonably expected of even the most altruistic of countries.

In addition, the arguments against compensated plasma collections appear to be very weak. We have barely any evidence that compensated plasma donors have an adverse effect on altruism or solidarity, or that they adversely affect non-commercial, non-compensated blood and plasma collection for transfusion. In fact, hardly any of the objections to commercial compensated plasma collections withstand minimal scrutiny.

First, consider safety. Every country in the world uses plasma from the United States. Countries would not use therapies made with US plasma if they were less safe.

Second, consider claims of wrongful exploitation. Exploitation is best understood as either presenting someone with undue risk, undue pressure, or an unfair division of the benefits from trade. There is no undue risk when it comes to plasma donations at European frequencies, and little evidence of any harm at the legally-permitted higher Canadian and American frequencies. We encourage people to give plasma. It is not a risky procedure. There is also no undue pressure. In Europe, donors receive €30 to €50 for the time and effort required to give plasma, which can last up to an hour and a half, while in Canada and the US donors get between \$50 and \$75 per donation. This payment represents the largest cost for plasma collection companies. Donors receive more as a proportion of revenue per litre than the company does in profit. This is not only not unfair, but is a good deal.

As for altruism and solidarity, few arguments could be more beside the point. The point of a plasma collection system is not to give donors an opportunity to express their altruism or to promote community solidarity. The point of a plasma collection system is to collect enough plasma to ensure that every patient who needs plasma therapy has access to it. Perhaps more importantly, what truly threatens community solidarity and altruism is enduring unnecessary but foreseeable shortages of the lifesaving medicine that patients need. Shortages express the view that we don’t care enough about our patient community to do what works, to do what we need to do to ensure that patients can have the medicine that they can’t go without. Our policies are also hypocritical. We don’t permit commercial compensated plasma collections within our borders, but every country relies on them. If it is immoral to pay New Zealanders or Canadians, why is it moral to pay Americans?

The world did not reach anywhere near 100 percent reliance on non-compensated plasma collections in 2020. In fact, that goal is even further away today than it was when it was

articulated in 2009. We will not reach this goal by 2030 or 2040. Instead, we are much more likely to approximate 100 percent reliance on commercial compensated plasma collections than we are to approximate 0 percent. With the facts as they are, it is time to steer away from the iceberg and to create a policy framework that permits rather than forbids commercial compensated plasma collections.

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