

Session 3
“Plasma supply and
plasma-derived medicinal
products manufacturing:
experiences from The
Netherlands

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Sanquin Blood Bank

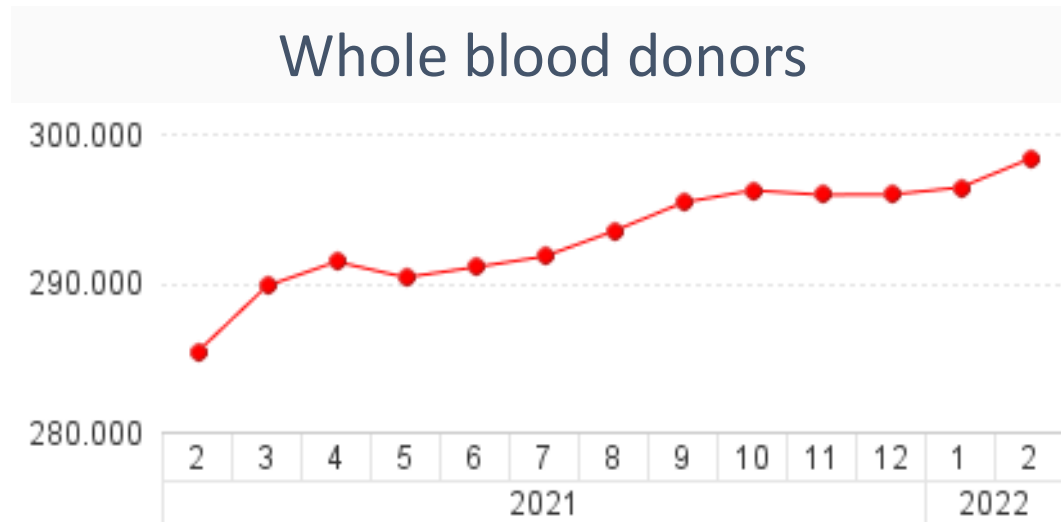


The Netherlands

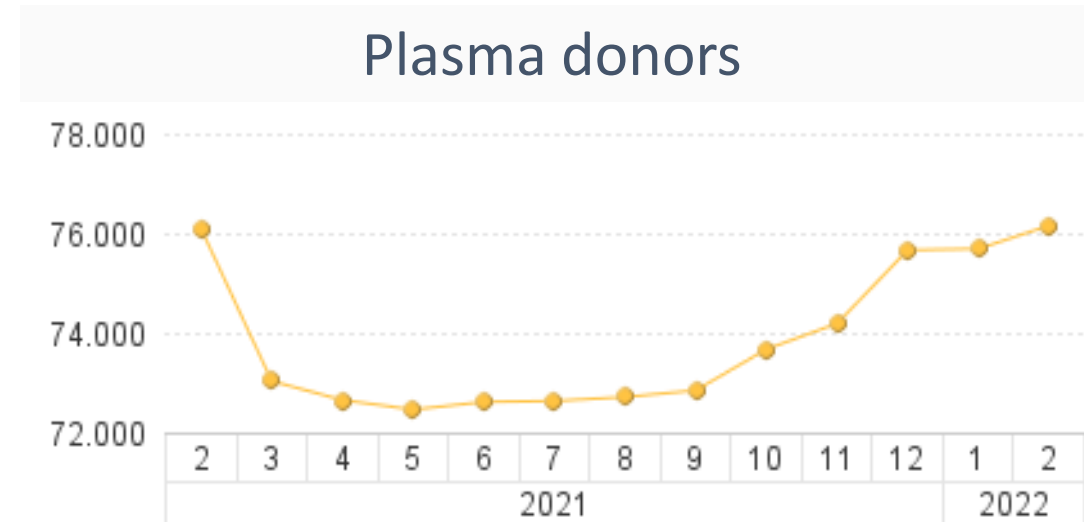


- **Centers**
- 43 Hybrid centers Whole blood and plasma
- 3 Whole blood-only centers
- 86 Mobile sites (4 trailers)
- 1 Plasma-only center: Powerbank
- 2 Processing centers: Amsterdam and Nijmegen

Donors country-wide



Whole blood donors (recovered plasma):
299,013



Plasma donors:
76,182

Amount of plasma collected and sent for fractionation (total amount and per 1,000 population);

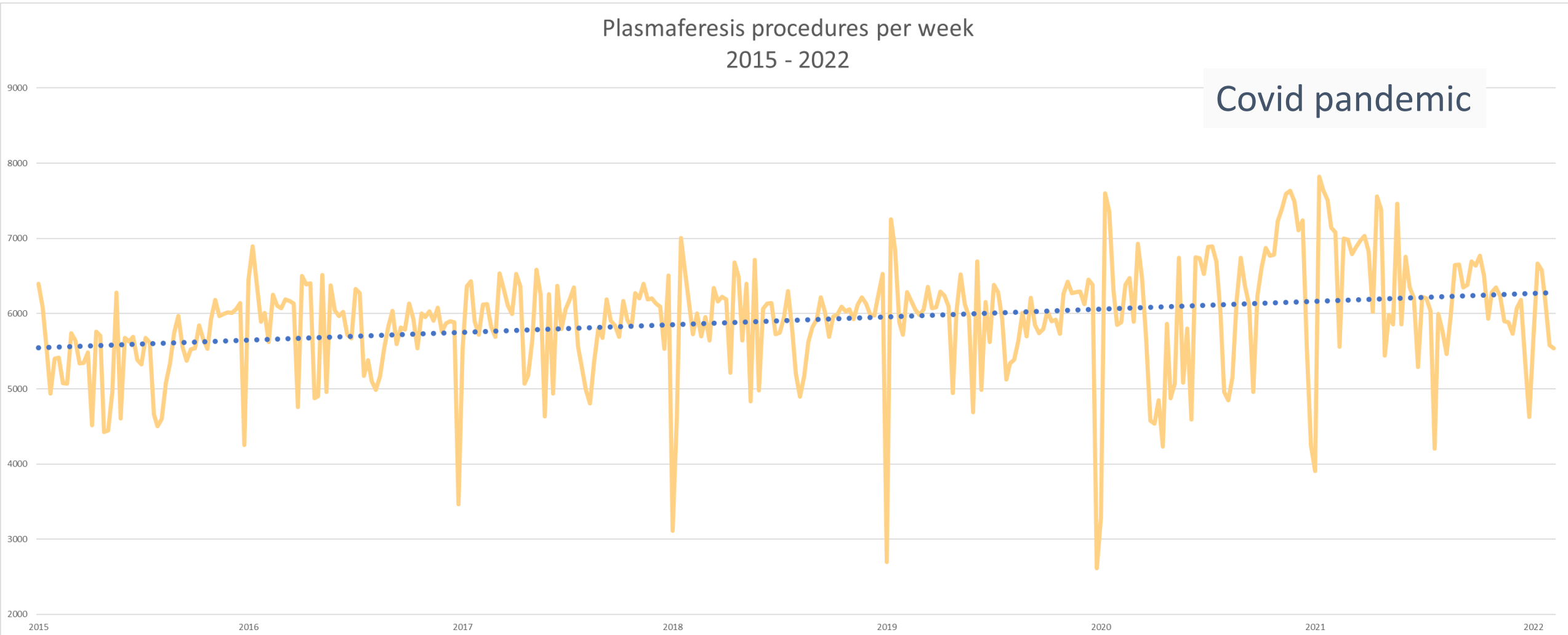
- **Plasma collection amount: around 350.000 kg per year**

Gebruik

	2020	2019	2018	2017	2016
Gebruik rodebloedcelconcentraten	400.646	405.338	403.900	406.938	418.384
Aantal bloedplaatjes (uit volbloed in donoreenheden)	226.480	235.360	247.625	249.870	252.775
Aantal eenheden vers bevroren plasma	1.991	1.153	1.875	1.499	2.491
Kilo's plasma totaal (inclusief aferese) geleverd aan Plasma Products B.V.	347.780	351.913	338.587	316.662	315.817

- **The overall market size is > 2.000 kg of lgs per year.**
- **Of a population of 17,5 million people in the NL this is:
>20 kg per 1000 inhabitants**

Clear effect of covid pandemic on plasmapheresis procedures



The PDMP product list in the Netherlands and trend of the demand for PDMPs, focused on the drivers

- The **Ig market** in the Netherlands is growing every year between 5 – 7%. The growth rate of SCIg is higher than that of IVIG. The main indications are Primary Immune deficiencies (PID), Secondary Immune deficiencies (SID) and Neuromuscular diseases like MMN and CIDP. Especially in SID and Neurology the pt numbers are increasing due to new cancer therapies in hemato-oncology and double aging in the population: the number of people above 60 is increasing and people live longer.
- The **albumin market** in NL is stable since years. Main indications are hypovolemia, shock, burns, replacement during plasmapheresis. The ban on HES might give some extra volume however the use of it in NL is limited. See link: [PRAC recommends suspending hydroxyethyl-starch solutions for infusion from the market | European Medicines Agency \(europa.eu\)](#)
- **Prothrombin Complex concentrate (PCC)** is used for major bleeding under VKA-therapy. Due to the growing use of direct oral anticoagulantia (DOAC) the use of PCC is declining. Antidotes for DOACs have become available but are very high priced and therefor PCC's are used off-label for this indication.
- Hemophilia: in NL **pdFVIII and FIX** have recently **disappeared** from the market due to national tenders where recombinant products are chosen. On top of that Hemlibra is getting a larger share rapidly.
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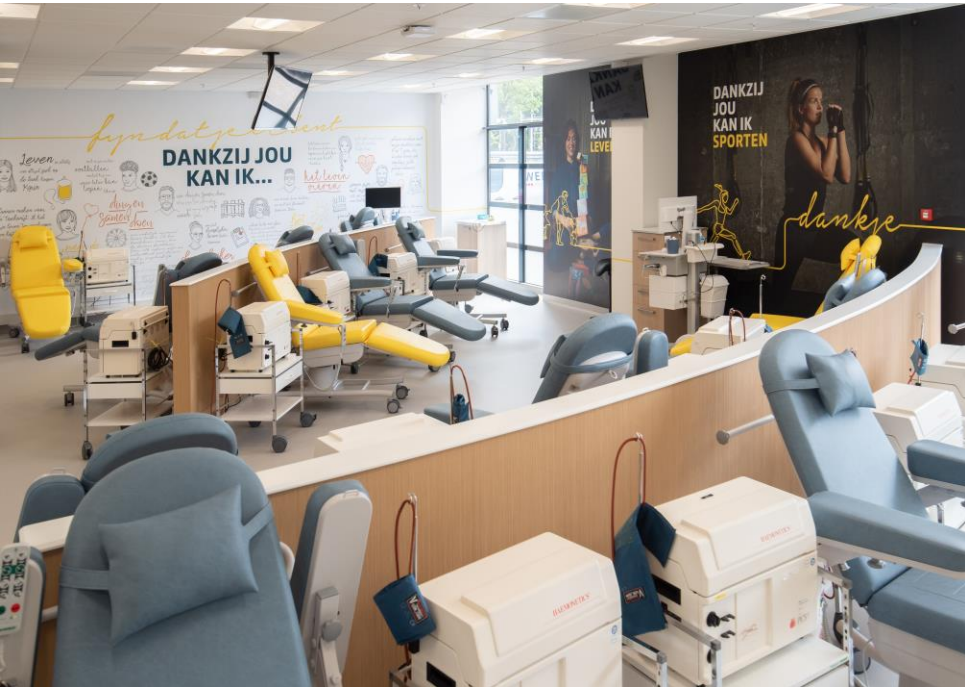
Levels of self-sufficiency, as the coverage of the demand for PDMPs following fractionation of national plasma and/or by market contribution

- The percentage of self sufficiency is 50-60 %.

Powerbank

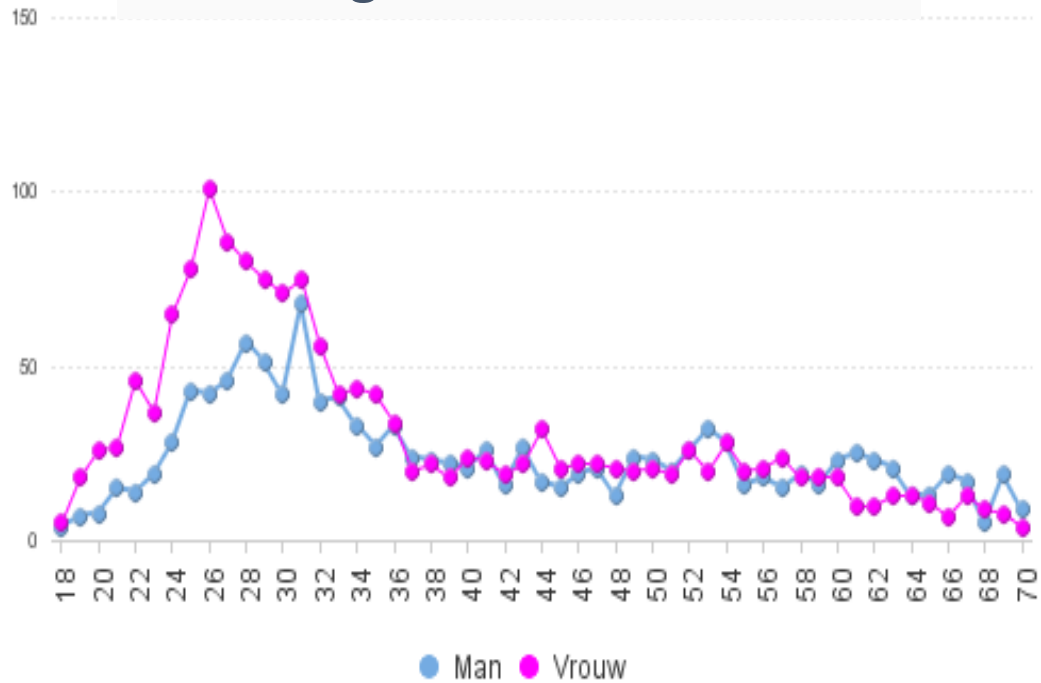
Plasma only center (open since September, 2020)

Utrecht, the Netherlands



Donors Powerbank

Age distribution

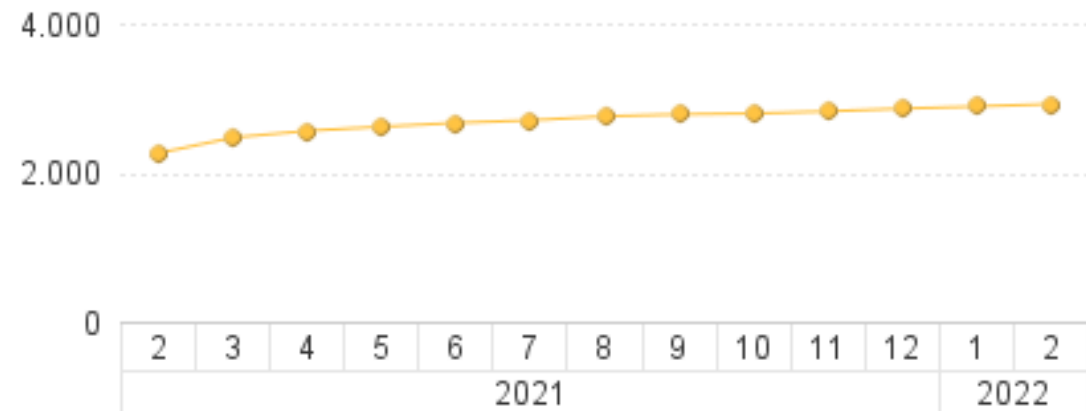


Male/Female

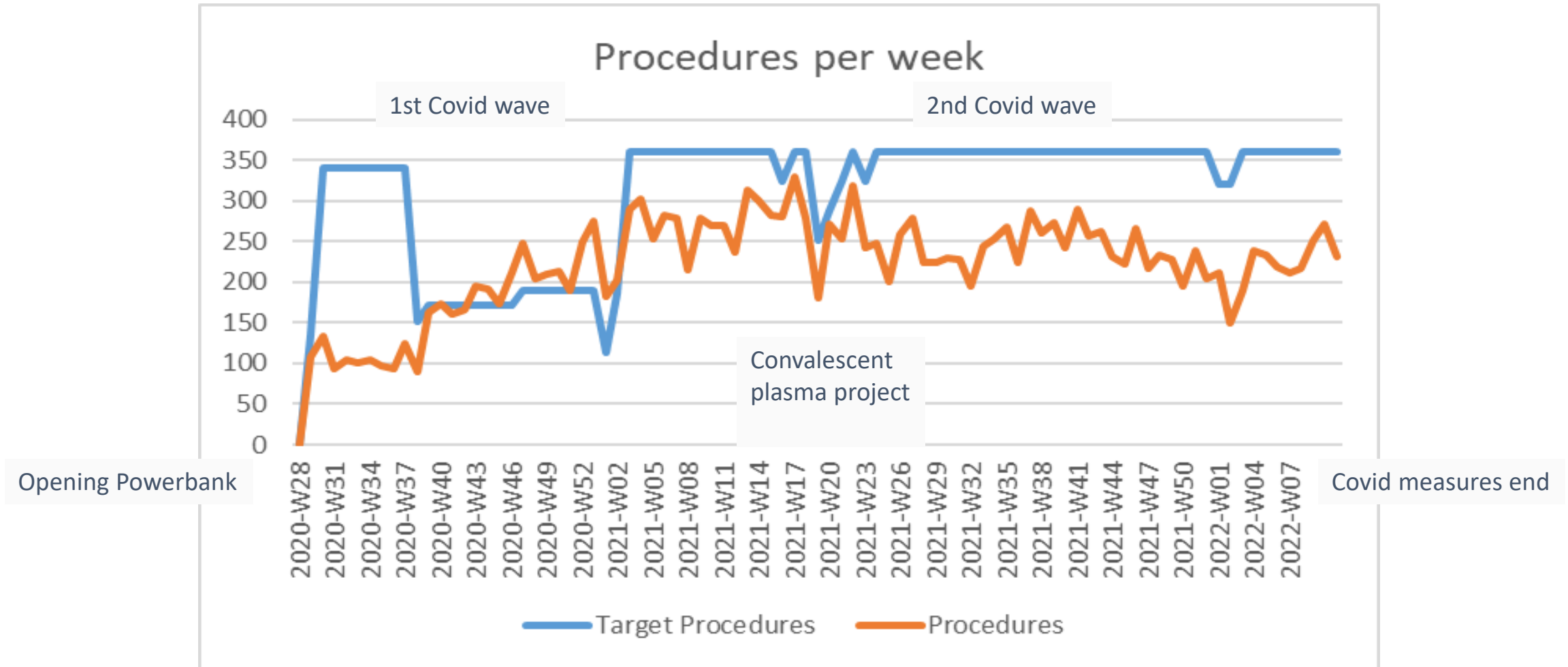
Man / PF Vrouw / PF



Plasma donors



Collection since September 2020



(Near) future targets

- Realise a donation frequency of 5;
- Target 2022:
 - 4000 donors;
 - 20,000 unpaid donations;
- Introduction loyalty program;
- Employing a welcome host to create more personal ambience



The Netherlands



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- 43 Hybrid centers W-P (+PL->21)
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- **Plans for 2025:**

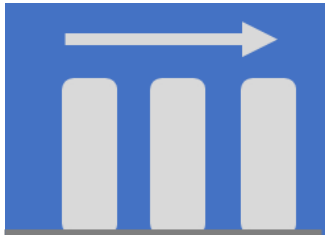
- **Hybrid center: 14,000 donors / 15,000 liter plasma per center, per year**
- **Plasma-only center: 5,000 donors / 25,000 liter plasma per center, per year**

Collection Ambition to 2025



Plasma target of **450,000** kg in 2025.

- Production costs have to decrease by 50% per liter plasma compared to our regular plasma product



The demand for whole blood will be stable for the coming years: **about 400,000 units** per year

Regulatory/organizational provision referred to PDMPs

- Open market, hospitals can choose their own products.
- Sanquin collects plasma, that is being sold to Prothya (the plasma manufacturer) to become available for the Dutch Health Care.
- A 10-year agreement with the Dutch Health Authority to deliver plasma for the Dutch health care system, approved by the Ministry of Health.

Acknowledgements

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- Peter Verheggen
 - Marloes Spekman

