DSKI

DANSK SELSKAB FOR KLINISK IMMUNOLOGI

DONORVIGILANCE ANNUAL REPORT

2023

DANISH HEMOVIGILANCE COMMITTEE

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DANSK SELSKAB FOR KLINISK IMMUNOLOGI

Forfattere

Region Hovedstaden
Christina Mikkelsen

Region Midtjylland
Sys Hasslund
Louise Ørnskov Drechsler

Region Nordjylland
Bitten Aagaard (chair)

Region Sjælland
Rune Larsen
Claess Henning Sørensen

Region Syddanmark
Mie Topholm Bruun

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INTRODUCTION

Since January 2020, the Danish Transfusion Centers have had a national guideline for reporting donor adverse reactions. This includes definitions of categories, severity, and imputability grading.

The Danish Hemovigilance Committee annually collects the donor adverse reaction data from the five regions to monitor and evaluate trends in donor health. Data are collected in the third quarter to allow a minimum of 6 months of follow-up for all reported adverse reactions.

Blood donation in Denmark has been proven a safe procedure, as shown in previous reports. The reports focus on serious adverse reactions as well as comparison of reaction categories across regions as part of the continuous work to improve the national standardization of the registration and to identify potential differences in procedure, equipment or prophylactic measures that could explain variances in the occurrence of a certain type of adverse event. To adhere to GDPR, numbers below 5 will not be displayed.

PREVIOUS REPORTS AND GUIDELINES

Guidelines for the reporting of adverse reactions in blood donors

https://dski.dk/guidelines-haemovigilance/

Previous donor vigilance reports

https://dski.dk/guidelines-haemovigilance/

MAIN FINDINGS FROM 2023

- A total of 5,946 adverse reactions were recorded across all donation types.
- Of these, 2% (121) occurred at other types of donations than whole blood or plasma donations e.g. blood tests for new donors.
- The adverse reaction rates for whole blood and plasma remain stable, whereas that of platelet donation is still largely influenced by the high number of citrate reactions registered in the Capital region.
- The rates of serious adverse reactions remain low at 5.7 per 100,000 donations and stable compared to 2022.
- The most common adverse reactions were vasovagal reactions, hematomas and infiltration.
- The rate of serious adverse reactions remains comparable or lower than other countries (UK 28 per 100,000 donations in the 2023 SHOT report[1] and Australia 53 per 100,000 donations in the 2021-22 report[2], France 296 per 100,000 donations in 2023[3] and Canada ~100-800 per 100,000 donations[4] in 2023, depending on donor status) however definitions of SAR vary across countries.

BLOOD DONATIONS AND ADVERSE REACTIONS IN DENMARK

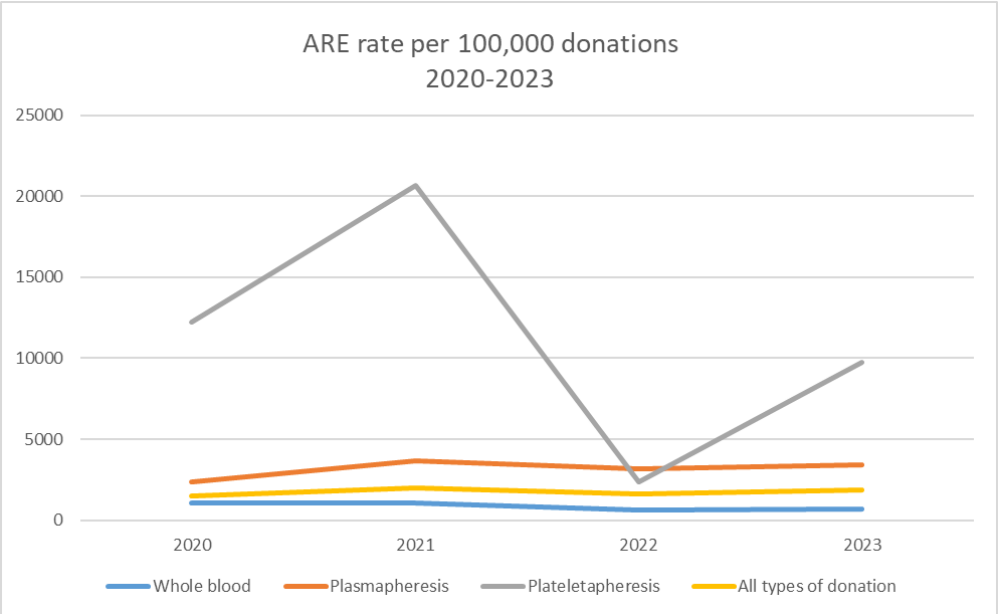
Compared to 2022, whole blood collections decreased by 8% in 2023, whereas plasma collection increased by 8.5% (Table 1). Platelet apheresis remained stable.

Table 1: Donations in Denmark 2023

Donations from 2023	North Denmark Region	Central Denmark Region	Region of Southern Denmark	Region Zeeland	Capital Region of Denmark	Total
Whole blood	19,901	42,201	34,595	27,731	59,175	**183,603**
Plasmapheresis	14,382	31,409	47,898	17,471	18,573	**129,733**
Platelet apheresis	68	186	229	297	268	**1,048**
Total number of donations in 2023	**34,351**	**73,796**	**82,722**	**45,499**	**78,016**	**314,384**

As shown in Figure1, the overall rate of adverse reactions remains stable across the last three years except for platelet apheresis. This, however, is due to the high number of citrate reactions registered in the Capital region, which has been the main driver of the high rates observed for platelet donation. The change in rates in the Capital region and the low rates in 2023, is most likely due to the implementation of a new IT system in mid-2023 which complicated data extraction for the 2022 report. Also, the new IT-system included a new registration procedure which most likely resulted in underreporting from the Capital region. The rates are expected to increase to the same level within the next year.

Figure 1: Rate of adverse reactions in Denmark from 2020-2023



Serious adverse reactions were defined according to the AABB severity grading tool as severity ≥3, which corresponds to symptom duration of more than 6 months, admission to hospital, surgery or impaired daily function for more than two weeks (grade 3), immediate need for medical assistance and life-threatening condition (grade 4) or death (grade 5).

As shown in Table 2, the total number of adverse reactions was 5,946. Less than 5 grade 4 AR were registered however with imputability unlikely/excluded. The SAR rate was 5.7 per 100,000 donations which is similar to that of 2022 (5 per 100,000 donations).

Table 2: Severity of adverse reactions in Danish blood donors 2023

Severity of adverse reactions in 2023	North Denmark Region	Central Denmark Region	Region of Southern Denmark	Region Zeeland	Capital Region of Denmark	Total
Grade 1	918	2,056	1,734	545	604	**5,857**
Grade 2	14	18	14	18	7	**71**
Grade 3	<5	8	<5	5	<5	**17**
Grade 4	<5	0	0	0	0	**<5**
Grade 5	0	0	0	0	0	**0**
Total number of adverse reactions	**934**	**2,082**	**1,749**	**568**	**613**	**5,946**
Total number of SAR			**18**			
Rate of SAR per 100,000 donations in Denmark			**5.7**			

ADVERSE RACTION SEVERITY AND DONATION TYPE

The 2022 report was the first time the Danish Hemovigilance Committee started reporting specifically on SAR in donors. Compared to last year the distribution of SAR looks slightly different. While nerve injuries still comprise around one-third of SAR, an increase in serious vasovagal reactions was observed. SAR rates across the different donation types were similar to 2022 with 3.8 vs 4.5 SAR per 100,000 donations for whole blood and 7.7 compared to 5.9 for plasma donation. For platelet donation no SARs were reported in either 2022 or 2023.

Figure 2: Serious adverse reactions by category, total 2023

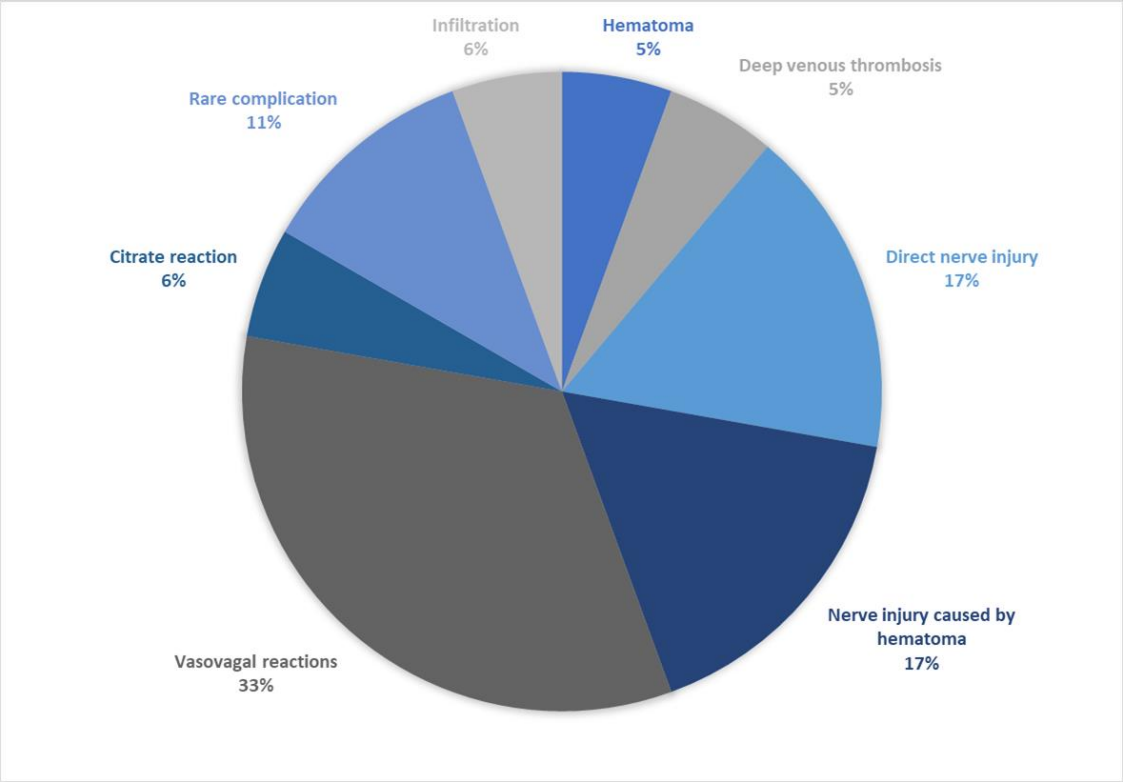


Table 3: Severity and donation types 2023 in total numbers

Severity of adverse reactions in blood donations 2023	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total number
Whole blood donation						
North Denmark Region	265	13	<5	<5	0	**280**
Central Denmark Region	435	13	<5	0	0	**450**
Region of Southern Denmark	225	5	0	0	0	**230**
Region Zeeland	160	8	<5	0	0	**170**
Capital Region of Denmark	177	6	<5	0	0	**184**
Plasma donation						
North Denmark Region	646	<5	0	0	0	**647**
Central Denmark Region	1,600	5	6	0	0	**1,611**
Region of Southern Denmark	1,485	9	<5	0	0	**1,495**
Region Zeeland	382	10	<5	0	0	**395**
Capital Region of Denmark	260	<5	0	0	0	**261**
Platelet donation						
North Denmark Region	<5	0	0	0	0	**<5**
Central Denmark Region	<5	0	0	0	0	**<5**
Region of Southern Denmark	14	0	0	0	0	**14**
Region Zeeland	<5	0	0	0	0	**<5**
Capital Region of Denmark	82	0	0	0	0	**82**

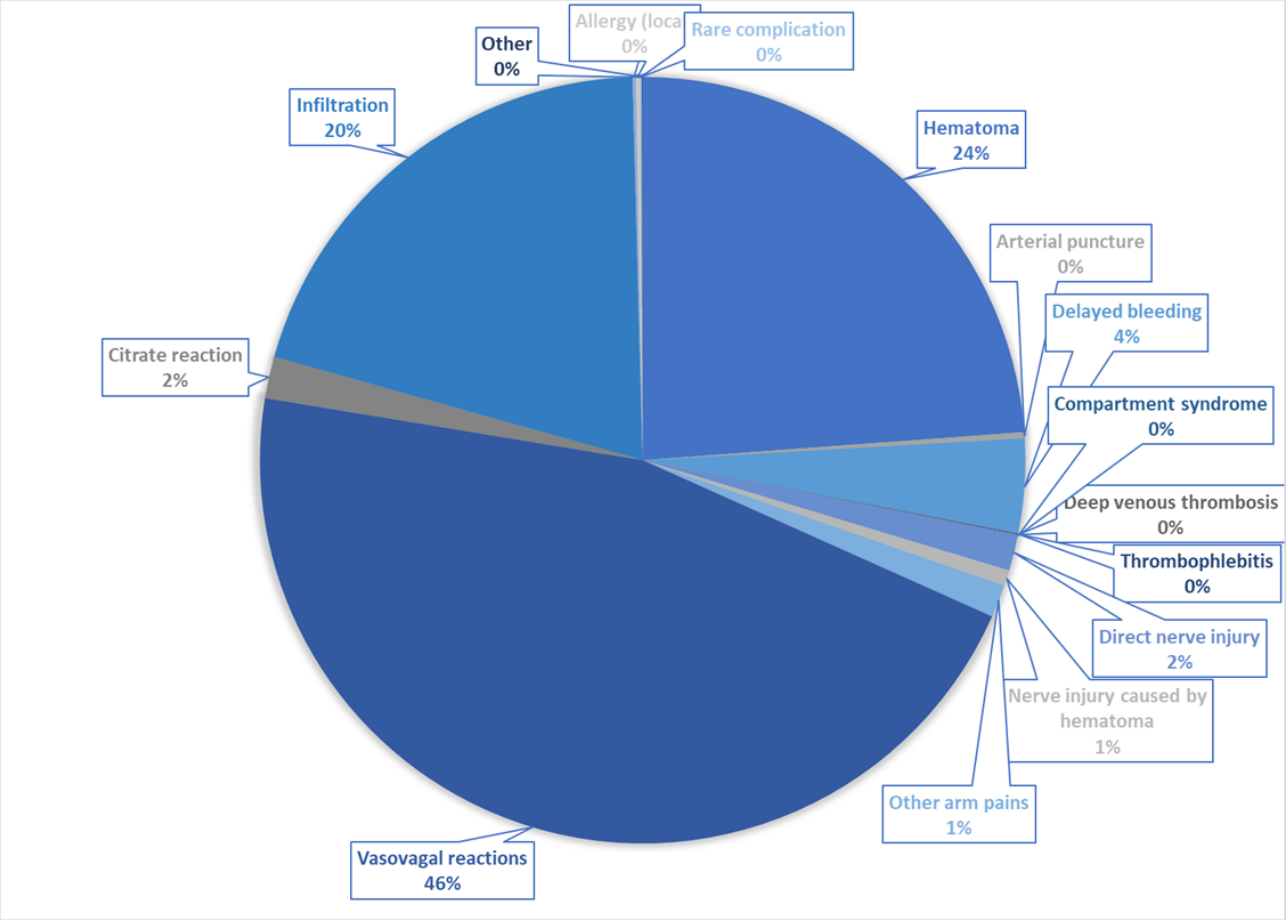
Rate of SAR per 100,000 whole blood donations in Denmark	**3.8**
Rate of SAR per 100,000 plasma donations in Denmark	**7.7**
Rate of SAR per 100,000 platelet donations in Denmark	**0**

ADVERSE REACTION CATEGORY AND DONATION TYPE

The distribution of adverse reactions across whole blood, plasma and platelet donations has small but potentially important differences compared to 2022 (Figure 3). While around 50% still comprise vasovagal reactions, an increase in the number of infiltrations from 14 to 20% was observed and number of hematomas decreased by 6%. Just like in 2022 <5 adverse reactions in whole blood have been misclassified as infiltration however this does not explain the increase observed. It could be speculated if staff have simply become more aware of the difference between hematoma and infiltration or if it is a genuine increase that may be associated with the increasing number of plasma donations.

For the 121 adverse reactions that occurred at other types of donations these were predominantly vasovagal reactions (80%) and hematomas (17%).

Figure 3: adverse reactions by category, total 2023



The total numbers of the different types of adverse reactions are listed in Table 4.

When looking into changes of rates for the different categories, the following was observed. The rate of infiltration in plasma donation increased from 592 per 100,000 plasma donations in 2022 to 922 per 100,000 plasma donations in 2023. For onsite vasovagal reactions without loss of consciousness an increase

was also observed, from 1,066 to 1,212 per 100,000 plasma donations. There has in many regions been a focus on correct registration for infiltration compared to hematoma in apheresis donations. The slight decrease in rate for hematomas in plasma donation could indicate that some of the changes for infiltration are due to improved registration practice. However, it does not explain the full increase in infiltration registrations which instead could be the effect of the 8.5% increase in plasma collection.

The Hemovigilance Committee has in the last three years had a focus especially on the number and rates of delayed bleeding in plasma donors. This was initiated because we observed a lower rate of delayed bleedings in blood banks that used cohesive compression bandages. After implementing cohesive compression bandages in other blood banks, the occurrences of delayed bleeding in plasma donors decreased, indicating that the regions' preventive strategies have been successful.

Table 4: Adverse reaction category and donation type in total number

Type of adverse reactions in 2023	Whole blood	Plasma donation	Platelet donation	Total number
Hematoma	285	1,104	7	**1,396**
Arterial puncture	11	<5	0	**14**
Delayed bleeding	32	205	0	**237**
Thrombophlebitis	0	<5	0	**<5**
Deep venous thrombosis	0	<5	0	**<5**
Compartment syndrome	0	<5	0	**<5**
Pseudoaneurysm	0	0	0	**0**
Arteriovenous fistula	0	0	0	**0**
Direct nerve injury	34	55	0	**89**
Nerve injury caused by hematoma	19	20	0	**39**
Other arm pains	26	55	0	**81**
Vasovagal reactions				
Onsite without LOC	779	1,573	6	**2,358**
Onsite with LOC	92	128	0	**220**
Offsite without LOC	18	18	0	**36**
Offsite with LOC	14	5	0	**19**
Citrate reaction	0	19	85	**104**
Infiltration	<5	1,197	<5	**1,203**
Air embolism	0	0	0	**0**
Hemolysis	0	8	0	**8**
Allergy (local)	<5	9	0	**10**
Anaphylaxis	0	0	0	**0**
Rare complication	<5	<5	0	**<5**
Other	0	<5	0	**<5**
Total number of adverse reactions	**1,314**	**4,409**	**102**	**5,825**
Rate of adverse reactions per 100,000 donations*	**716**	**3,399**	**9,733**	**1,891**

*Off the corresponding donation type

Some donors donate blood to use for test validation and other laboratory uses. In total, 121 (2%) of the adverse reactions occurred at other types of donations and are not included in this table.

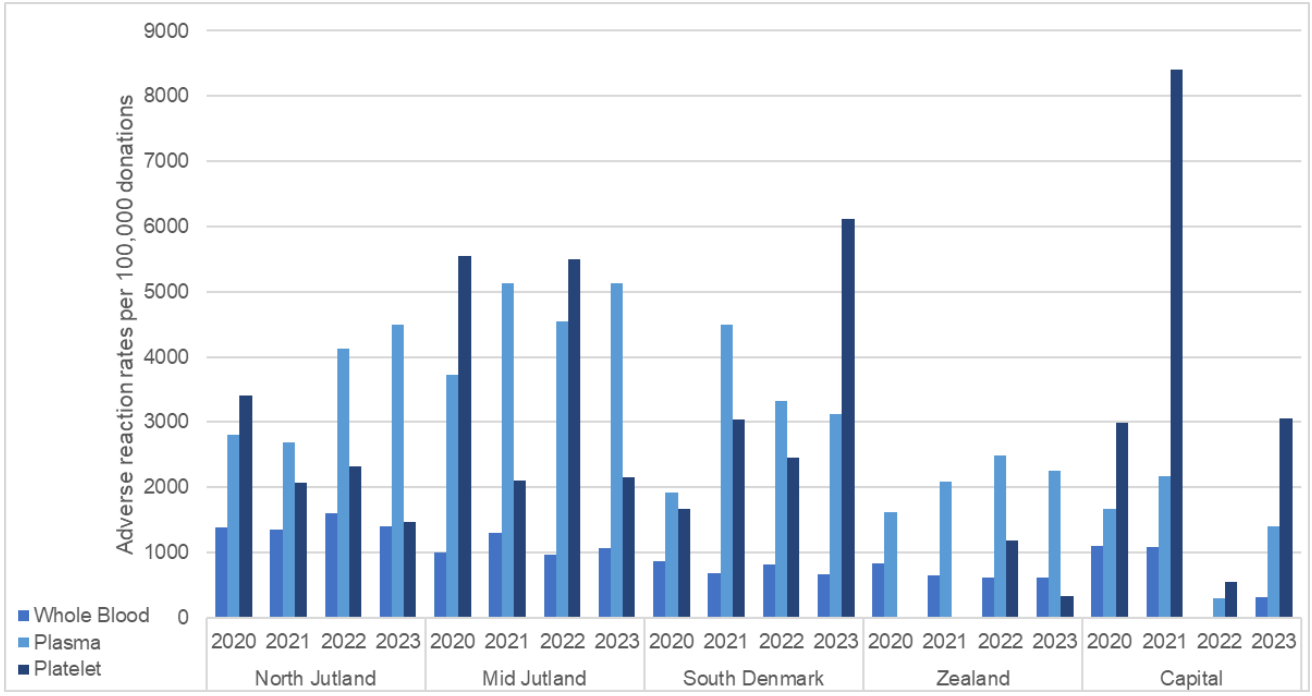
ADVERSE REACTION RATES IN THE DIFFERENT REGIONS

The regional rates remain quite stable within each region for whole blood donation. However, there continues to be a large variation across the country. For the Capital Region there seems to be a slow adjustment to the new IT-solution implemented in June 2023 as rates are now starting to resemble those prior to summer 2023. As mentioned previously, the Capital region data extraction for 2022 was complicated by the change in IT-system resulting in very low rates.

For plasma donation, the rates continue to be highest in the regions with the highest collection numbers and plasma centers.

The platelet adverse reactions rates are highly sensitive to even small changes in absolute numbers due to the relatively low number of platelet apheresis performed. It is clear, that the low threshold for registration of citrate reactions in the Capital Region persist as rates are 10-fold higher than the rest of the country. And as shown in Figure 5, it is almost exclusively comprised of citrate reactions.

Figure 4: adverse reaction rates per 100,000 donations in the five regions, 2020-2023



*In this figure the rates of adverse reactions per 100,000 donations of the corresponding donation type are shown. Due to very high rates for platelet donation in the Capital region in 2020-2021, 2023, these rates (on the figure marked with *), are calculated as rate per 10,000 platelet donations to allow one combined figure. As noted in previous reports the high rates are due to a lower threshold for registration of citrate reaction.*

RATES OF DIFFERENT CATEGORIES IN THE DIFFERENT REGIONS

Figure 5: adverse reaction rates in whole blood by category in the five regions, 2023

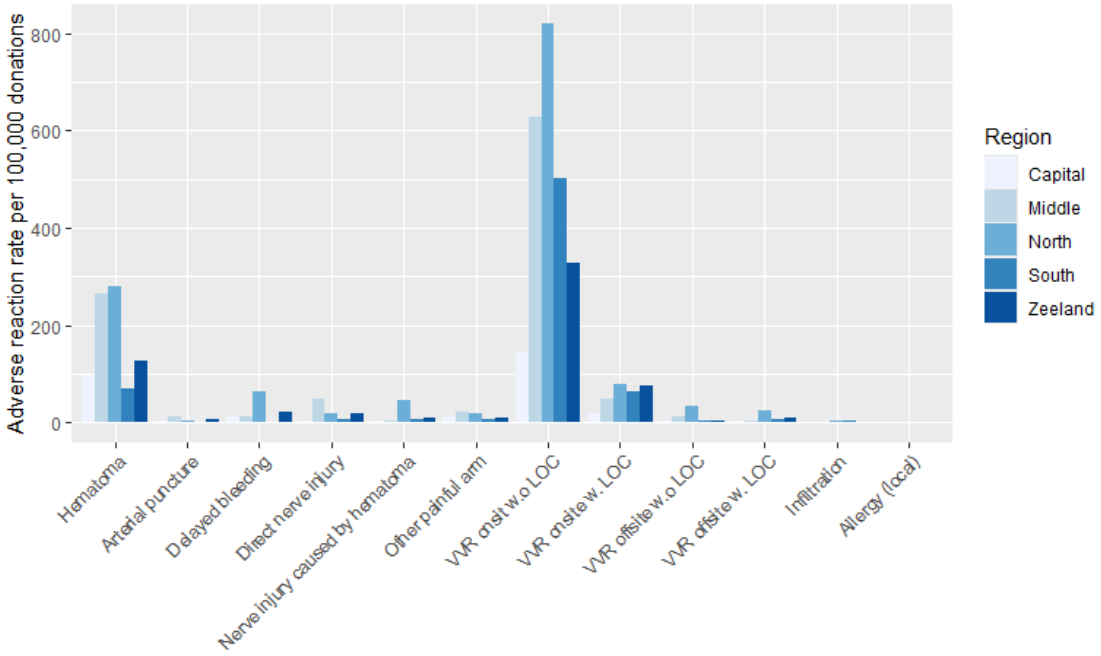


Figure 6: adverse reaction rates in plasma donation by category in the five regions, 2023

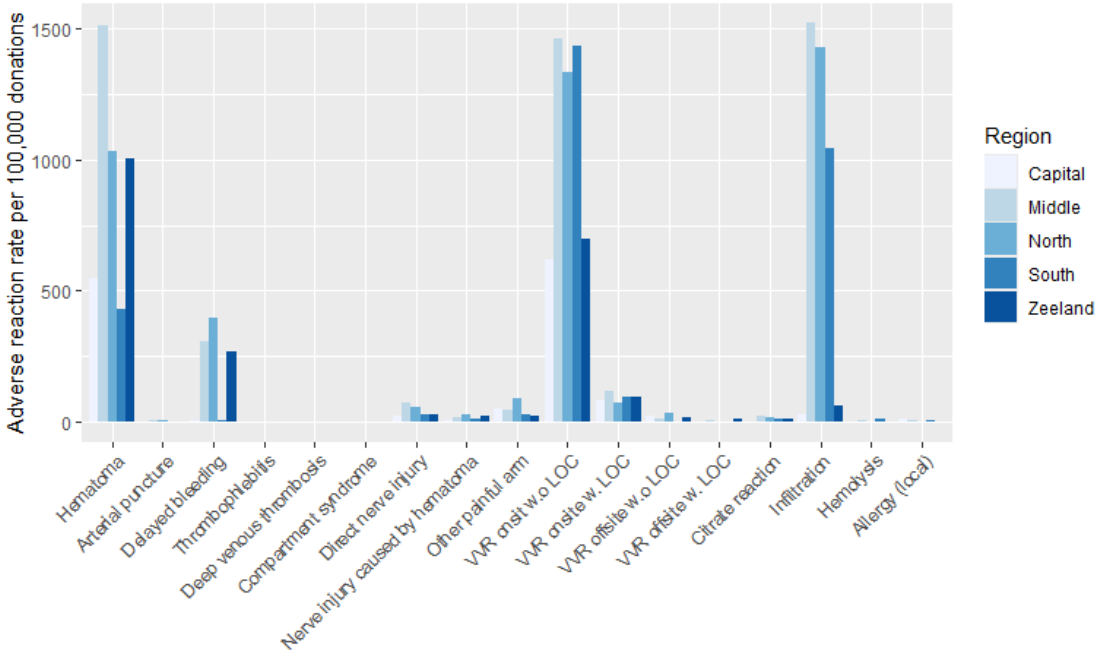
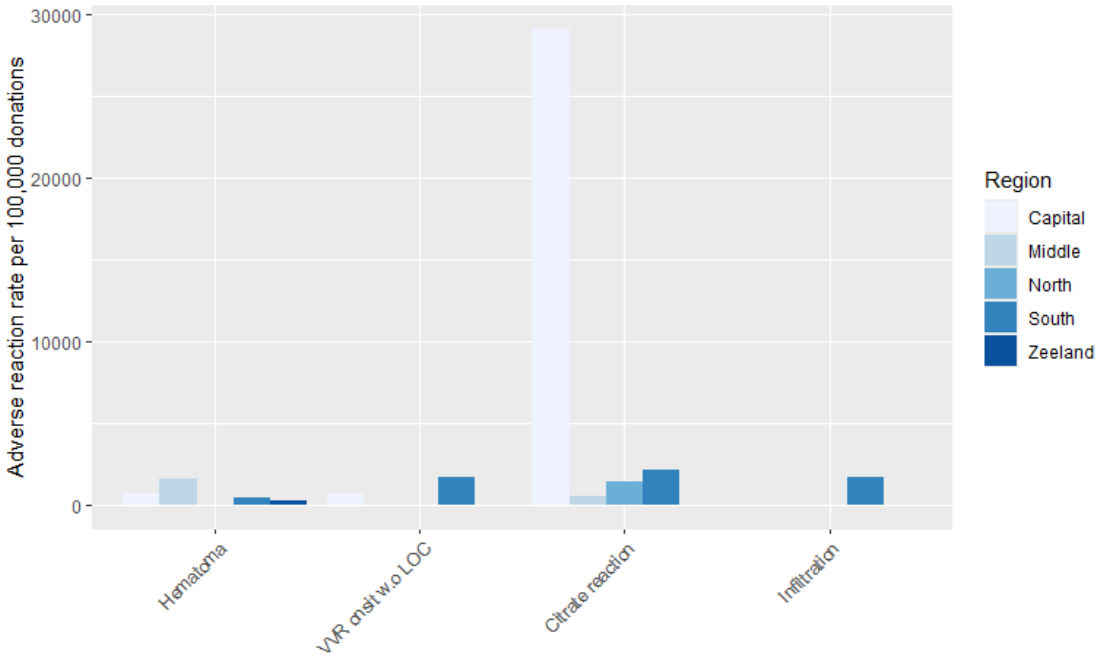


Figure 7: adverse reaction rates in platelet donation by category in the five regions, 2023



CONCLUSION

This is the fourth year with a national donor vigilance system. Across all regions and donation types, the rates appear quite stable (Figure 1) apart from platelet apheresis where the regional difference in registration of citrate reactions remains an issue. In addition, the relatively low number of platelet apheresis causes a great variability in rates across the four years of registration (Figure 4).

In the coming years, the plasma collection in Denmark will be vastly increased with many regions building new designated plasma centers. So far, the increase in plasma collection has had very little effect on the overall AR rates, but there has been an observed increase in delayed bleeding which the Hemovigilance Committee will continue to monitor.

The SAR rates also remain stable and comparable or even lower than other countries supporting the conclusion that it remains extremely safe to donate blood in Denmark.

In the coming years, the committee will work to further harmonize registration practices across Denmark with a strong focus on citrate reactions in platelet apheresis. There will also be a separate study of delayed bleeding and the effect of elastic bandages.

REFERENCES

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2. https://www.blood.gov.au/haemovigilance-reporting
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