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A Danish national, multicentre evaluation of the new donor vigilance system among different staff groups

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Abstract

Background and Objectives: Two years after implementing a new national donor vigilance system, the Danish Haemovigilance Committee conducted a nationwide survey to evaluate the implementation among different staff groups. We present the results here.

Materials and Methods: The study was designed as an anonymous online survey to evaluate the satisfaction with the new registration, understanding of the parameters used and the user-friendliness. The REDCap platform was used. The questionnaire consisted of 22 questions. Ordinal variables were answered using five-point Likert scale (1 = strongly disagree to 5 = strongly agree). The data were analysed using descriptive statistics. Successful implementation was defined as mean overall satisfaction ≥4 and mean understanding of the individual components (adverse reaction category, severity and imputability) in the registration ≥4.

Results: In all, 104 staff members (77.9% donation staff) participated. The mean (SD) overall satisfaction among all participants was 3.96 (0.94), highest among medical doctors (4.43 (0.78)) and lowest for administrative or other personnel (2.78 (1.09)). The mean scores for understanding the adverse reaction categories, severity and imputability were 3.92 (0.94), 3.92 (0.94) and 3.88 (1.00), respectively. Experience with a previous donor vigilance system was associated with lower scores. The most successful implementation programme included a medical doctor for introduction and a contact person.

Conclusion: The goal for successful implementation was not met. However, the overall attitude towards the new registration was positive and indicates that the system is suitable for different staff groups. Our results suggest that implementation could benefit from special attention to administrative staff and those accustomed to another donor vigilance system.

Keywords

donors, donor health, haemovigilance

Highlights

- International standards for the categorization of adverse reactions and for their severity and imputability were found to be easy for donation staff to apply.
- Implementation of a new donor vigilance system is more challenging when a donor vigilance system is already in place.
- Implementation can be improved by an in-person introduction to the system and by having a defined contact person.

INTRODUCTION

Denmark is divided into five healthcare regions. In each, a regional blood establishment (BE) manages blood donation and registration of donation-related adverse reactions in blood donors.

In January 2020, the Danish Haemovigilance Committee implemented a new national donor vigilance system. The system was based on three parameters: (1) adverse reaction categories as defined by the ISBT; (2) severity as defined by the AABB; and (3) a modified version of imputability levels adapted to donor vigilance by the ISBT [1].

In the new donor vigilance system, registration of donation-related adverse reactions is performed on-site at the donation facilities in case of immediate reactions or later in case of delayed reactions.

The registration is done directly in the blood bank IT system and is a standardized code that includes a category number and a severity and imputability score. It is registered in the donor's donation chart, as a separate entry under the corresponding donation. Staff members can access previous registrations using donor id.

The staff member initially notified about the adverse reaction is responsible for ensuring immediate and correct registration. Therefore, donation staff and secretaries perform the majority of registrations. More complicated or severe reactions can be passed on to the attending physician for clinical assessment and subsequent registration of the adverse reaction. The Haemovigilance Committee provided national guidelines that included definitions of the three parameters used and examples of how to rate severity and imputability. This was included in regional standing operating procedures, which staff members had to sign off when read.

The regional BE annually provides the Haemovigilance Committee with data extraction using a predefined template. The committee then prepares the national report.

Currently, two IT systems are used in the Danish BE. One region uses Blodflödet and the remaining four, ProSang. In Blodflödet, three separate entries are made during the registration, one for each parameter. In ProSang, all three parameters are embedded in a single three-digit code.

The ISBT definitions and AABB severity tool have already been validated across different staff groups [2, 3], and users especially found imputability hard to assess. However, participants were predominantly senior staff members.

Following implementation of this new registration in Denmark, the Haemovigilance Committee repeatedly received questions concerning imputability ratings, in particular from staff at donation sites. Therefore, to evaluate the success of the implementation and to identify areas for improvement, a national survey was planned in order to study both the user attitude towards the system and the feasibility including user-friendliness of the system. The survey included all staff members working with blood donors in any of the Danish blood banks and blood collection sites, which enables us to investigate potential differences among staff groups, different age groups and to evaluate the potential differences between educational groups, age groups among staff and to evaluate the different methods of implementation on a national level.

MATERIALS AND METHODS

Survey design

The survey principles by Dillmann et al. [4] and Schleyer and Forrest [5] were followed, while the results were reported in accordance with Eysenbach [6]. The survey design was a structured format comprising a maximum of 22 questions, with adaptive questioning to reduce complexity and volume for the participants. For staff members in the Capital region, two follow-up questions were included due to a different IT system than in the other four regions. Single and multiple-choice questions were included with answer types assigned to nominal, ordinal and ratio scales. Ordinal variables were answered using five-point Likert scale (1 = strongly disagree to 5 = strongly agree). The fully translated questionnaire is included in the Supplementary Material. In the following, we present a brief overview.

The survey-landing page described the survey topics and length, goals and provided information about data handling according to the European General Data Protection Regulation (GDPR). The survey was voluntary, non-incentivized and fully anonymous. Survey information was not suitable to draw any conclusions to the participant, nor were technical identifiers (IP address, or other) stored. To start the survey, participants were required to give consent to their participation. The first survey section included demographical questions related to the respondent's age, gender, professional position, educational background, time of employment in a BE and healthcare region. In the second section, participants were asked a series of questions concerning the previous donor vigilance system and the implementation procedure of the new system. The third section addressed participant satisfaction with different aspects of the system including IT solutions and the three parameters. The fourth section addressed the

system's user-friendliness and understanding both overall and for each of the three parameters. The fifth and final section asked participants whether they were aware of different ways to add comments or do follow up registration and whether they knew that data were routinely published.

Successful implementation was defined from the point of view of feasibility and user satisfaction as an overall satisfaction score of ≥4 and a score of ≥4 in understanding each of the three parameters.

Survey draft and validation

The Haemovigilance Committee drafted the questionnaire. Then, —one or two staff members from each region were invited to participate in a focus group meeting to inquire about: (1) the overall perception and understanding of the donor vigilance system; (2) the course of implementation; (3) expectations to results from the system; and (4) others. The participants in the focus group meeting unanimously commented that the survey should address the following: (1) Are users familiar with the option to provide additional comments if deemed relevant? (2) Do users omit registration due to lack of routine or time? (3) Do users know that results are used to improve donor safety and whether they know where to find more information about the results? (4) Do the users understand how to rate severity and imputability and are they satisfied with the guidelines? Item one through three were addressed in the survey's fifth section and item four in the fourth section as previously described in Section 2.1.

These four points were included in a revised version of the questionnaire. We then asked the focus group to fill out the questionnaires and provide their comments.

We received five responses. They commented on the use of abbreviations and highlighted that questions addressing technical issues in the IT system Blodflödet should be limited to participants from the relevant region. Based on these comments, we revised the questionnaire and asked a new group of staff members to test it and provide their comments. We received nine responses in total from three different regions, five include comments/suggestions and four respondents had no comments.

The respondents reported that the questionnaire took between 5 and 10 min to complete, which we considered acceptable. Furthermore, they asked that the Danish translation of imputability be used. Also, to add the possibility to reply if they themselves did not do the actual registration. Finally, for a couple of multiple-choice questions, they missed the opportunity to reply, "Do not know".

Recruitment

The target group included BE staff members working with the new donor vigilance system and included IT staff, secretaries, medical doctors, nurses, phlebotomists and all other staff members in contact with blood donors. The survey was administered between 01.04.2022 and

TABLE 1 Presentation of the study cohort

Study cohort	Number (percentage)
Sex	
Female	99 (95.2)
Male	5 (4.8)
Age	
20–29	8 (7.7)
30–39	18 (17.3)
40–49	31 (29.8)
50–59	23 (22.1)
>60	24 (23.1)
Education	
Medical laboratory technologist	42 (41.3)
Nurse	42 (40.4)
Medical doctor	7 (6.7)
Other[a]	12 (11.5)
Position in the blood establishment	
Donation staff	81 (77.9)
Medical doctor	7 (6.7)
Other	16 (15.4)
Time employed in the blood establishment	
<1 year	13 (12.5)
1–3 years	13 (12.5)
3–5 years	9 (8.7)
>5 years	15 (14.4)
>10 years	54 (51.9)
Region	
1	43 (41.3)
2	23 (22.1)
3	17 (16.3)
4	17 (16.3)
5	<5 (<4)
Response rate by region	
1	61%
2	33%
3	57%
4	22%
5	29%
National response rate	40%
IT system	
Blodflödet	43 (41.3)
ProSang	61 (58.7)
Previous donor vigilance system	
Yes	66 (63.5)
No	8 (7.7)
Do not know	30 (28.8)

[a]Includes administration, secretary, other health and non-health background.

30.04.2022 (01.05.2022–31.05.2022 in the Zeeland region) via REDCap [7, 8]. REDCap is a freeware system approved for research projects in the Capital Region by the Danish Data Protection Agency (I-suite Nb. 05196).

Information about and a link to the survey was administered from the Danish Society of Clinical Immunology to the Organization of Transfusion Centers in Denmark (OTCD), who distributed the email to their staff members. Reminder emails were sent 2 weeks before the survey ended.

Data exclusion

The estimated target study population was 260 staff members. Only completed questionnaires were included. Of 140 participants, 36 were excluded due to missing data, defined as a questionnaire that had not been fully completed. In total, the completion rate was 74%, and 104 participants were included in the analysis.

Statistical analysis

The main outcome variables of the survey were overall user satisfaction, user-friendliness and understanding of the parameters. All outcome variables mentioned can be assigned to ordinal scales. Descriptive variables include nominal scales (gender, position, professional background, region, implementation and follow-up), ordinal scales (five-point Likert scale for user satisfaction, friendliness, understanding and attitude) and ratio scales (age and time of employment in BE). The percentage of respondents who chose each item was calculated. The descriptive data analysis was carried out using R studio. Results are presented as mean and standard deviation (SD). Groups with less than five individuals are either combined with other groups or presented as <5. Data were analysed in R studio 2022.02.03 Build 492.

RESULTS

Details of the study cohort are given in Table 1. The regional distribution of participants largely follows the size and activity of the BEs, with the highest number of participants coming from the two largest regions. Regions with a larger geographical coverage and fewer centralized donation sites have lower participation. The sex distribution is extremely skewed but is thought to reflect the gender composition of BE staff.

From Table 2 it can be seen that the overall satisfaction on a scale from 1 (very dissatisfied) to 5 (very satisfied) did not reach the goal of a score of 4 or higher. However, all were still above the neutral value of 3, thus in the positive part of the scale. Slightly surprising was the fact that 12%–24% of the included 104 participants were not able to

TABLE 2 Results from the survey presented as mean (SD)

	Number (percentage) of responses	Mean (SD)	Percentage of non-responders
Satisfaction with the new registration			
Overall satisfaction	83 (79.8)	3.96 (0.94)	20.2
Satisfaction with the IT solution	79 (76.0)	4.05 (0.90)	24
Satisfaction with the construction of the registration codes	91 (87.5)	3.76 (0.90)	12.5
Satisfaction with the three categories used (type of complication, severity and imputability)	90 (86.5)	3.79 (0.83)	13.5
User-friendliness and understanding of the new registration			
The new registration is easy to use	88 (84.6)	3.93 (1.05)	15.4
The new registration is not time-consuming	89 (85.6)	3.82 (1.09)	14.4
The adverse reaction categories are easy to use and understand	88 (84.6)	3.92 (0.94)	15.4
The severity categories are easy to use and understand	91 (87.5)	3.99 (0.91)	12.5
The imputability categories are easy to use and understand	91 (87.5)	3.88 (1.00)	12.5
Did you know an annual donor vigilance report is published			
Yes	54 (51.9)	–	
No	50 (48.1)	–	
Do you think the new registration will improve donation safety?			
Yes	17 (16.3)	–	
No	42 (40.4)	–	
Do not know	45 (43.3)	–	

TABLE 3 Responses stratified according to demographics

	Overall satisfaction ($n = 83$)	Overall user-friendliness and understanding ($n = 88$)
Sex		
Female	3.95 (0.95)	3.89 (1.05)
Male	4.20 (0.84)	4.75 (0.50)
Age group		
20–29	4.00 (0.86)	4.13 (0.99)
30–39	4.33 (0.99)	3.88 (1.02)
40–49	3.81 (0.69)	3.85 (1.08)
50–59	3.74 (1.24)	4.05 (1.10)
>60	4.17 (0.86)	3.89 (1.08)
Time employed in BE		
<1 year	4.00 (0.71)	4.09 (0.83)
1–3 years	4.17 (0.94)	4.25 (0.75)
3–5 years	4.33 (0.82)	4.33 (1.21)
>5 years	3.69 (1.18)	3.86 (1.03)
>10 years	3.93 (0.94)	3.78 (1.15)
Position		
Donation staff	4.07 (0.82)	4.04 (0.96)
Medical doctor	4.43 (0.78)	4.50 (0.55)
Other	2.78 (1.09)	2.80 (1.23)
IT system		
Blodflödet	3.75 (0.98)	3.53 (1.08)
ProSang	4.10 (0.90)	4.19 (0.95)
Introduction of the new system		
New standard of operations		
Yes	3.96 (0.83)	3.93 (1.03)
No	3.97 (1.13)	3.94 (1.09)
Introduction by daily leader		
Yes	3.64 (1.15)	4.13 (0.99)
No	4.03 (0.89)	3.89 (1.06)
Introduction by medical doctor		
Yes	4.00 (0.78)	4.15 (0.80)
No	3.96 (0.98)	3.89 (1.09)
Introduction by a colleague		
Yes	4.08 (0.78)	3.82 (1.09)
No	3.92 (1.00)	3.98 (1.03)
No introduction		
Yes	2.50 (0.71)	2.33 (0.58)
No	4.00 (0.92)	3.99 (1.02)
Designated contact person		
Daily leader	4.00 (1.10)	4.06 (0.66)
Appointed medical doctor	4.20 (0.78)	4.43 (0.65)
Appointed colleague	3.90 (0.72)	3.68 (1.04)
Other	4.00 (1.26)	3.71 (1.25)
No	3.67 (1.05)	4.00 (1.32)
Do not know	4.09 (1.04)	3.67 (1.30)

Note: In total, 87 females and 5 males are included in the satisfaction results and 84 females and 4 males in the user-friendliness and understanding results. Results are presented as mean (SD).

give a score and instead replied "Do not know" (here named non-responders). When looking deeper into the groups of non-responders, we found that they had a higher percentage of participants replying that they did not do the registration themselves compared with the responders. For the satisfaction questions listed in Table 2, 14.3% of non-responders versus 6.0% of responders had replied that they themselves did not perform the registration. For user-friendliness, the numbers were 25.0% versus 3.4%, respectively. No difference in demographics between responders and non-responders was seen.

In the three specific questions addressing user-friendliness and understanding of the adverse reaction categories, severity and imputability, 10%, 5.5% and 11%, respectively, answered that they did not find the parameters easy to use or understand. Of these, 70%–75% further replied that this was because they did not understand the grading.

Despite the overall positive responses, only 16.3% believed that the registration would improve donation safety and only half of the participants knew that the Haemovigilance Committee publishes an annual report.

When looking closer into the responses for overall satisfaction and user-friendliness, we observed some interesting patterns (Table 3). First, mean scores were higher among men and medical doctors. For age and employment time in BB, the youngest and newest colleagues were in general more positive towards the new system. Most interesting was that non-donation/medical staff, that is, administrative personnel rated much lower than the other groups and below neutral. The new registration had the largest impact on daily routine for Blodflödet users and they had lower overall satisfaction as well as lower satisfaction with the technical aspect of the registration compared with ProSang users (3.83 (1.05) vs. 4.18 (0.78)).

The method of introduction to the system seemed to have some effect. While new standard of operations, newsletters or information on the intranet did not seem to have an effect, introduction by a daily leader, medical doctor or colleague did. Participants who responded that they had an appointed medical doctor or leader as their primary contact person also had improved satisfaction.

We proceeded to investigate regional variation and the effect of a previous donor vigilance system (Table 4). The higher the percentage of staff members who were acquainted with a previous registration in their region, the lower the scores for the two main parameters. This was not dependent on region, size, time of employment in the BE, IT system or participant age. However, as previously observed, administrative personnel had lower ratings (data not shown). This could indicate that even though familiar with a previous system, performing "bed side" registration in close collaboration with the donor improves the experience compared with those who have simply changed from one system to another without the clinical context.

To access the specific challenges in Blodflödet, where three separate entries must be made per registration, a follow-up question was included for Blodflödet users only. When asked to estimate how often they registered all three parameters, 51% replied "always" and 14% replied "always, if I find all three relevant", 7% registered more than 75% of the time, another 7% registered it half of the time, 12% did not register themselves and the remaining 9% replied "do not know".

TABLE 4 Responses stratified by healthcare region and previous donor vigilance system.

	Region 1	Region 2	Region 3	Region 4	Region 5
Previous registration					
Yes	78.1	40	80	53.8	66.7
No	0	20	6.7	23.1	0
Do not know	21.9	40	13.3	23.1	33.3
Survey responses					
Overall satisfaction	3.75 (0.98)	4.30 (1.03)	3.87 (0.74)	4.15 (0.69)	3.67 (1.53)
Overall user-friendliness	3.53 (1.08)	4.50 (0.802)	3.93 (1.10)	4.15 (0.801)	3.50 (1.29)

Note: Previous registration is presented as percentage and responses by mean (SD).

DISCUSSION

The overall attitude towards the new donor vigilance system in Denmark is positive. Based on this survey, we did not meet our criteria for a successful implementation, although we were extremely close. However, if looking only at donation staff, our primary group of interest, we did succeed.

The donor vigilance system in Denmark builds on validated, international standards. However, the ISBT and AABB validations were limited to senior and academic staff. As the primary users in Denmark are donation staff, the Danish Haemovigilance Committee wished to evaluate their perception of the new system, both to identify areas with a need for revision or better guidelines, and also in the interest of colleagues elsewhere, who are in the process of implementing new guidelines for donor vigilance.

Our results show that even though the system was implemented during the COVID-19 pandemic, most staff members are positive towards the system and its individual components. We initially anticipated that imputability would receive low ratings for user-friendliness and understanding as this was the parameter that sparked the most debate and questions. Nevertheless, even though the ratings were marginally lower, they were still overall positive.

One of the main challenges of the implementation phase was to design a system that could work in two very different IT systems. In particular, the registration in Blodflödet was a concern, as the three parameters (category, severity and imputability, respectively) had to be registered with three separate entries, whereas the staff had previously been accustomed to a three-digit single entry. Given this, it is not surprising that Blodflödet users have the lowest satisfaction and find the new registration harder to use than ProSang users, who were subject to very few changes in their daily registration routine. As Denmark is preparing a national implementation of a shared ProSang-based IT system, no further actions will be taken by the Haemovigilance Committee on this matter.

The new system was differently implemented in all five regions. Based on our results, an in-person presentation improved the user's experience and understanding, whereas a written guideline did not seem to make a difference in how the users perceived and understood the registration.

One concern is the low number of staff members who know that donor vigilance data are compiled and published in an annual report. It could be suspected that this is also one of the reasons why more than 40% did not believe that the new system will improve donation safety. The Haemovigilance Committee is currently working on a strategy to improve the information provided to our staff as well as the possibilities to use the data in, for example, national campaigns to reduce donation-related adverse reactions.

The main strength of our survey is the large number of responses from donation staff. To our knowledge, this is the first time these international standards have been evaluated by this staff group. However, the study also has some important limitations. First, for comparison, a higher number of medical doctors and administrative staff should have been preferred. Second, in the design of the survey, the option to answer, "Do not know" instead of a score does mean that for some of the key questions, we have a high number of non-responders. However, given that not all staff groups use the new registration in the same way, that is, some do not register themselves, this was considered the best option. In addition, it also revealed that some staff members do not consider themselves informed well enough to answer, which also gives cause for reflection.

In total, 36 incomplete responses had to be excluded. As most staff members do not have designated office times, they had to fill out the questionnaire while working at the donation site with the risk of being interrupted. We therefore expect that the incomplete response reflects this, as the design of the survey did not give the possibility to save and resume at another time point.

In conclusion, even though the implementation of the Danish donor vigilance system did not meet our criteria for successful implementation, staff members were predominantly positive towards the new registration in terms of satisfaction, user-friendliness and understanding. Our results show that international standards for adverse reaction categories, severity and imputability are suitable for most staff groups.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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