### Deferral rate variability in blood donor eligibility assessment

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**BACKGROUND:** Both donors and the blood bank rely on the result of the donor health interview. However, survey data suggest that substantial variability in deferral rates among interviewers exist. We studied whether variability remained after adjusting for conditional factors. **STUDY DESIGN AND METHODS:** The data set included Dutch interview data on whole blood donor visits in 2015, where one of their visits was selected randomly. We applied logistic regression and multilevel regression analyses with the donor visit, with the interviewer representing the levels. We set up four models: 1) all reasons deferral, 2) low-hemoglobin-level deferral, 3) infectious disease risk deferral and 4) other medical reasons deferral.

**RESULTS:** In total, 138,398 visits were included in the study, of which 60,534 (43.7%) related to male donors. The overall deferral rate for men was 7.91% and for women 12.25%. Deferral rates among interviewers ranged from as low as 1.19% up to 28.8%. Models 2 (low hemoglobin level) and particularly 4 (other medical reasons), for both men and women, showed significant intraclass correlation coefficients, implying considerable deferral rate variability among interviewers. Donor age, the number of previous visits, and the season had relatively large effects. However, explained variances of the logistic regression models were relatively low, ranging from 2.53% to 7.35%.

**CONCLUSION:** Deferral appears to be a random process, while substantial variability was found among interviewer deferral rates, suggesting that some interviewers are more cautious than others. Our results suggest heuristic and subjective diagnosing to be prevalent. Steps should be taken to improve interview result validity.

decisive moment in the transfusion chain of events is the on-site donor eligibility assessment. At that instant, blood bank interviewers judge whether risks to either donor health or recipient health are sufficiently low as to allow the donor to proceed to the actual collection procedure aiming at acquiring a unit of whole blood to be processed into transfusion products.

Throughout Europe, the United States, and Canada, deferral rates average approximately 10%, with a considerable variation from as low as 1.4% up to as high as 25%.<sup>1</sup> Laboratory testing for infectious diseases after donation can also result in rejecting a donated unit. However, such product rejections are infrequent compared to on-site deferrals; for example, in the Netherlands less than 0.02% of donation attempts test positive.<sup>2,3</sup> To our knowledge, no explanatory studies on deferral rate variability have been reported.

**ABBREVIATIONS:** DHQ = donor health questionnaire; ICCs = intraclass correlation coefficients; IDR = infectious disease risk; OMR = other medical reasons

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Interobserver disagreement with regard to diagnostic decisions is known to exist. Indeed, long-standing literature suggests that important differences exist in judgments on medical situations or interpretation of data, and heuristic judgment methods seem to be prevalent.<sup>4–9</sup> In occupational health settings, studies on medical interviews of job applicants have previously been shown to have substantial interobserver disagreement.<sup>10–12</sup> Such disagreements are not limited to health care-related judgments or diagnoses but also show up in other areas where human decision making comes into play, for example, in economics and in court.<sup>4,13–15</sup>

Notwithstanding, in blood banking both the donors and the blood bank rely on the validity of the interview result in terms of accuracy and reproducibility. In this respect, and without prior knowledge, they likely expect similar deferral rates given similar interviews, interviewers, and donor conditions. Arguably, conditional factors at several levels—donor, interviewer, and regional/local level might at least in part explain existing differences, for example, random variation in donor characteristics, such as sex, age, and behavioral issues; random variation in interviewer characteristics, such as sex, age, training, and job experience; or possibly regionally deviating deferral policies.

The question arises as to what extent the "human factor" is at play in assessing donor eligibility. We postulate that it is hard to explain whether donors end up with a deferral by one interviewer where the very same donor would have been judged eligible if being seen by another interviewer. An important next concern arises as to whether these differences might imply blood product safety or donor safety issues. In this respect, it is conceivable that interviewers with less strict judgments, reflected in lower deferral rates, might produce higher numbers of donors testing positive in infectious disease screening.

Hence, our research question was to what extent differences exist in deferral risk at individual donor visits and whether these differences are associated with donor, interviewer, and collection site-related variables at Sanquin Blood Supply in the Netherlands, the sole blood organization responsible for the collection and supply of blood and its components in the Netherlands.

#### MATERIALS AND METHODS

#### Sanquin interview procedure

After registering the attending donor, an interviewer assesses his or her eligibility to donate. Both physicians and trained nonphysicians perform interviews. On average, an interview team consists of one physician and two to three nonphysicians. Physicians perform various parts of the interviews of all donors, with nonphysician collection staff performing the remainder.

The interviewers, both physicians and nonphysicians, judge donor eligibility on the spot. The tools and data

available to interviewers in assessing donor eligibility are the donor health questionnaire (DHQ, paper, non-electronic), which is filled out and signed by the donor on-site immediately before the interview: the complementary personal interview results, including discussion and clarification of the DHQ results; an eligibility assessment reference manual; in cases of doubt, nonphysicians may consult the on-site present physician (a physician in doubt may consult a nationally operating backup senior donor physician for complex cases); limited online interview data on previous interviews in the blood bank information system (MAK system, eProgesa); direct assessment of capillary hemoglobin (Hb) level through a finger stick (HemoCue 201/301 Hb System, HemoCue), blood pressure (Omron HEM-907XL, Omron Healthcare), and body weight when the donor could weigh less than 50 kg. In performing a finger stick, applying some pressure on the finger is allowed. Hb level and blood pressure may be reassessed once in cases where values are outside eligibility specifications.

Subsequently, the interviewer records all donor interview findings, and their (non)eligibility in the blood bank information system. In case of a deferral, the interviewer attaches one or more deferral codes related to the reason for deferral.

Screening tests on infectious diseases are performed in serum, sampled at the start of the collection procedure, and may in hindsight change eligibility status from eligible to noneligible, leading to discarding the donation products and discussing the result with the donor.

#### Data

All interview data were retrieved from the blood bank information system; relevant personal data on interviewers are from Sanquin's human resources files.

The data set included interview data on all whole blood donor visits in 2015. In 2016, discussing deferral rates of individual interviewers became part of annual evaluation meetings between interviewers and their supervisors, possibly introducing bias in interview results; we therefore did not include data later than 2015.

Further interview data inclusion criteria included:

- The number of interviews of a particular interviewer in 2015 should exceed 100 to avoid incidental interview experience.
- To avoid heterogeneity in deferral criteria, data should be on whole blood donations intended for nonautologous transfusion purposes.
- In case a donor had visited the blood bank more than once in 2015, one of these visits was selected randomly to minimize correlated interview results.

Possibly site-specific deferral policy parameters, such as interview or deferral protocol variation, were discussed in a panel of five experienced donor physicians from different blood collection sites. The panel concluded that no obvious, elaborated site-specific parameters existed.

#### Data handling and study reporting

The researcher(s) conducted analyses on a data set in which interviewer and donor related data had been anonymized. All results are reported on an aggregate level and cannot be traced back to individual respondents.

#### Statistical analyses

We performed descriptive analyses of key variables for the whole sample, broken down by interviewer and organizationally distinct collection units (clusters). To analyze variation in individual deferral risk, we applied logistic regression analyses and logistic multilevel regression analyses, with the donor visit, the interviewer, and the clusters representing the three levels and individual donor visits being nested within interviewers and clusters.

The aim of the multilevel analysis was twofold: 1) to estimate variance at the three levels and 2) to predict individual visit deferral risk.

Because men and women are known to show different deferral rates, most strikingly in low-Hb deferrals, we performed analyses for men and women separately. Moreover, we set up four models for different deferral reason categories: 1) all reasons; and for three subsets of deferral reasons, that is, for 2) low Hb level; 3) infectious disease risk (IDR) to recipients, that is, deferral for traveling to endemic regions, small surgery/needle-related events, and/or risky (sexual) behavior taken together; and 4) other (almost exclusively) medical reasons (OMR). In each model, deferrals were contrasted with nondeferrals for any reason, leading to lower numbers of visits included in the latter three models.

To estimate the variance at the three levels, intraclass correlation coefficients (ICCs)—reflecting the extent to which variance depends on individual interviewers and clusters, respectively—were calculated in an intercept-only model.

Management of the Medical Donor Affairs Department has been discussing individual interviewers' deferral rates with the interviewers since 2016. These discussions suggested that regional differences; interviewer experience, age and training; or donors' blood group, notably O-negative donors, might be of influence in interviewers' individual deferral rates. We therefore included these visit and interviewers' variables in the models.

Because missing data were expected to be completely at random, we decided to refrain from imputing and included only data records without any missing items on the variables in the analyses.

All analyses were performed with computer software (SPSS version 23, SPSS Inc.; Stata version 14.1, StataCorp).

To create logistic regression models for deferral risk, the following independent variables were used:

Level 1. Visit-related variables:

• Spring and summer are seasons with higher deferral rates for low Hb and for traveling to endemic regions<sup>16,17:</sup>

Season: spring/summer (1); fall/winter (0)

• Literature suggests that time of day affects deferral risk for low Hb, with increasing deferral rates over the day<sup>18</sup>:

Time of day: morning (0); afternoon (1); evening (2)

• Laboratory infectious disease screening result: confirmed positive (1) or negative (0)

#### Donor-related variables:

- Blood group: O-negative (1); other (0).
- Donor age at time of visit.
- Number of visits in the previous 5 years, a proxy for donor career. A previous visit could relate to a plasmapheresis donation attempt.

Level 2. Interviewer-related variables:

- Sex: male (0); female (1)
- Age and employment duration in years on 1 July 2015
- Interviewer training: physician (1); nonphysician (0)
- Number of interviews in 2015
- Average deferral rate for low Hb level; IDR; OMR

Level 3. Cluster/Collection site-related variables:

- Number of interviews in 2015
- Deferral rate for low Hb level; IDR; OMR

#### RESULTS

#### Descriptives

Table 1 gives an overview on the variables in our study. In total, 138,398 visits were included in the study, of which 60,534 (43.7%) were visits by male donors. A difference in age between men and women was apparent: 49.0 (standard deviation [SD], 14.0) years, and 42.4 (SD, 14.8) years, respectively. The overall deferral rate was 10.35% (7.91% in men, 12.25% in women). In women, higher rates were present in all deferral reason categories, notably for low-Hb deferral. In all, about half of the deferrals were for low Hb; the remainder were roughly equal for IDR and OMR. Within the group of IDR deferrals, the deferral rates for each of the subcategories-that is, deferral for traveling to endemic regions, small surgery/needle-related events, and/or risky (sexual) behavior-are also shown. Given the low deferral rates of these subcategories, no separate models for each subcategory have been elaborated here.

The number of interviewers was 474, including 52 (11.0%) physicians, and 89 (18.8%) men. Interviewers saw

	Total	Male donors	Female donors
Number of visits, N (%)	138,398 (100%)	60,534 (43.7%)	77,864 (56.3%)
Donor variables			
Age in years, mean (SD)	45.3 (14.8)	49.0 (14.0)	42.4 (14.8)
Number of previous visits, mean (range)	11 (1–98)	14 (1–98)	9 (1–73)
Blood group O-negative, %	12.8	12.4	13.1
Testing positive for infectious disease, N	23 (0.017%; ≈ 1:6000)	12	11
Season of visits, %			
Spring/Summer	48.4	52.4	51.0
Fall/Winter	51.6	47.6	49.0
Time, %			
Morning	23.4	23.6	23.3
Afternoon	45.4	42.6	47.6
Evening	31.1	33.8	29.1
Deferral rates, %			
Total*	10.35	7.91	12.25
Low Hb level	5.16	2.99	6.85
Infectious disease risk	2.54	2.36	2.68
Travel	1.63	1.59	1.66
Small surgery/needles, blood contact	0.83	0.71	0.92
Risky sexual behavior	0.11	0.08	0.12
Other (medical) reasons	3.13	2.83	3.36
Interviewer variables	0.10	2.00	0.00
N	474		
Physicians, %	11.0		
Male interviewers, %	18.8		
Age in years, mean (SD)	46.0 (13.0)		
Employment duration in years, mean (range)	13.5 (0–47)		
Number of interviews in data set, N (range)	369 (50–3286)		
Number of interviews in 2015, N (range)	697 (106–6151)		
Interviewer deferral rates	697 (106–6151)		
Mean % (range)	0.00 (1.10, 00.0)		
Total*	9.80 (1.19–28.8)		
Low Hb level	5.14 (0.0–15.0)		
Infectious disease risk	2.45 (0.0–10.6)		
Travel	1.64 (0.0–7.5)		
Small surgery/needles, blood contact	0.73 (0.0–4.8)		
Risky sexual behavior	0.08 (0.0–2.6)		
Other (medical) reasons	2.67 (0.0–15.9)		
Cluster variables, N	29		
Number of interviews, N (range)	4,772 (2,096 – 8,462)		
Cluster deferral rates			
Mean % (range)			
Total*	10.30 (7.57–13.35)		
Low Hb level	5.15 (3.68–7.21)		
nfectious disease risk	2.63 (1.94–4.78)		
Other (medical) reasons	3.13 (1.63-3.92)		

\* More than one deferral reason in one visit is possible. Total number/rate of deferrals therefore is lower than the sum of individual reason numbers/rates.

on average 292 (range, 35–3286) donors; these numbers were lower than the total number of interviews for these interviewers in 2015 because the visits in the study group were a sample of all visits in 2015. The total number of interviews per interviewer in 2015 was on average 697 (range, 106–6151).

The number of previous visits averaged 11 (range, 1–98), where 99.4% had fewer than 30 visits. In the Netherlands, donors at their first visit do not donate blood; therefore, the lowest number of previous visits is one. The higher numbers included donors with a history of plasmapheresis donation attempts.

The deferral rates among interviewers showed an average of 9.80%, from as low as 1.19% up to 28.8%. In subcategories for individual interviewers with low numbers of interviews in the sample, deferral rates could be zero. Cluster deferral average results reflected the study group averages with somewhat lower ranges as compared to the interviewers' averages.

#### Logistic regression analyses

The results of the univariable and the multivariable multilevel logistic regression analyses are shown in Tables 2–3, and 4, respectively.

ICCs, calculated in the intercept-only models, ranged from 2.37 to 15.13 across the four models.

Adding cluster as a third level produced ICCs for this level well below 1% without substantially affecting the Level 2 ICCs.

Logistic regression	Men		Women	
Variable	Coefficient (SE)	p value	Coefficient (SE)	p value
Blood group O-negative	-0.014 (0.046)	0.765	-0.096 (0.034)	0.004
Donor age	0.012 (0.001)	0.000	-0.010 (0.001)	0.000
MAE	-0.083 (0.021)	0.000	-0.016 (0.016)	0.324
Season	0.200 (0.031)	0.000	0.141 (0.022)	0.000
Number of visits	-0.002 (0.002)	0.232	-0.021(0.002)	0.000
Interviewer training	0.098 (0.086)	0.256	0.079 (0.072)	0.271
Interviewer age	-0.001 (0.002)	0.732	0.001 (0.002)	0.448
Interviewer sex	-0.032 (0.070)	0.650	0.016 (0.059)	0.782
Tenure	-0.003 (0.003)	0.269	0.0001 (0.002)	0.958
Number of interviews/100	0.011 (0.003)	0.003	0.007 (0.003)	0.029
Mean deferral rate	х <i>У</i>		× ,	
All reasons	0.418 (0.013)	0.000	0.389 (0.010)	0.000
Low Hb*	0.456 (0.022)	0.000	0.469 (0.014)	0.000
Infectious disease risk*	0.404 (0.022)	0.000	0.389 (0.017)	0.000
Other medical reasons*	0.571 (0.023)	0.000	0.491 (0.019)	0.000

MAE = morning, afternoon, evening; SE = standard error.

Multilevel logistic regression     60,534     57,555     57,172     57,457       ntraclass correlation coefficient (%)       5.49     6.05     2.37     15.13       Cluster level     <1.00     <1.00     <1.00     <1.00     <1.00       Full model		Model 1: all reasons deferral	Model 2: low-Hb deferral	Model 3: IDR deferral	Model 4: OMR deferra
N     60,534     57,555     57,172     57,457       ntraclass correlation coefficient (%)     5.49     6.05     2.37     15.13       Cluster level     <1.00	ntercept-only model				
Intraclass correlation coefficient (%) 5.49 6.05 2.37 15.13   Cluster level <1.00	Nultilevel logistic regression				
Individual level     5.49     6.05     2.37     15.13       Cluster level     <1.00	N	60,534	57,555	57,172	57,457
Cluster level     <1.00     <1.00     <1.00     <1.00     <1.00     <1.00       Full model     _ogistic regression     _ogistic regression	ntraclass correlation coefficient (%)				
Full model     Logistic regression     Coefficients     ntercept   -3.129   -5.559   -3.395   -3.939     Donor age   0.014***   0.0024***   0.0002   0.020***     Blood group O-negative   -0.010   -0.031   -0.0660   0.091     Collection time, MAE   -0.046*   0.140***   0.106**   -0.174***     Season   0.189***   0.377***   0.167**   0.0039     Number of previous visits   -0.013**   0.025***   -0.031***   -0.048***     Number of interviews/100   0.0011   0.0047**   -0.0004   0.0045**     Mean deferral rate   0.421****   0.460***   0.405***   0.540***	ndividual level	5.49	6.05	2.37	15.13
Logistic regression       Coefficients       ntercept     -3.129     -5.559     -3.395     -3.939       Donor age     0.014     0.024     0.002     0.020       Blood group O-negative     -0.010     -0.031     -0.060     0.091       Collection time, MAE     -0.046*     0.140     -0.106*     -0.174***       Season     0.189***     0.377***     0.166**     -0.048**       Number of previous visits     -0.013**     0.025**     -0.031***     -0.048**       Number of interviews/100     0.0011     0.0047**     -0.0004     0.0045**       Mean deferral rate     0.421****     0.460***     0.405***     0.540***	Cluster level	<1.00	<1.00	<1.00	<1.00
Coefficients     -3.129     -5.559     -3.395     -3.939       Donor age     0.014 <sup>+++</sup> 0.024 <sup>+++</sup> 0.002     0.020 <sup>++++++++++++++++++++++++++++++++++</sup>	Full model				
ntercept     -3.129     -5.559     -3.395     -3.939       Donor age     0.014 <sup>***</sup> 0.024 <sup>***</sup> 0.002     0.020 <sup>***</sup> Blood group O-negative     -0.010     -0.031     -0.060     0.091       Collection time, MAE     -0.046*     0.140 <sup>***</sup> -0.106 <sup>***</sup> -0.174 <sup>***</sup> Season     0.189 <sup>****</sup> 0.377 <sup>***</sup> 0.167 <sup>***</sup> 0.0039       Number of previous visits     -0.013 <sup>****</sup> 0.025 <sup>*****</sup> -0.031 <sup>************************************</sup>	Logistic regression				
Donor age     0.014 <sup>***</sup> 0.024 <sup>***</sup> 0.002     0.020 <sup>***</sup> Blood group O-negative     -0.010     -0.031     -0.060     0.091       Collection time, MAE     -0.046*     0.140 <sup>***</sup> -0.106 <sup>**</sup> -0.174 <sup>***</sup> Season     0.189 <sup>***</sup> 0.377 <sup>***</sup> 0.167 <sup>***</sup> 0.0039       Number of previous visits     -0.013 <sup>***</sup> 0.025 <sup>***</sup> -0.031 <sup>***</sup> -0.048 <sup>***</sup> Number of interviews/100     0.0011     0.0047 <sup>**</sup> -0.0004     0.0045 <sup>***</sup> Mean deferral rate     0.421 <sup>****</sup> 0.460 <sup>****</sup> 0.405 <sup>*****</sup> 0.540 <sup>************************************</sup>	Coefficients				
Blood group O-negative     -0.010     -0.031     -0.060     0.091       Collection time, MAE     -0.046*     0.140***     -0.106**     -0.174***       Season     0.189***     0.377***     0.167**     0.0039       Number of previous visits     -0.013***     0.025***     -0.031***     -0.048***       Number of interviews/100     0.0011     0.0047**     -0.0004     0.0045***       Vean deferral rate     0.421****     0.460****     0.405****     0.540****	ntercept	-3.129	-5.559	-3.395	-3.939
Blood group O-negative     -0.010     -0.031     -0.060     0.091       Collection time, MAE     -0.046*     0.140***     -0.106**     -0.174***       Season     0.189***     0.377***     0.167**     0.0039       Number of previous visits     -0.013***     0.025***     -0.031***     -0.048***       Number of interviews/100     0.0011     0.0047**     -0.0004     0.0045***       Vean deferral rate     0.421****     0.460****     0.405****     0.540****	Donor age	0.014***	0.024***	0.002	0.020***
Season     0.189 <sup>***</sup> 0.377 <sup>***</sup> 0.167 <sup>***</sup> 0.0039       Number of previous visits     -0.013 <sup>***</sup> 0.025 <sup>****</sup> -0.031 <sup>*****</sup> -0.048 <sup>************************************</sup>	Blood group O-negative		-0.031	-0.060	
Season     0.189 <sup>***</sup> 0.377 <sup>***</sup> 0.167 <sup>***</sup> 0.0039       Number of previous visits     -0.013 <sup>***</sup> 0.025 <sup>****</sup> -0.031 <sup>*****</sup> -0.048 <sup>************************************</sup>	Collection time, MAE	-0.046*	0.140***	-0.106**	-0.174***
Number of previous visits     -0.013 <sup>***</sup> 0.025 <sup>***</sup> -0.031 <sup>***</sup> -0.048 <sup>***</sup> Number of interviews/100     0.0011     0.0047 <sup>**</sup> -0.0004     0.0045 <sup>**</sup> Vean deferral rate     0.421 <sup>***</sup> 0.460 <sup>***</sup> 0.405 <sup>***</sup> 0.540 <sup>***</sup>	Season	0.189***	0.377***		
Number of interviews/100     0.0011     0.0047*     -0.0004     0.0045 <sup>**</sup> Vean deferral rate     0.421 <sup>***</sup> 0.460 <sup>****</sup> 0.405 <sup>***</sup> 0.540 <sup>****</sup>	Number of previous visits	-0.013****	0.025***	-0.031***	-0.048***
	Number of interviews/100	0.0011	0.0047*	-0.0004	0.0045**
	Vean deferral rate	0.421***	0.460***	0.405***	0.540***
	Pseudo R <sup>2</sup> %				7.36

With regard to the regression models, interviewer training background, sex, age, and employment duration had no significant effect in any of the models. All other variables were significant in at least one model. For comparison reasons, we show the analysis results where each of these variables that were significant in one or more models were included, but leaving out the nonsignificant variables in any model.

Donor age, number of previous visits, and season had the largest effect on deferral rates, taking into account that the first two coefficients related to a 1-year age difference and one previous visit, respectively. With regard to age, the coefficients for men were positive in Models 1, 2, and 4, while the coefficients for women were positive in Models 1, 2, and 3. Not unexpectedly, Model 2 on low Hb showed the largest difference between the sexes.

The number of previous visits showed an increasing effect on low-Hb deferrals and a decreasing effect on IDR and OMR deferrals.

The explained deferral risk variance (pseudo  $R^2$  in the Stata output on logistic regression) of the models is relatively low, with values between 2.53% (Model 3) and 4.92% (Model 4) in women; and between 2.86% (Model 3) and 7.35% (Model 4) in men. These values imply a considerable deferral risk variance to remain after adjusting for variables considered to be of interest.

Multilevel logistic regression     77,864     73,660     70,419     70,943       Intraclass correlation coefficient (%)     4.63     5.98     3.13     10.34       Cluster level     4.63     5.98     3.13     10.34       Cluster level     <1.00     <1.00     <1.00     <1.00       Full model            Logistic regression      -0.009 <sup>***</sup> -0.019 <sup>***</sup> -0.004 <sup>**</sup> 0.007 <sup>***</sup> Donor age     -0.009 <sup>****</sup> -0.067     -0.060     -0.059        Collection time, MAE     -0.032 <sup>***</sup> 0.038     -0.073 <sup>**</sup> -0.160 <sup>***</sup> Season     0.152 <sup>****</sup> 0.196 <sup>****</sup> -0.018 <sup>***</sup> -0.055 <sup>***</sup> Number of previous visits     -0.007 <sup>***</sup> 0.015 <sup>****</sup> -0.018 <sup>***</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>**</sup> Mean deferral rate     0.385 <sup>****</sup> 0.464 <sup>****</sup> 0.391 <sup>****</sup> 0.468 <sup>****</sup>		Model 1: all reasons deferral	Model 2: low-Hb deferral	Model 3: IDR deferral	Model 4: OMR deferra
N     77,864     73,660     70,419     70,943       Intraclass correlation coefficient (%)     4.63     5.98     3.13     10.34       Cluster level     4.63     5.98     3.13     10.34       Cluster level     <1.00	Intercept-only model				
Intraclass correlation coefficient (%)     Interviewer level   4.63   5.98   3.13   10.34     Cluster level   <1.00	Multilevel logistic regression				
Interviewer level     4.63     5.98     3.13     10.34       Cluster level     <1.00	N	77,864	73,660	70,419	70,943
Cluster level   <1.00	Intraclass correlation coefficient (%)				
Full model   Logistic regression     Coefficients     Intercept   -1.638   -2.164   -3.284   -3.157     Donor age   -0.009***   -0.019***   -0.004*   0.007***     Blood group O-negative   -0.071*   -0.067   -0.060   -0.059*     Collection time, MAE   -0.032*   0.038   -0.073*   -0.160***     Season   0.152***   0.196***   -0.019***   -0.055**     Number of previous visits   -0.007**   0.015***   -0.018**   -0.055***     Number of interviews/100   0.0011   0.0027**   0.0041**   0.0033*     Mean deferral rate   0.385***   0.464***   0.391***   0.468**	Interviewer level	4.63	5.98	3.13	10.34
Logistic regression       Coefficients       Intercept     -1.638     -2.164     -3.284     -3.157       Donor age     -0.009***     -0.019***     -0.004*     0.007***       Blood group O-negative     -0.071*     -0.067     -0.060     -0.059       Collection time, MAE     -0.032*     0.038     -0.073*     -0.160***       Season     0.152***     0.196***     -0.019***     -0.055**       Number of previous visits     -0.007**     0.015***     -0.018**     -0.055***       Number of interviews/100     0.0011     0.0027**     0.0041**     0.0033*       Mean deferral rate     0.385***     0.464***     0.391***     0.468***	Cluster level	<1.00	<1.00	<1.00	<1.00
Coefficients       Intercept     -1.638     -2.164     -3.284     -3.157       Donor age     -0.009***     -0.019***     -0.004**     0.007***       Blood group O-negative     -0.071*     -0.067     -0.060     -0.059       Collection time, MAE     -0.032*     0.038     -0.073*     -0.160***       Season     0.152***     0.196***     -0.019***     -0.055**       Number of previous visits     -0.007**     0.015***     -0.018***     -0.055***       Number of interviews/100     0.0011     0.0027**     0.0041***     0.0033**       Mean deferral rate     0.385****     0.464****     0.391****     0.468***	Full model				
Intercept     -1.638     -2.164     -3.284     -3.157       Donor age     -0.009 <sup>***</sup> -0.019 <sup>***</sup> -0.004 <sup>**</sup> 0.007 <sup>***</sup> Blood group O-negative     -0.071 <sup>**</sup> -0.067     -0.060     -0.059       Collection time, MAE     -0.032 <sup>**</sup> 0.038     -0.073 <sup>**</sup> -0.160 <sup>***</sup> Season     0.152 <sup>***</sup> 0.196 <sup>****</sup> 0.119 <sup>***</sup> 0.059       Number of previous visits     -0.007 <sup>***</sup> 0.015 <sup>****</sup> -0.018 <sup>***</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>**</sup> Mean deferral rate     0.385 <sup>****</sup> 0.464 <sup>****</sup> 0.391 <sup>*****</sup> 0.468 <sup>************************************</sup>	Logistic regression				
Donor age     -0.009 <sup>***</sup> -0.019 <sup>***</sup> -0.004 <sup>*</sup> 0.007 <sup>***</sup> Blood group O-negative     -0.071 <sup>*</sup> -0.067     -0.060     -0.059       Collection time, MAE     -0.032 <sup>*</sup> 0.038     -0.073 <sup>*</sup> -0.160 <sup>***</sup> Season     0.152 <sup>***</sup> 0.196 <sup>***</sup> 0.119 <sup>***</sup> 0.059       Number of previous visits     -0.007 <sup>**</sup> 0.015 <sup>***</sup> -0.018 <sup>***</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>*</sup> Mean deferral rate     0.385 <sup>***</sup> 0.464 <sup>****</sup> 0.391 <sup>*****</sup> 0.468 <sup>************************************</sup>	Coefficients				
Blood group O-negative     -0.071*     -0.067     -0.060     -0.059       Collection time, MAE     -0.032*     0.038     -0.073*     -0.160 <sup>***</sup> Season     0.152 <sup>***</sup> 0.196 <sup>***</sup> 0.119 <sup>***</sup> 0.059       Number of previous visits     -0.007 <sup>**</sup> 0.015 <sup>***</sup> -0.018 <sup>***</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>**</sup> Mean deferral rate     0.385 <sup>***</sup> 0.464 <sup>****</sup> 0.391 <sup>****</sup> 0.468 <sup>***</sup>	Intercept	-1.638	-2.164	-3.284	-3.157
Collection time, MAE     -0.032*     0.038     -0.073*     -0.160 <sup>***</sup> Season     0.152 <sup>***</sup> 0.196 <sup>***</sup> 0.119 <sup>***</sup> 0.059       Number of previous visits     -0.007 <sup>**</sup> 0.015 <sup>***</sup> -0.018 <sup>***</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>**</sup> Mean deferral rate     0.385 <sup>***</sup> 0.464 <sup>****</sup> 0.391 <sup>*****</sup> 0.468 <sup>****</sup>	Donor age	-0.009***	-0.019***	-0.004*	0.007***
Season     0.152 <sup>***</sup> 0.196 <sup>***</sup> 0.119 <sup>**</sup> 0.059       Number of previous visits     -0.007 <sup>**</sup> 0.015 <sup>***</sup> -0.018 <sup>**</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>**</sup> Mean deferral rate     0.385 <sup>***</sup> 0.464 <sup>****</sup> 0.391 <sup>****</sup> 0.468 <sup>****</sup>	Blood group O-negative	-0.071*	-0.067	-0.060	
Season     0.152 <sup>***</sup> 0.196 <sup>***</sup> 0.119 <sup>**</sup> 0.059       Number of previous visits     -0.007 <sup>**</sup> 0.015 <sup>***</sup> -0.018 <sup>**</sup> -0.055 <sup>***</sup> Number of interviews/100     0.0011     0.0027 <sup>**</sup> 0.0041 <sup>***</sup> 0.0033 <sup>**</sup> Mean deferral rate     0.385 <sup>***</sup> 0.464 <sup>****</sup> 0.391 <sup>****</sup> 0.468 <sup>****</sup>	Collection time, MAE		0.038	-0.073*	-0.160***
Number of previous visits     -0.007*     0.015***     -0.018**     -0.055***       Number of interviews/100     0.0011     0.0027*     0.0041**     0.0033*       Mean deferral rate     0.385***     0.464***     0.391***     0.468***	Season	0.152***	0.196***	0.119**	
Mean deferral rate 0.385 <sup>***</sup> 0.464 <sup>***</sup> 0.391 <sup>***</sup> 0.468 <sup>***</sup>	Number of previous visits		0.015***	-0.018**	-0.055***
	Number of interviews/100		0.0027*		0.0033*
	Mean deferral rate	0.385***	0.464***	0.391***	0.468***
	Pseudo R <sup>2</sup> %		4.00		4.92
* p < 0.05;	** p < 0.01;				

interviewers inv	erviewer mean deferral rates of olved in donors testing positive or re for infectious diseases		
	Infectious di	sease testing	
	Donors testing positive (N = 23)	Donors testing negative (N = 138,375)	
	Mean deferral rate	s of the interviewers	
Deferral category	involve	d % (SD)	
All reasons	10.05 (3.17)	9,80 (4.13)	
Low Hb	4.84 (1.98)	5.14 (2.35)	
Infectious disease risk	2.68 (1.33)	2.55 (1.20)	
Travel	1.85 (1.08)	1.64 (1.08)	
Small surgery/ needles, blood contact	0.76 (0.65)	0.73 (0.72)	
Risky sexual behavior	0.11 (0.02)	0.08 (0.02)	
Other medical reasons	2.99 (1.24)	2.67 (2.26)	

Differences are neither statistically significant nor relevant. For example, the interviewers of the donors testing positive had a mean IDR deferral rate of 2.68% (SD 1.33%), being almost equal to the mean IDR deferral of the interviewers without donors testing positive, 2.55% (SD 1.20%). In subcategories of IDR deferrals, again no substantial differences are apparent.

# Interviewers' IDR deferral rate variability of donors testing positive/negative on transfusion transmissible infections

We hypothesized that interviewers judging less stringently in weighing IDR in donors might show higher rates of donors testing positive for infectious diseases. A proxy for strictness is the interviewers' deferral rate for IDR in donors. To challenge this hypothesis, we compared the average IDR deferral rates of interviewers involved in donors testing positive with the other interviewers' average IDR deferral rates. Table 5 shows the results. No significant differences were apparent in any of the deferral categories. In particular, IDR deferral rates of interviewers who had donors testing positive in their cohort were almost equal to IDR deferral rates of interviewers without donors testing positive.

When comparing analogous deferral rates within the group of IDR deferrals—that is, deferral rates for traveling to endemic regions, small surgery/needle-related events, and/or risky (sexual) behavior—again no substantial differences became apparent.

#### DISCUSSION

#### General

To our knowledge, this is the first study reporting on variability in deferral rates in general and on deferral rate variability among blood bank interviewers. We emphasize that our results do not imply any judgment on the fairness or correctness of the individual interviewers' judgments, nor does this study allow for any conclusion on the correct deferral rate. For example, the average deferral rate may or may not be the appropriate deferral rate, and more or less stringent deferral policies may be appropriate, depending on the aim of the interview.

This study does show substantial differences in deferral rates between male and female donors. The most striking difference was on low Hb level, but higher deferral rates for women were apparent in every deferral category. The more than double difference in low-Hb deferral rates between men and women is a common finding. The higher deferral rates for IDR and OMR are less striking, and we could not identify a straightforward explanation for these differences.

## Modeling deferral variability at interviewer/cluster level

Although overall the models showed a relatively low explained variance, it also became clear that several models showed considerable deferral rate variability at the interviewer level, being highest for OMR deferrals, lower for low-Hb deferrals, and lowest for IDR deferrals. As anticipated, clear age effects were found in low-Hb deferrals, where men were deferred more often with increasing age and women were deferred less often with increasing age. Apart from the mean deferral rates, interviewer variables showed no effect on deferral rates, with comparable deferral rates for physicians and nonphysicians. In agreement with the literature, both the warm season and progressing time of day had an increasing effect on low-Hb deferrals, although this time-of-day-effect was nonsignificant in women.

The number of previous visits was associated with higher deferral risks in the low-Hb model but with lower deferral risks in the IDR and the OMR models, present more clearly in the male models. We suggest that more visits and donations could imply a greater risk of iron depletion, with a subsequent higher risk of low-Hb deferral. This effect overshadows the so-called healthy donor effect, which, adjusted for age effects, could help explain lower deferral risks when having visited the blood bank more often.

Unexpectedly, a substantial variability at the interviewer level was found in the low-Hb deferrals. We anticipated assessing Hb level, having rather stringent procedures, to show minimal variability. This finding supports reconsidering and revising procedures and protocols on assessing Hb levels and its consequences.

Another remarkable finding was that adding the Level 2 variable "mean deferral rate" to each of the models made the random intercept variance vanish almost completely. We interpret this finding by stating that the mean deferral rate was the main driver for random intercept variance at that level and added significantly to the explanation of donor deferral rate variability: that is, some interviewers are more cautious than others.

In clinical diagnosing, variability between doctors is known to exist, among others due to differences in their prior knowledge and in valuing prior knowledge.<sup>15,19,20</sup> In a public health setting, that is, in assessing donor eligibility on IDR and OMR, a complexity arises because low prevalence exists regarding conditions sought for, bringing about an increased risk of false-positive results. Moreover, the vast majority of donors with correctly diagnosed IDR are not infected or infectious. All donors positive on IDR are deferred and sent home without additional testing, precluding judgment on correctness of this decision. We suggest that testing (temporarily) deferred donors can be of help in assessing the validity of such DHQ deferrals.

A previous study of our group did not identify any rate difference in being deferred temporarily for IDR between donors testing positive for infectious disease and donors testing negative.<sup>2</sup> In that part of the study, relevant results were gathered from new donors. In the Netherlands, new donors at their first visit undergo a full eligibility procedure. without donating a unit of blood, where testing for infectious diseases takes place in all but the permanently deferred donors (which comprise only a small minority of about 100 donors annually).<sup>2</sup> The present study showed that interviewers who interviewed donors testing positive for infectious diseases had almost equal IDR deferral rates compared to interviewers without such donors, turning a statistical power discussion into a nonissue, and not exactly supporting the efficacy of the DHQ in the current IDR deferral policy. Actually, our finding suggests, but does not prove, the current IDR deferral policy to be nonefficacious. Assessing interobserver agreement on eligibility could be helpful in assessing reproducibility and subsequently lowering deferral variability. We note that in an occupational health care setting on medical eligibility for a job, interobserver agreement was limited,<sup>10</sup> which we do not consider a good sign for study results of interobserver agreement in donor eligibility.

With regard to non-low-Hb, non-IDR deferrals, that is, virtually all of the OMR deferrals, the true risk of such a condition to either the donor or the recipient is generally unknown, but these donors are deferred and sent home, and this to a degree varying substantially among individual interviewers.

Being cross-sectional in nature, this study leaves no room for assessing causal relations or for assessing exact differences in eligibility testing among the interviewers. To that purpose, testing interobserver agreement is mandatory.

This study accordingly does not justify any opinion on the correctness of donor eligibility policies, meaning that no conclusions can be drawn on whether high or low deferral rates would be the preferred policy. In this respect, we want to add that we did not find evidence in support of stringent deferral policies being more efficient in avoiding infected donations than less stringent policies.

Extrapolating our study results across blood establishments in other countries should be done cautiously and may require additional evaluations.

In conclusion, donor interview results suggest heuristic, subjective diagnosing to be prevalent. The key consequence of diagnostic uncertainties is that existing prior (valuing of) knowledge among interviewers inevitably leads to varying deferral rates, despite extensive standard operating procedures. The fairly low explained variances of the full models further suggest that considerable random variation remains after adjusting for conditional variables hypothesized to be of interest. This high variability itself gives food for thought: Is deferral rate variability a natural phenomenon, or does it cover less desirable, arbitrary practices? It is tempting to state that the risk of deferral is a random, poorly understood phenomenon. Steps should be taken to improve interview result validity with the goal of decreasing the gap between interviewer extremes of deferral rates.

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#### CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

#### REFERENCES

- De Kort W, Mayr W, Jungbauer C, et al. Blood donor selection in European Union directives: room for improvement. Blood Transfus 2016;14:101-8.
- 2. de Kort W, van den Burg P, Geerligs H, et al. Cost-effectiveness of questionnaires in preventing transfusion-transmitted infections. Transfusion 2014;54:879-88.
- Sanquin Blood Supply. Jaarverslag Sanquin 2016. 2016. Available from: https://www.sanquin.org/binaries/content/assets/ nl/over-sanquin/jaarverslagen/sanquin\_jaarverslag\_2016.pdf.
- Tversky A, Kahneman D. Judgment under uncertainty: heuristics and biases. Science 1974;185:1124-31.
- 5. McDonald CJ. Medical heuristics: the silent adjudicators of clinical practice. Ann Intern Med 1996;124:56-62.

- 6. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med 2005;165:1493-9.
- 7. Klein JG. Five pitfalls in decisions about diagnosis and prescribing. BMJ 2005;330:781-3.
- Marewski JN, Gigerenzer G. Heuristic decision making in medicine. Dialogues Clin Neurosci 2012;14:77-89.
- 9. Phua DH, Tan NC. Cognitive aspect of diagnostic errors. Ann Acad Med Singapore 2013;42:33-41.
- de Kort WL, Uiterweer HW, van Dijk FJ. Agreement on medical fitness for a job. Scand J Work Environ Health 1992;18:246-51.
- Hulshof CT, Verbeek JH, van Dijk FJ, et al. Evaluation research in occupational health services: general principles and a systematic review of empirical studies. Occup Environ Med 1999; 56:361-77.
- Serra C, Rodriguez MC, Delclos GL, et al. Criteria and methods used for the assessment of fitness for work: a systematic review. Occup Environ Med 2007;64:304-12.
- Kaheny EB, Haire SB, Benesh SC. Change over tenure: voting, variance, and decision making on the US courts of appeals. Am J Polit Sci 2008;52:490-503.
- Moyer LP. The role of case complexity in judicial decision making. Law Policy 2012;34:291-312.
- Mishra S. Decision-making under risk: integrating perspectives from biology, economics, and psychology. Pers Soc Psychol Rev 2014;18:280-307.
- 16. Hoekstra T, Veldhuizen I, van Noord PA, et al. Seasonal influences on hemoglobin levels and deferral rates in whole-blood and plasma donors. Transfusion 2007;47:895-900.
- Groot R, Prinsze F, Broekman-Piets R, et al. On-site deferral of whole blood and plasma donors in the Netherlands between 2006 and 2013. ISBT Sci Ser 2015;10:73-81.
- Backman S, Larjo A, Soikkeli J, et al. Season and time of day affect capillary blood hemoglobin level and low hemoglobin deferral in blood donors: analysis in a national blood bank. Transfusion 2016;56:1287-94.
- Elstein AS, Schwartz A. Clinical problem solving and diagnostic decision making: selective review of the cognitive literature. BMJ 2002;324:729-32.
- 20. Mamede S, van Gog T, van den Berge K, et al. Effect of availability bias and reflective reasoning on diagnostic accuracy among internal medicine residents. JAMA 2010;304:1198-203. ■