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Titre abrégé : Validation d'un outil de sensibilisation au don du sang acceptable.

Mots clés : don du sang, acceptabilité, éthique médicale, soins premiers, outil de sensibilisation

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Abstract:

Background: There is a need to develop an awareness raising tool for GPs to reach out their patients in order to increase blood donation.

The main objective was to create and validate a tool to raise awareness about blood donation that meets acceptability and preference criteria and is applicable in general practice.

Material and Methods: This cross-sectional study was conducted in three phases. 1. Tool creation: A stakeholder meeting co-developed three potential tools to raise awareness about blood donation: a consulting room poster, a waiting room poster and a lapel badge for the doctor. Three GPs pilot-tested each tool for one day during their regular consultations. Then, once the pilot was completed each GP assessed acceptability and preference using a semi-structured interview, and patients were also interviewed. 2. Consensual tool selection: An appropriate tool was selected based on pilot data using nominal group technique and expert review. 3. The tool was validated for its acceptability in practice via a quantitative questionnaire distributed electronically to GPs.

Results: The consensual tool selected by the nominal group was a combination of elements from all three tools trialled in the pilot, reported to be non-intrusive and convenient for both GPs and patients. Patient responses indicated a high level of acceptability and indicated a strong preference for self-generated discussion of the topic with their GP. In the validation step, 217 responses to the quantitative questionnaire were received: 74.5% of responses fulfilled the acceptability criteria for using this combined tool in general practice. Furthermore, 93.1% of GPs indicated they would use the tool in the proposed format for the purpose of raising awareness.

Discussion: The validation of our blood donation awareness tool for use in general practice justifies its evaluation on a larger scale as part of a wider blood donation awareness campaign.

Résumé en Français :

Contexte : Il est nécessaire de développer un outil de sensibilisation pour que les médecins généralistes puissent sensibiliser leurs patients afin d'augmenter les dons de sang.

L'objectif est de créer et de valider un outil de sensibilisation au don de sang qui réponde aux critères d'acceptabilité et de préférence et qui soit utilisable en médecine générale.

Matériel et méthode : Cette étude transversale a été menée en trois phases. 1. Création de l'outil : Un groupe de discussion composé d'experts et d'utilisateurs de santé a développé trois outils potentiels pour sensibiliser au don de sang : une affiche pour

le cabinet de consultation, une affiche pour la salle d'attente et un badge pour le médecin. Trois médecins généralistes ont testé chaque outil pendant une journée au cours de leurs consultations habituelles. Une fois le pilote terminé, l'acceptabilité et la préférence de chaque médecin généraliste pour les outils ont été évaluées à l'aide d'un entretien semi-structuré, et les patients ont également été interviewés. 2. Sélection consensuelle de l'outil : un outil approprié a été sélectionné sur la base des données pilotes en utilisant la technique du groupe nominal et la validation des experts. 3. L'acceptabilité de l'outil pour la pratique a enfin été validé via un questionnaire distribué électroniquement aux médecins généralistes français.

Résultats : L'outil consensuel sélectionné par le groupe nominal était une combinaison d'éléments des trois outils testés dans le cadre du projet pilote. Il a été identifié comme étant non intrusif et pratique à l'usage pour les médecins généralistes et les patients. Les réponses des patients ont indiqué un haut niveau d'acceptabilité et d'une forte préférence pour une discussion autonome des patients avec leur médecin généraliste. Lors de l'étape de validation, 217 réponses au questionnaire quantitatif ont été reçues : 74,5% des réponses remplissaient les critères d'acceptabilité pour l'utilisation de cet outil combiné en médecine générale. En outre, 93,1% des médecins généralistes ont indiqué qu'ils utiliseraient l'outil dans le format proposé à des fins de sensibilisation.

Discussion : La validation de l'outil combiné de sensibilisation au don de sang utilisable en médecine générale justifie son évaluation à plus grande échelle dans le cadre d'une large campagne de sensibilisation au don de sang.

Introduction

In France, at least a million patients a year rely on donated blood products. Alongside routine emergency use, this need is increasing with improved longevity and new treatment avenues in other pathologies with, for instance, the use of plasma-derived medicines (1).

Blood products have a limited shelf-life, which means donors must be regularly mobilised to renew stocks. To ensure national stocks and ethical blood donation

standards are maintained, the French blood bank (Etablissement Français du Sang [EFS]), regularly promotes blood donation awareness campaigns to existing and potential donors, but acceptability of the media campaigns remains to be seen (2). Thus, there is a need to find alternative avenues for donor recruitment.

General practitioners (GPs) are well-placed to recruit potential donors, and a survey of public health stakeholders, suggested GPs mediate blood donation awareness among their patients (3). In fact, patients interested in donating blood actively seek information about how to donate and what it entails. Having a discussion with their GP could provide accurate information and prompt them to donate blood (4). However, GPs have limited time with their patients and lack appropriate discussion tools to approach the subject. This prevents GPs from discussing blood donation with patients (4,5).

To support GPs in managing a blood donation discussion, GPs request a tool to be used in primary care consultations and suitable for both GPs and patients (4). Therefore it would encourage the patients, at their own initiative, to question their GP to obtain information that would help them decide whether to donate or not.

The principal aim of this study was to create a tool, suitable for both GPs and patients, and to evaluate its acceptability in general practice, with a view to its eventual deployment in a large-scale promotional campaign. The secondary aim was to determine the preferences of GPs concerning the means by which the tool would be used.

Materials and methods

Study design

This study, conducted in a regional primary care setting in Brittany, France, consisted of three phases. The first qualitative phase was to design a blood donation awareness tool acceptable to both practitioners and patients. Then in a second phase, data obtained from both GPs and patients were subsequently considered using the nominal group technique, selecting the final tool by consensus. The third assessed the final acceptance of the chosen tool.

Study details – Phase 1

The stakeholder meeting was composed of a range of social actors and potential users that would provide a unique perspective to co-develop a set of tools to be tested in the study : three GPs, one voluntary patient, a marketing professional, a psychologist and two experts in blood donation, recruited on a voluntary basis. Decisions were made collectively on the basis of discussion and collective consensus choices based on existing literature on the effectiveness of awareness campaigns in general. The tools were developed on the basis of existing EFS campaigns and improved according to the preferences of the patients of giving age and the doctors who would use them in consultation, with equal speaking weight. Preferences were assessed in terms of content and form: which message? Which informations? Which tone? Which form? Which place in the medical practice?

Over a 3-day testing period, each volunteer GP tested each tool for one day during their regular clinical consultations. If any patient expressed interest, or asked questions about blood donation, the GP gave them an information sheet about blood donation. Patients were recruited from the same three GP practices where the pilot study was conducted. Every and each consulting patient on a donating age, exposed to the tools during the day was immediately invited to contribute to the study by being interviewed, on a voluntary basis, in a purposive sampling (6). After the 3-day testing period, the GPs testing the tools participated in a semi-structured interview to assess their acceptance of the different tools (Supplementary material).

All participants were provided with information concerning the use of their data and consented to their participation.

Data from the 30 minutes interviews were recorded with a digital dictaphone, the verbatim responses were transcribed and transferred to the secure program Zed![®] to protect data and participant anonymity. A double qualitative content analysis (7) was carried out on both the patient and GP verbatim responses.

Study details – Phase 2

In the second phase, as a consensus technique, a nominal group (NGT) was conducted in order to select the final tool(s) used in the survey. The NGT entails face-to-face discussion in small groups, and provides a prompt result for researchers. The classic NGT involves four key stages: silent generation, round robin, clarification and voting (ranking) (8). The NGT is a highly structured face-to-face group interaction,

designed by Delbecq and Van de Ven (8, 9), which empowers participants by providing an opportunity to have their voices heard and opinions considered by other members. This group included the three GPs and four patients who had experienced the tools in phase 1, on a voluntary basis. They were presented with summary data from the GP and patient interviews, enabling this consensus technique to select the promotional tool, confirming its internal validity.

Study details – Phase 3

The last phase tested the final acceptance of the selected tool, based on four dimensions of a theoretical model of acceptability (10), among a broader GP group. GPs in Brittany were recruited by invitation, distributed through the French Medical Association, the union of health professionals. The survey was directly emailed followed by a reminder one month later for some, while others received the survey-link from their medical society newsletter. Participating GPs completed the anonymous survey using Lime Survey secured software. Responses were collected over 8 weeks (December 6 2019 to January 30 2020). The database was added to the French blood bank register, in accordance with French regulations on privacy and data acquisition and storage.

The questionnaire design was based on published data on the theoretical framework of acceptability (TFA) (10) that inspired a composite judgment criterion for assessment of prospective acceptability. It combined in three items the first four TFA criteria, *i.e.* emotional attitude and ethics (grouped under the same item), work burden and consistency of the intervention. This composite criterion was considered to be met if the GPs validated each of the three items (or two were validated and one neutral). A single negative response to an item invalidated the set, reflecting low prospective acceptability in this situation.

Statistical analysis

Univariate analysis of the survey results was performed automatically in the Lime Survey program. Multivariate analysis of the data was performed using R software. Variables were expressed as numbers and percentages and were compared using Chi-squared tests or Fisher's exact tests. All analyses were performed using SAS 9.4 software (SAS Institute, Cary, NC, USA). Statistical significance was defined as $p < .05$.

Results

Phase 1a: Tool creation and reactions - pilot study.

The stakeholder meeting designed and proposed three tools differing in their delivery location, medium and the message contained (Figure 1): a waiting room poster, a GP consultation poster, and a GP badge. An information sheet was also made available in consultation room, in case patient asked for some more details on blood donation. Following patient interviews during the pilot study, this same brochure was added to the waiting room poster. This revised tool combination was tested for a further day of patient consultations, to validate its addition.

Phase 1b Semi-structured interviews with patients and GPs (supplementary material)

Patients (Table1)

Interviews were conducted with 60 patients (median age 34.6 years) (Table 1). Two thirds were female and most, 46 (76.7%), had never donated blood, 6 (10%) were regular blood donors and 8 (13.3%) were occasional donors.

Views on donation

Patients acknowledged the essential need and importance for donated blood were essential: *"It's important"* (P6), *"It should almost be mandatory"* (P12), *"There is a shortage"* (P4). Yet patients expressed feelings of guilt: *"It makes me a little guilty"* (P17), *"I don't take the time to do it and always feel guilty about not doing it"* (P20), *"I am almost ashamed that I do not go often enough"* (P23). Other patients admitted having no particular personal sensitivity about blood donation: *"I don't feel particularly concerned"* (P12), *"If I can avoid donating and there are others who will, then so much the better"* (P49).

Views on involving GPs

While the majority of patients interviewed in general practice were *a priori* in favour of blood donation, few among them had addressed the subject with their GP. Concerning the use of donation promotion tools in medical offices, the majority of patients saw it as appropriate, since it was perceived as relevant to the domain of medicine: *"Raising*

awareness" (P21), *"Reassuring about the risks of donation, answering their questions"* (P8), *"Breaking down prejudices"* (P42).

Views on tools

All patients understood the purpose of tools, *"to raise awareness about blood donation"* (P21), *"to reassure people about the risks of donating blood, to answer their questions"* (P8), *"to break down prejudices"* (P42), *"to inform people "* (P45), *"to talk about it"* (P14), *"to bring about a discussion between the patient and his doctor "* (P15). All of the proposed tools were judged acceptable by all patients.

Patients found the tools suitable and the approach benefited from the trust inherent in the patient-GP relationship. The tools *"allowed a discussion between the patient and their doctor about blood donation"* (P15). *"I find this more practical and enabling, when something is suggested, it is left up to the patient if they want to raise the subject, it's up to the patient to take the next step and take charge of their decision to donate"* (P42).

GPs (Table 2)

Views on donation and on their involvement

On their side, the GPs (Table 2) stated that the subject of blood donation fitted perfectly with their medical role related to prevention: *"important, rather interesting and simple, cruelly topical"* (GP1) *"as doctors we have an important role to play in raising our patients' awareness"* (GP2) *"it's part of our role"* (GP3). GPs added value to the information provided *"the added value of the GP is there, it is in the message that we are also transmitting"* (GP1). The trusting relationship between doctor and patient also produced efficiency: *"the advantage of follow-up in general medicine is that people come back and thanks to that, we are much more efficient too, (...) it helps us to have a stronger impact"* (GP2). The study approach was considered acceptable by the three practitioners who tested the tools in their practice. *"important, rather interesting and simple, cruelly topical"* (GP1). They found the subject to be important and relevant to public health care.

Views on tools

Opinions diverged on the design of a tool with the most impact, for some the badge was most impactful while for others it was the waiting room poster. The badge was

considered as innovative and different: *"it's a change"* (P3), *"he (the GP) is out of the ordinary"* (P19), *"I have never seen a doctor with a badge like that"* (P30). Nevertheless, some patients seemed to be discomfited *"it's a statement (...), for me the doctor is supposed to be neutral"* (P41). Some negative comments concerned the poster in the waiting room or in the consultation room itself: concerning the poster in the waiting room one GP state it was *"not at all or only slightly effective, lost in the middle of other posters"* (GP1).

Common ground about blood donation promotion between patients and GPs

The patient and GP consensus revealed that using these tools was neither restraining nor time-consuming *"no particular influence (...), no need to highlight it, it didn't bother me"* (GP1). The GP was thought to be the most appropriate person to discuss blood donation and the consultation room was the best place for this discussion.

No consensus concerning which person should initiate a blood donation discussion was reached. Some comments indicated that patients preferred to initiate the discussion. However, a proactive approach by the GP would have been perceived by some as intrusive: *"It would be out of place, while it would not be coercive, I would not like it at all"* (P4), *"People would see it as an obligation and feel judged"* (P15).

Phase 2: Consensual tool selection

The consensus group (NGT) was presented with data from the pilot study. The group unanimously chose a combination of three tools: the waiting room poster, the self-service information sheets and the GP badge, as shown in Figure 2.

Confirming the interviews, patients and GPs of the nominal group agreed as a formal consensus that using the tool during patient consultations was neither a constraint nor time-consuming for the practitioner (supplementary data). The general practitioner appears to be the best channel to provide blood donation information and discussion.

Phase 3: Final acceptance

A total of 243 responses from GPs to the information distributed through the local area health networks. Of these, 217 complete responses were able to be analysed (Figure 3).

Characteristics of participating GPs

The sociodemographic characteristics of the participating GPs (Table 2) was compared to the entire French GP population (supplementary material SD2) retrieved from the French health professional database. The GPs in the present study were younger, mostly in the age groups 25-34 and 35-44, compared to French GPs as a whole, and fewer were in the older age groups, 45-54 and >55 years, 155 practiced in the Ile-et-Vilaine area. Additionally, the cohort had more female GPs (57.1%) than is seen in French GPs as a whole (49%).

Questionnaire

One hundred and sixty-two GPs (74.7%) fulfilled the composite judgement criterion validating acceptability of the tool (Table 3).

Most GPs, 167 (77%), agreed or strongly agreed that the awareness-raising approach was adapted to general practice. Concerning workload (Table 4), 114/217 (52.5%) participants would be willing to participate over a 1-week period, whereas 41/217 (18.9%) would choose one consulting day to use the tool. Nevertheless, 93.1% of respondents (202) indicated that they were willing to use the tool as part of an awareness-raising campaign for blood donation in general practice.

Comparing the sociodemographic characteristics, only GP practice location differed significantly ($p=0.022$) (Table 5). Rural GPs were significantly more accepting than those in semi-rural or urban zones. No other significant differences were observed.

GP views about a broader campaign rollout

Among 217 respondents, 202 agreed to use the tool as part of a coordinated awareness campaign (Table 3), most preferred during the national blood donation campaign (101, 46.5%) (Table 4).

Discussion

Topic particularities

Discussing blood donation in the context of general practice could be considered somewhat unusual, as there is no direct benefit for either the GP or the patient, only raises awareness about blood donation as an act for public health and solidarity. It seems important to us to underline the originality of such an approach, which does not consist in dealing with donation within the framework of the institution provided for it (i.e. between the donor and the transfusion centre) but in a primary care and prevention context. The motivational levers for donation are already very diverse, and those in play in this context are probably even different. However, it is worth mentioning that awareness-raising about the donation of human body parts already exists in France, but only in the context of organ donation, for patients from the age of 16. Once again, the motivations for organ and blood donation cannot be totally superimposed (11) and this specific context is not taken into account.

One of the difficulties GPs highlighted was the manner in which addressing this subject between GP and patient. The consensus group remained divided on who should initiate the discussion. Raising awareness of blood donation differs from health prevention or promotion initiatives (where the GP would generally raise the subject), GPs acting as 'informants' about blood donation rather than 'promoters', to avoid behaving in an intrusive manner towards their patients (5). Here, focusing on the patient as the initiator of the information exchange with the GP reduces the patient's possible feelings of guilt and is a better fit with the logistical and time constraints of the GP. Thus, nearly 80% of participating GPs responded that they either agreed or strongly agreed with this proposed approach. The fact that rural GP's were significantly more accepting to contribute to this promotion is probably explained by their high exposure to "blood collection campaigns" organized by local blood donor associations. So they could be more aware and familiar to blood donation promotion. On contrary, in cities or suburban areas : blood donation is done at fixed donation sites, with less associative promotion, so it is more unlikely for GPs to already project on them.

Our proposed approach differs from a pro-active GP process, proposed in a model of minimal advice about donation (4), assessed in a separate study (12). In that publication, the authors noted a probable increase in the donor numbers, and so

donated blood products, following GP initiated awareness-raising. Although short and simple, that intervention required a pro-active time- and personal-investment on behalf of the GP. Moreover, this approach was intended to modify patient behaviour, specifically blood donation behaviour. Whereas a non-intrusive approach could remove some of the usual barriers to donation while respecting the self-determination of actors, in order to improve the efficiency of the intervention.

Indeed, sociological research provides useful insights, strengthening our model. Deci and Ryan's psychological self-determination theory is a well-recognised behaviour model, and can be used to explain various health behaviours (13). This theory describes the different reasons that motivate an individual to initiate and maintain a particular behaviour, from intrinsic motivation, the highest level of autonomy, to extrinsic motivation where the individual behaves according to social environmental pressures. When applied to donor behaviour, this psychological model suggests that the donors with greater self-determination are most likely to maintain regular donations (14). Donors who initiated discussion with blood collection staff about their expectations were found to be more likely to donate than when the discussions were solicited by others (15).

Additionally, identifying obstacles to donation is as important as understanding the mechanisms by which people choose to donate. Bagot et al. (15) highlighted that information available on demand and interactions between donors and collection staff led to better donor retention. Also, donors who initiated discussion or questions themselves showed better conversion of their blood donation to plasma donation. We could expect that this mechanism would be the same in patients who would initiate a discussion on blood donation with their doctor.

Based on the self-determination sociological model, the potential donor becomes more autonomous being the author of their own choices and the initiator of their own actions. This means, the patient would be then more inclined to actively donate and continue donating in the long term.

Assessment

In the quantitative phase performed through the survey, prospective acceptability was used as a criterion to evaluate tools and adapt it to the physician preference.

To date, no published study has evaluated the impact of self-employed healthcare professionals wearing a health promotional badge on patients. Few studies have been conducted on the impact of waiting room posters in private practice waiting rooms (16), but they appear to be an effective vehicle for health education on several topics (17, 18, 19). Directly measuring the effectiveness of our tools on active donations would be difficult, due to the numerous confounding local factors including the environment, influence of local blood donor associations, simultaneous communication campaigns, etc. However, it would be interesting in the future to compare the number of donations made in the wake of an awareness campaign where a prompting tool is employed *versus* one without tool, between regions that are comparable with regard to blood donations.

Strength and limitations

One of the principal impediments to promote blood donation previously identified (4) was the lack of time available during a standard 15-minute consultation to respond to patient needs, without adding additional discussion topics. We validated the first suitable awareness-raising tool for GPs to facilitate promoting blood donation in general practice, respecting patient preferences.

A selection bias in the respondent population was possible: participating GPs who voluntarily responded to the survey may have already been more interested in the subject of blood donation. Additionally, there may have been a recruitment bias, induced by the means of distributing the questionnaire, which varied between areas. Unsurprisingly, the direct contact method resulted in a greater GP uptake. This resulted in a response rate bias. Nevertheless, this finding may be informative in planning larger scale deployment.

The question of tool efficacy was not assessed. According to GPs, few patients responded immediately to the awareness-raising tool on the test day, initiating questions and discussions about it. Hence, deferring evaluation several days or more after exposure to the tool might have enabled us to assess any delayed effect and evaluate the tools.

Conclusion

This study validates a combined awareness-raising tool, consensually approved by both patients and GPs. This non-intrusive approach encourages patients to elicit information from their GP about blood donation, which is more likely to lead them to an effective donation, according to the literature. It does not require additional GP training, nor special investment, nor dedicated time. The prospect of an awareness campaign in general practice, based on these specific validated tools, at a regional and a national level could assess the efficiency on donation behaviour.

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Figure 1: Tools created and evaluated. a) Badge “Blood donation: a question?”; b) Poster behind the physician “Blood donation: do you have any questions?”; c) Poster in the waiting room “Blood donation: what are your questions? Where? When? Why? How? Who?” ; d) Institutional leaflet, “Blood donation guide” in the waiting room and given to GPs.

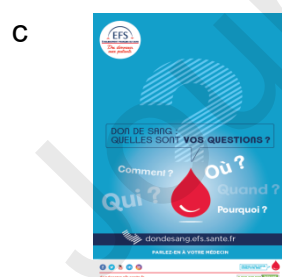
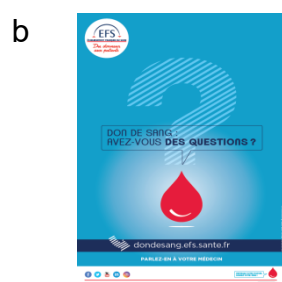




Figure 2: Consensus group tool selection : Badge +Poster in the waiting room “Blood donation: what are your questions? Where? When? Why? How? Who?” + Institutional leaflet.

leaflet

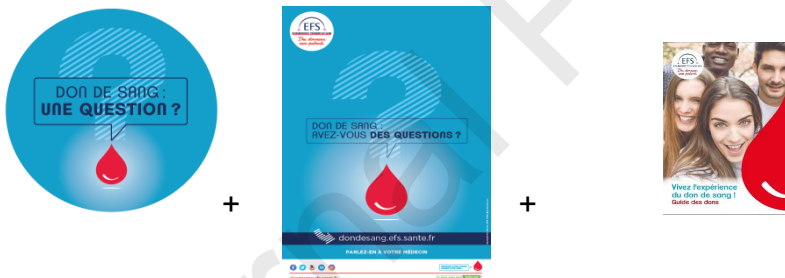


Figure 3: Study flow chart

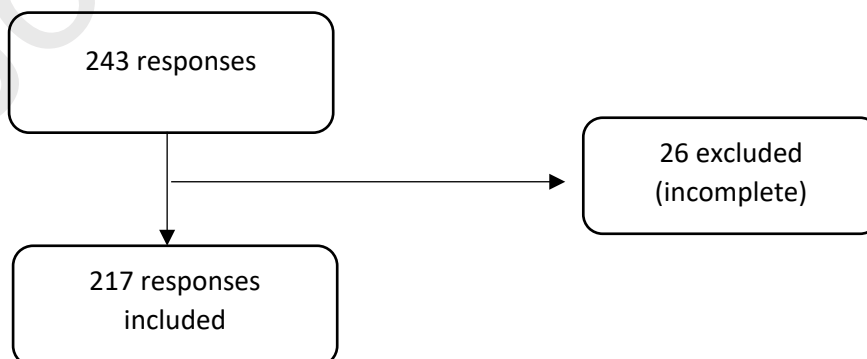


Table 1. Socio-demographic characteristics of patients participating in the tool test

Gender	67% Female 33% Male
Median Age (y)	34.6
Patients and blood donors (declared)	23.3% (10% regular donors, 13.3% occasional donors)
Patients exposed to 3 tools (poster in the waiting room, poster in the doctor's office and badge)	30
Patients exposed to 4 tools (poster in the waiting room, poster in the doctor's office, badge and poster in the waiting room + brochure)	30

Table 2. Socio-demographic characteristics of GPs participating in the tool test

	GP1	GP2	GP3
Gender	Male	Female	Female
Age (y)	32	42	60
Place of practice	Semi-rural	Urban	Semi-rural
Estimated patient base	450	1800	1520
Length of time in practice (y)	1.5	13	24

Table 3. Composite acceptability criterion for the awareness raising tool

	N=217(%) [95%CI]
Composite judgement criteria satisfied	
= « acceptability of the tool »	
Yes	162 (74.7) [68.9 - 80.4]
No	55 (25.3) [19.6 - 31.1]
Awareness-raising approach adapted to GP practice	
<i>(Affective attitude and Ethicality) (217)</i>	

Neither agree nor disagree (<i>considered as "No"</i>)	30 (13.8)	[9.5 - 19.1]
Strongly disagree (<i>considered as "No"</i>)	2 (0.9)	[0.1 - 3.3]
Rather disagree (<i>considered as "No"</i>)	18 (8.3)	[5.0 - 12.8]
Rather agree (<i>considered as "Yes"</i>)	116 (53.5)	[46.6 - 60.2]
Totally agree (<i>considered as "Yes"</i>)	51 (23.5)	[18.0 - 29.7]
Contribution to the awareness campaign with current workload (<i>Burden</i>) (217)		
Yes	182 (83.9)	[78.3 - 88.5]
No	35 (16.1)	[11.5 - 21.7]
Use of the tool as part of a coordinated awareness campaign (<i>Intervention coherence</i>) (217)		
Yes	202 (93)	[88.9 - 96.1]
No	15 (6.9)	[3.9 - 11.1]

Table 4. Preferences towards the awareness-raising campaign.

	N=217(%)	[95%CI]
Participation in the awareness-raising campaign in relation to workload		
No, absolutely not	27 (12.4)	[8.1 -16.8]
Yes, over 1 day	41 (18.9)	[13.7 - 24.1]

Yes, over 1 week	114 (52.5)	[45.9 - 59.2]
Other	35 (16.1)	[11.2 - 21.0]
Campaign dissemination period		
Other	8 (4.0)	[1.7 - 7.7]
No preference	79 (39.1)	[32.3 - 46.2]
September, over the back-to-school period	14 (6.9)	[3.8 - 11.4]
During the national campaign period in June (around the World blood donor day).	101 (50.0)	[42.9 - 57.1]
Dissemination scope of the campaign		
Other	2 (0.9)	[0.1 - 3.3]
No preference	108 (49.8)	[42.9 - 56.6]
Local campaign	34 (15.7)	[11.1 - 21.2]
National campaign	55 (25.3)	[19.7 - 31.7]
Regional campaign	18 (8.3)	[5.0 - 12.8]

Table 5. Comparison of sociodemographic characteristics of respondents according to acceptance criteria

