Informed Consent for Blood Transfusion

What Do Medicine Residents Tell? What Do Patients Understand?

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Abstract

Blood transfusion is a common intervention in the hospital setting, and its benefits may not be clear but it has associated risks. Despite this, transfusion consent may not be obtained satisfactorily. We assessed transfusion consent effectiveness by comparing information given by residents with information understood by patients who receive transfusions. Medicine department residents who obtained consent were surveyed via telephone in conjunction with bedside surveys of adult inpatients who received transfusions. A total of 43 patient and 34 resident surveys were completed. Deficiencies in the transfusion consent process were noted. Discussed transfusion benefits (such as wound healing) were not always true benefits whereas some important risks (such as transfusion-related acute lung injury) were infrequently conferred. Risks were more often reported as “not discussed” than benefits. Only a few participants were aware of the hospital’s Transfusion Health Guide, which provides information on transfusion benefits, risks, and alternatives.
emerging risks are being identified. Despite improvements in donor screening and testing methods, such risks cannot be entirely eliminated, as evidenced by recent documented cases of human immunodeficiency virus (HIV) transmitted via blood transfusion. Finally, many people do not accept blood product transfusions, often because of religious beliefs (eg, Jehovah’s Witnesses). For all of these reasons, it is important to properly discuss all planned transfusions of blood products in terms of benefits, risks, and alternatives with patients. Therefore, in this study, we evaluate residents’ understanding of the principles of blood transfusion as well as proper collection of patient consent using a survey-based method to compare information given by medicine service residents with information understood by the corresponding patients.

Materials and Methods

Study Design

Between March and August 2010, bedside surveys were conducted on adult inpatients with recent transfusions in the medicine service department. In conjunction, telephone surveys were conducted of the medicine service residents who obtained transfusion consent. Before the study, all investigators received training, including the use of prepared introductory scripts explaining the nature of the study, to minimize variation in the way that the surveys were conducted. Investigators were instructed to ask questions in an open-ended fashion with “best fit” choices selected. Some questions allowed for multiple answers to be selected. Eligible patients were identified by the lead investigator (M.F.) through the use of daily written tracking logs maintained by blood bank staff on issuing blood. Once confirmed that the patient was eligible via review of the medical record, 2 separate investigators were contacted: investigator 1 to conduct the bedside patient survey and investigator 2 to conduct the medicine resident telephone survey. Both completed surveys were returned to the lead investigator for review. The study was approved by the hospital’s institutional review board, and eligible patients were required to sign a consent form to participate.

Patient Selection

The inclusion criteria were as follows: adult (≥18 years) inpatients, recent RBC transfusion (within the preceding 3 days), and recent transfusion consent (within the preceding 7 days of RBC transfusion) obtained by a medicine department health care provider (the study criteria allowed for inclusion of residents, fellows, attending physicians, and physician assistants). However, all but 2 of the surveyed health care providers were residents, and only 1 of the consenting health care providers whom we were unable to survey among the group of surveyed patients was not a resident, therefore we refer to this group as “residents.” (The nonresident participants included a fellow, a physician assistant, and an attending physician.) Patients were excluded from the study if they did not speak English (ie, the Spanish language consent was used or an interpreter was required), were unable to give consent (ie, consent obtained from family members), were given the surgery consent form (which includes a single line for transfusion consent) rather than the standard transfusion consent, were asked for consent by residents from departments other than medicine, or were in critical care units. In addition, patients were not included in the study if the survey could not be conducted within 3 days of the transfusion.

Statistical Analysis

The data were analyzed using GraphPad software (GraphPad, LaJolla, CA). Results were considered to be significant for P values less than .05.

Results

A total of 45 patients were interviewed; however, 2 of the survey respondents were excluded from further analysis because the consent for transfusion was obtained by health care providers from departments other than medicine. An additional 78 patients met the study criteria for acceptance, but were not included because they refused, were discharged before study inclusion, or were not identified as eligible at the time of the transfusion (ie, patients who were later identified on review of transfusion records in the blood bank information system), including 1 patient who could not be interviewed for transfusions given on 2 separate hospital admissions. Of the 43 interviewed patients included for analysis, 17 were men and 26 were women, ranging in age from 28 to 90 (mean, 62.1) years. Telephone surveys were conducted of 28 health care providers (24 junior [postgraduate year, or PGY, 1/PGY-2] residents, 3 senior [PGY-3] residents or fellows, and 1 physician’s assistant), including 6 junior residents who were interviewed for 2 separate patients for a total of 34 resident-group surveys. The survey from 1 additional junior resident was excluded from analysis (though the patient survey results were included as “unmatched patient survey,” described later) because it was discovered from the survey responses that the resident who signed the consent form did not actually discuss the planned transfusion with the patient (the discussion was carried out by an attending physician the prior day). There were 29 matched-pair surveys (both patients and residents surveyed), 14 unmatched patient surveys (residents not surveyed—refused participation or otherwise could not be contacted within a reasonable time frame for interview), and 5 unmatched resident surveys (patients not surveyed—refused or discharged before interview [Figure 1]). No significant differences were
found between characteristics of surveyed patients and eligible patients not surveyed [Table 1]. Of the 48 total cases included in the study (paired and unpaired), consent was taken on the day of the transfusion in 36 cases, 1 day before transfusion in 11 cases, and 2 days before transfusion in 1 case.

Survey Questions

Patients: What is the main reason that you required a blood transfusion?

Residents: What was the primary indication for the transfusion discussed with your patient?

Only one choice could be selected. Anemia owing to cancer/chemotherapy, chronic disease, and acute blood loss were the most often cited main indication by both patients and residents [Figure 2]. Resident surveys (18%) cited anemia with cardiovascular disease more than patients (7%) but this did not reach statistical significance ($P = .165$). Some patients (14%) were unsure of the indication. Among other main reasons for requiring blood transfusion cited by patients were fight infections, improve breathing, and improve anemia (without specified cause or underlying risk). Other primary indications cited by residents were treatment of anemia caused by sepsis and anemia not otherwise specified. One resident did not recall the main indication and the response was excluded from the analysis (“not sure” was not accepted as a resident response to this question); thus, only 33 resident responses were included for this question.

Patients: What did you understand were the benefits of having a blood transfusion?

Residents: What benefits of blood transfusion did you discuss with the patient?

More than 1 choice could be selected. Improve anemia, improve strength, and improve breathing/blood circulation were the most often cited benefits by both patients and residents [Figure 3]. Resident surveys did cite alleviate anemia symptoms more than patients and the difference was statistically significant (21% vs 0%; $P = .0022$). Of note, wound healing, not known to be a transfusion benefit, was cited by 15% of resident surveys and 5% of patients. A small but not insignificant number of patients (12%) were unsure or could not recall the benefits and 2% stated that benefits were not discussed. Other benefits cited by patients included replace

### Table 1

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PGY, postgraduate year; PA, physician assistant.

[Figure 2] Main indications for blood transfusion. Resident surveys do not equal 100% because of rounding; 1 resident response was excluded. NA, not applicable.
iron/correct iron-deficiency anemia, improve well-being, improve immune system/fight infection, improve oxygenation, and improve anemia (cause not specified). Other benefits cited by residents included improve/correct coagulopathy, decrease risk of cardiac events, and improve well-being.

Patients: What did you understand were the risks of having a blood transfusion?

Residents: What risks of blood transfusion did you discuss with the patient?

More than 1 choice could be selected. HIV transmission, allergic, anaphylactic, hemolytic, fever/chills, and hepatitis transmission risks were most often cited by both patients and residents. Of interest, transfusion-related acute lung injury (TRALI), the highest cause of transfusion-related fatality, was cited by few residents (3 of 34 surveys, 9%) and by no patients. Slightly more patients reported risks than benefits as not discussed (7% vs 2%). Other risks cited by patients included transmissible diseases (not otherwise specified), breathing problems, nausea, and death. Other risks cited by residents included transmissible diseases (not otherwise specified), and 2 residents (6%) cited fluid overload. Residents tended to focus more on common but minor risks than did patients (fever/chills: 79% vs 12%, $P = .0001$; allergic reactions: 71% vs 21%, $P = .0001$) as well as anaphylactic reactions (53% vs 14%, $P = .0004$) and hepatitis transmission (41% vs 9%, $P = .0022$) but a small number also cited unusual risks such as graft-vs-host disease (GVHD) and protozoal disease transmission. Patient responses were more balanced between minor febrile/chills and allergic reactions and the more significant reactions such as hemolytic and anaphylactic reactions as well as hepatitis and HIV transmission (though there was a tendency toward emphasis of HIV transmission—cited by 33% of patients—compared with other risks).

Patients: Did the doctor who discussed the blood transfusion with you give you the opportunity to ask questions regarding the blood transfusion before you received the blood transfusion?

Residents: Did the patient ask any questions regarding the reason for, benefits of, or risks of the planned blood transfusion?

Most patients (88%) indicated that they had the opportunity to ask questions. Among residents, only 41% indicated that the patient did ask questions and 6% reported that they did not recall whether the patient asked questions. Questions asked by patients, as reported by residents, focused on the reason for the blood transfusion as well as benefits and risks, specifically the risks of infection and incompatibility.

Patients: Did you receive the health guide titled Blood Transfusion: What You Need to Know which lists some benefits and risks of blood transfusion as well as alternatives to blood transfusion? This may have been given to you by your nurse. (Show health guide to patient.)
Residents: Have you ever reviewed or are you aware of the St. Luke’s-Roosevelt patient health guide titled Blood Transfusion: What You Need to Know which is available on the Continuum/St. Luke’s-Roosevelt Hospital intranet site as well as at nursing stations on patient care units and includes information on risks and benefits as well as alternatives to blood transfusion?

Most patients (25 of 43, 58%) stated that they did not receive the hospital’s transfusion health guide which explains information on transfusion benefits, risks, and alternatives. An additional 8 patients (19%) did not recall whether they had received the guide. Thus, only 10 (23%) of 43 patients were aware of the guide. Similarly, most residents (17 of 28, 61%) were not aware of the guide, and, of the 11 residents (39%) who were aware of the guide, only 7 (25% of all 28 residents) had reviewed the guide during the past year.

Patients: Approximately how much time did the doctor spend discussing the planned blood transfusion with you, including time spent for any questions asked by you regarding the blood transfusion?

Residents: Approximately, how much time did you spend discussing the planned blood transfusion with the patient before the transfusion was given?

The majority of patients (61%) and residents (88%) indicated that the transfusion consent encounter lasted no more than 10 minutes, with a significant number of the surveys (patients: 21%; residents: 44%) indicating less than 5 minutes. Twelve (28%) patients indicated that the encounter lasted more than 10 minutes, and only 5 (15%) of 34 resident surveys reported this. Few patients (12%) and residents (3%) did not recall the amount of time spent on the transfusion consent encounter.

Survey Questions for Residents

In your opinion, on a scale of 1 to 5 (1 = no understanding; 5 = full understanding), how much did the patient understand of the explanation given for the reason for the blood transfusion?

Most residents (20 of 34 surveys, 59%) reported moderate (scale 3-4) patient understanding of the reason and 13 (38%) reported full patient understanding. One (3%) resident reported poor (scale 1-2) patient understanding.

In your opinion, on a scale of 1 to 5 (1 = no understanding; 5 = full understanding), how much did the patient understand of the benefits given for the blood transfusion? (Mark NA if not discussed.)

Most residents (21 of 34 surveys, 62%) reported moderate (scale 3-4) patient understanding of the benefits and 13 (38%) reported full patient understanding.

In your opinion, on a scale of 1 to 5 (1 = no understanding; 5 = full understanding), how much did the patient understand of the risks given for blood transfusion? (Mark NA if not discussed.)

Most residents (22 of 34 surveys, 65%) reported moderate (scale 3-4) level of patient understanding of the risks while 9 (27%) reported full understanding. Two (6%) reported poor patient understanding. One response was marked NA (not applicable) because the resident reported that risks were not discussed.

On a scale of 1 to 5 (1 = not comfortable; 5 = very comfortable), how comfortable were you in discussing blood transfusion therapy, including the reason for, benefits of, and risks of blood transfusion, with your patient?

Most residents (17 of 28, 61%) indicated that they were very comfortable and 11 (39%) indicated that they were moderately (scale 3-4) comfortable.

Survey Question for Patients

What, if anything, could have been done differently to improve your understanding of the reason for as well as the benefits and risks of the blood transfusion given to you?

More than 1 choice could be selected. The majority (77%) of patients indicated satisfaction with the transfusion consent process and did not make any recommendations for changes to be made. A few indicated that more time to think before signing the consent (7%), more time discussing the consent (2%), or more information about the benefits (2%) and risks (5%) should have been given. Other responses given were to receive a Transfusion Health Guide and to receive more information on transfusion alternatives as well as use of layperson terminology.

Discussion

We used a survey-based comparison method to assess transfusion consent effectiveness by comparison of information given by medicine service residents with information understood by patients who received transfusions. We believe that this is the first published study to compare information discussed by residents who obtained transfusion consent directly (because the majority of the surveys were matched pairs) with information as understood by the consenting patients.

The results show, not unexpectedly, that the transfusion indications cited, for the most part, reflect the underlying condition or treatment associated with anemia (eg, chronic illness, cancer, chemotherapy); however, a small but not insignificant number of responding patients were unsure of the indication

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for the transfusion. The data, furthermore, show some correlation of discussed benefits and risks between the resident and patient groups, in options for benefits, such as improve anemia and improve strength, and risks such as HIV. However, compared with patients, residents appear to focus more on alleviation of anemia symptoms (eg, lightheadedness, shortness of breath, etc) as beneficial rather than just the correction of the anemia itself. Benefits tended to be overstated (ie, citing false benefits of transfusion such as wound healing) and risks tended to be understated (for example, few residents and no patients cited TRALI as a risk). Residents tended to focus on common but minor risks (ie, febrile and allergic reactions) more so than more consequential risks such as HIV and hepatitis transmission whereas patients tended to focus on HIV transmission. Of interest, more residents reported discussing unusual risks such as GVHD, human-T-lymphotropic virus, West Nile virus, and protozoal infections (eg, malaria, babesiosis, Trypanosoma cruzi-related [Chagas disease]) than TRALI, transfusion-associated circulatory (ie, volume) overload, and septic (bacterial contamination) reactions, which are the most common causes of transfusion-related deaths.

This is surprising in light of the fact that some authors consider that giving too much information may be a hindrance to the consent process by shifting the focus away from more significant concerns. Finally, though not statistically significant, a slightly greater number of responding patients reported that risks rather than benefits (7% vs 2%; P = .616) were not discussed. This finding is supported by resident survey responses, which also reported more frequently that risks rather than benefits were not discussed (3% vs 0%, although this amounts to only 1 resident response). This may reflect the fact that residents may be more reluctant or may feel less comfortable to discuss the risks.

The majority of patients reported having the opportunity to ask questions. Residents reported, however, that fewer than half the patients actually asked questions and their perception was that patients had only poor to moderate understanding of the indication (62%), benefits (62%), and risks (71%) of the planned transfusion. This may reflect a significant communication barrier between residents and patients, and that patients are reluctant to ask questions, perhaps in part because of perceived time constraints. Indeed, the majority of both residents and patients reported that their consent discussions lasted no more than 10 minutes, with a significant proportion of both groups indicating discussions of 5 minutes or less.

Interestingly, despite all of the aforementioned issues, and in spite of the fact that the majority of the surveyed residents were junior level trainees (ie, PGY-1 and PGY-2 residents), more than half (61%) indicated a high level of comfort in obtaining the consent, with the remaining 39% indicating a moderate comfort level. This is somewhat surprising given that most, if not all, lack any formal training in transfusion medicine. O’Brien et al also reported marked knowledge deficits in transfusion medicine based on an evaluation of the baseline knowledge of recently graduated medical students entering residency programs at a single medical center. Indeed, published data, including data from our own hospital center, showed marked knowledge deficits in transfusion medicine among clinicians and house staff in various specialties including internal medicine. Of 14 questions assessed regarding topics covering blood components, transfusion reactions, transfusion-transmitted infections, and laboratory techniques, the mean score for correctly answered questions was only 31.4%.

Our study has a number of limitations, including recall bias, which we attempted to minimize by focusing on recent transfusions (ie, within the prior 3 days). Because consent could have been obtained up to 7 days before the transfusion (ie, up to 10 days before the survey), recall bias may be a contributing factor for some patients; however, in no case was consent taken more than 2 days before the transfusion, with the majority (31 of 43, 72% of surveyed patients) occurring on the same day as the transfusion. We recognize that the accuracy of the responses from the 1 resident who did not recall the main indication may be questionable; yet, except for the main indication, we included the responses in the analysis because all of the other questions were answered definitively. In addition, interobserver variability in the way the surveys were conducted could have affected the results. We tried to minimize this with a prestudy discussion among the investigators on how to conduct the surveys to establish uniformity as well as how to use the introductory script to explain the nature of the study to the residents and patients being surveyed.

Finally, the results also could have been affected by the fact that a number of eligible patients and residents were not surveyed; in some cases, they refused participation whereas in other cases, we could not survey the patients in a timely manner (ie, within 3 days of the transfusion) either because we did not identify them in time or because they were discharged from the hospital. We relied on the blood bank staff to record issued RBC products on a daily log sheet as a means to identify eligible study patients and the corresponding residents. However, it was later recognized through blood bank information system records that, in fact, not all eligible patients were recorded on the daily log. Nevertheless, a comparison of the surveyed patients with the nonsurveyed, study-eligible patients showed no significant differences between the characteristics of the 2 groups.

In conclusion, although the majority of patients indicated satisfaction with the transfusion consent process, the results of our study point to significant deficiencies within our institutions. We believe that more education of house staff is necessary to improve knowledge of transfusion indications, benefits, and risks, which may lead to more meaningful discussion.
of planned transfusions with patients. Furthermore, increased awareness of available resources, such as the Transfusion Health Guide (of which only a minority of surveyed residents and patients were aware), should lead to better utilization of such resources by health care providers and better dissemination to the patients who may require transfusion.

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