Reflective student narratives: honing professionalism and empathy

UPREET DHALIWAL, SATENDRA SINGH, NAVJEEVAN SINGH

Abstract
The affective domain is not explicitly targeted during medical studies and poor skills in this domain may lead to conflict when dealing with patients. Reflective narratives are said to promote humanitarianism and professional development. We aimed to examine reflective narratives written by medical students in our institution for content relating to ethical and professional attitude and behaviour, communication, respect for diversity and disability, and empathy (the ABCDE paradigm). We were also interested in understanding how far the students enjoyed learning through the writing of narratives and in determining their perceived learning from the exercise. Volunteer medical students were introduced to Gibbs' reflective cycle during a half-day workshop. After giving written informed consent, they submitted anonymous reflective narratives (online), based on an interaction that they witnessed between a patient and a doctor/student. The authors performed directed content analysis of the submissions, using predetermined codes pertaining to ABCDE. At the end of the study, the participants sent in their feedback through a questionnaire on the process and the learning acquired, if any. Twenty-six students volunteered and 15 narratives were submitted. The issues that had been identified were discussed with the students. Feedback was submitted by 12 students, who strongly felt that the writing of narratives enhanced learning and professional development. They were interested in understanding how far the students enjoyed learning from the narratives and how far the writing of these narratives contributed to their enjoyment. In the long term, this exercise could be used to assist medical students in acquiring competencies in the affective domain.

Introduction
In their dealings with patients or peers, some medical professionals demonstrate poor skills in the affective domain, leading to conflict that affects the care of patients and interpersonal relationships in the workplace (1,2). Contrary to the recommendation of the Medical Council of India (MCI), the affective domain is not actively targeted during medical education (3). Skills pertaining to communication, ethical functioning, respect for diversity, the attribute of empathy and professionalism are expected to be picked up by observing peers or role models (4–5). Reflective narratives are known to hone the development of the affective domain among medical students (6–10). In the context of medicine, narratives describe an event or a personal experience, while reflective narratives go much further and critically analyse the experience. Gibbs' reflective cycle is a useful tool to promote reflection: it provides a framework to encourage the narrator to analyse thoughts and feelings, consider alternative solutions, and draw up action plans for the future (11).

According to the western literature, reflective writing profoundly improves students' levels of empathy (6), their professionalism (7,8), their respect for the diversity of patients, and their communication skills (7). Narratives have only very rarely been used in the Indian context (10). We have earlier used other humanities tools as a means to hone the ethical and professional attitude and behaviour, communication, respect for diversity and disability, and empathy (ABCDE) attributes of medical students (12). Using a directed approach to content analysis rather than starting from a naive perspective, we set out to explore reflective narratives written by medical students for content relating to the ABCDE attributes. Further, we aimed to determine their perceived learning from the narratives and how far the writing of these narratives contributed to their enjoyment. In the long term, this exercise could be used to assist medical students in acquiring competencies in the affective domain.

Methods
The present qualitative study was conducted between May and December 2015 at the University College of Medical Sciences and GTB Hospital, Delhi, India. After we had obtained approval from the institutional ethics committee, we introduced the project to all clinical batch students in their classrooms during a routine lecture. Thereafter, the social media, class visits and posters were used to request students to volunteer to participate in the project. The volunteers were introduced to the guidelines for and concept and rules of reflective writing, using Gibbs' reflective cycle, during a workshop lasting half a day (11). Gibbs' reflective
cycle encourages narrators to describe the event that they wish to reflect upon (Description), to record what they felt at the time (Feel), to consider what was good or bad about what happened and the problems that arose (Evaluation), to contemplate alternative perspectives to figure out why the problems arose and whether others were similarly affected (Analysis), to draw personal and general inferences (Conclusions), and to think about what they would do in the future to deal with or prevent such events (Action plan).

A list of questions/suggestions that prompt deeper self-reflection was provided. For example, to promote analysis of the experience, the participants could choose to “think about the things that went badly and write why you think they went badly; or, think about what the consequences were; or, think about what could have been done to avoid the negative consequences”.

The students were informed about the need for this project with the help of a participant information sheet. They were assured anonymity, safety and confidentiality, and were told that they had the power to withdraw at any time. We requested the volunteer students to submit reflective narratives based on an encounter that they had observed or experienced between a doctor (or student) and a patient. The submission of a narrative was taken as implicit consent to participate. The submissions were made online through SurveyMonkey®, with an option for anonymity, and could be in English or Hindi, depending on which language the narrator was comfortable with. So as to obviate recall bias in case of a time gap between the workshop and the posting of the narrative, a copy of Gibbs’ reflective cycle and a list of questions/suggestions that could help in deeper reflection were posted online with the participant information sheet.

Anonymous submissions were uploaded in a Google document that was shared with the participating students. To maintain anonymity, the first author copied all the narratives into an online Google document without attributing authorship; only the title of the narrative and its contents were made available for reading.

**Qualitative analysis of submitted narratives**

The authors performed directed content analysis of the narratives submitted, using predetermined codes based on the ABCDE paradigm (12). Each author independently read each narrative and highlighted portions of the text in which, in their opinion, a particular ABCDE issue had been reported by the narrator. The authors also highlighted portions in which reflection was evident.

For the purpose of this study, if the text under consideration referred to the rightness/wrongness, justness/unjustness or goodness/badness of a motive or action, it was given the code of “Ethics” (13); if it referred to a fulfilled/broken contract of responsibility for care by the physician, it was coded “Professionalism” (13); text referring to appropriate/inappropriate sending/receiving of information was coded “Communication”; when the participants noticed and wrote about issues arising out of differences in ability, gender, socioeconomic status, religion, language, caste or culture, the code was “Diversity” (12); and when the text referred to detecting or missing emotional cues and responding to them appropriately/inappropriately, it was coded “Empathy” (14). If the text raised an issue that did not fit into ABCDE, it was to be given a new code. Once this was done, the authors met to discuss the coding. Any discrepancy in the codes was resolved through discussion. The meaningful portions in each narrative text were marked to be used in the results and discussion as exemplar quotes.

**Student debriefing and feedback**

During a debriefing session with the participants, the authors discussed the issues raised in their narratives. This session was used to introduce them to the core competencies listed by the MCI in the Vision 2015 document (3). Following this, the students completed an anonymous questionnaire, which sought to assess whether they had enjoyed the process of writing narratives (Likert scale and open-ended questions), and determine if they had learnt anything through the process (open-ended). Enjoyment was assessed by three items (“I enjoyed writing narratives”, “I enjoyed reading narratives”, and “I would take part in this activity again”). We chose to measure enjoyment as it is a positive, activating emotion and is known to encourage learning and achievement (15). Perceived learning was assessed through direct questions pertaining to the specific ABCDE attributes – the questionnaire items are shown in Table 2. The feedback questionnaire was developed by the authors, and was pretested and modified after being shared on an international medical education Listserv (Christian Medical College, Ludhiana – Foundation for the Advancement of International Medical Education and Research Listserv). Data analysis was carried out using descriptive statistics and qualitative methods.

**Results**

Twenty-six students volunteered; 16 were from the 8th semester and 10 from the 6th. While all the students attended the reflective writing workshop, only 15 narratives were submitted over the following two-month period.

**Analysis of narratives for codes**

One narrative was about counselling a friend who smoked; one consisted of self-reflection; and 13 were about doctor–patient interactions. Of the latter, many narratives (n=7) reflected on incidents that were unpleasant and caused the patient some degree of physical or emotional distress. The remaining six shared incidents that showed the doctor–patient interaction in a positive light.

Each narrative raised more than one issue (the presence or lack of ethics, professionalism, communication, empathy or diversity). In fact, during analysis, the authors occasionally found that it was not possible to ascribe a single code to even short portions of a text. See, for example, Table 1, which...
Table 1

Excerpts from narratives submitted by medical students that depict reflection on multiple issues

<table>
<thead>
<tr>
<th>Excerpts</th>
<th>Issues identified in submitted narratives</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;I had to rise above things such as stigma and not let it affect my judgement.&quot;</td>
<td>Empathy, diversity</td>
</tr>
<tr>
<td>&quot;The consultant didn’t even once ask the sons what their expectations were. He didn’t even properly say if the mass was operable or not.&quot;</td>
<td>Ethics, professionalism, communication, empathy, diversity</td>
</tr>
<tr>
<td>As soon as the doctor arrived, she shouted, &quot;Why haven’t you taken off your clothes yet? Are you waiting for an invitation or have you come for a walk in the park?&quot; (Translated from Hindi)</td>
<td>Ethics, professionalism, communication, empathy, diversity</td>
</tr>
<tr>
<td>&quot;People using government healthcare are generally from the lower socioeconomic strata and are obviously not very well aware of their rights, because of which they get exploited.&quot;</td>
<td>Diversity</td>
</tr>
<tr>
<td>&quot;The patient was uncomfortable about exposing her abdomen probably because eight male students were standing around her and staring at her, so she refused.&quot;</td>
<td>Ethics, professionalism, diversity</td>
</tr>
<tr>
<td>&quot;...he was able to build that rapport with the patient and instil confidence ...... the way my friend talked to him made the patient feel good ... there was a feeling of comfort, understanding and positivty amongst them.&quot;</td>
<td>Professionalism, communication</td>
</tr>
<tr>
<td>&quot;We deliberated, yet did not speak our minds to the attending physician. There were a lot of wrongs that I felt happened in those 2–3 minutes, but they remained unaddressed.&quot;</td>
<td>Ethics, professionalism, communication</td>
</tr>
<tr>
<td>&quot;... patient screamed in pain......the postgraduate student’s behaviour made it even worse. I think he needed to be more polite with the patient.&quot;</td>
<td>Ethics, professionalism, communication, empathy</td>
</tr>
<tr>
<td>&quot;Ma’am asked the girl’s relative to leave the room. Then, in a very compassionate tone, she asked the girl about her problem.&quot;</td>
<td>Professionalism, communication, empathy</td>
</tr>
</tbody>
</table>

Evidence that students were reflecting on issues

"That day, I realised that humanity and ethics still reside in the hearts of doctors. From that day onwards, I decided to be more vigilant about my behaviour with patients, and even stopped my colleagues if I saw any of them being harsh or insensitive."

"I learned that ...if you have the will, the resources and the way will turn up eventually."

"My plan now is to behave cordially with all patients, regardless of the severity or type of their illness – I will not allow myself to judge them."

"After that incident, I had a very clear picture in my head that, regardless of whether I become a successful doctor or an ordinary one, I will never talk to my patient like this in my entire career..."

"I realised that we are dealing with someone’s father, someone’s husband."

"...there are people out there for whom a fare of even INR 20/- holds some importance."

---

The respondents had been given an option to make free-flowing comments during feedback. On analysis of these comments (Table 2), the students were found to have reported that there were changes in the way they now communicated with patients; they had a better understanding of their roles as professionals; they felt greater empathy; and the exercise had made them more observant and reflective. Overall, although the activity was fun ("structured classes would have made the same thing boring"), many students wished it had run longer, had included more participants in addition to faculty and postgraduate students, and had been face-to-face rather than online.

Discussion

Medical students should graduate with an understanding of ethics and professionalism, and should be able to communicate effectively, show empathy and demonstrate respect for diversity (16). The MCI includes these attributes...
Table 2

Student responses (n=12) on a 5-point Likert scale and to open-ended items in the feedback questionnaire that assessed their enjoyment and learning from the activity

<table>
<thead>
<tr>
<th>Questionnaire item</th>
<th>Strongly agree Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I enjoyed writing reflective posts</td>
<td>5 (41.7)</td>
</tr>
<tr>
<td>I enjoyed reading other students’ posts</td>
<td>5 (41.7)</td>
</tr>
<tr>
<td>I now wish that my post had been attributed to me by name and NOT posted anonymously</td>
<td>5 (41.7)</td>
</tr>
<tr>
<td>This activity enhanced my learning of reflective practice</td>
<td>7 (58.3)</td>
</tr>
<tr>
<td>This activity helped me to adopt a patient-centred attitude</td>
<td>7 (58.3)</td>
</tr>
<tr>
<td>This activity enhanced my learning of ethical issues in medicine</td>
<td>8 (66.7)</td>
</tr>
<tr>
<td>This activity enhanced my learning of effective communication</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>I believe this activity enhanced my learning of humanistic issues in medicine</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>I believe this activity enhanced my learning of empathy in medicine</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>I believe this activity enhanced my learning of professionalism issues in medicine</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>I believe this activity enhanced my learning of diverse patient needs</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>I would choose to take part in this activity again given another chance</td>
<td>6 (50.0)</td>
</tr>
</tbody>
</table>

I found that this activity helped me in the following ways:

"Now whenever I interact with a patient, I try to be more polite. I give them time to explain their complaints. This has helped me to present the case better because I am able to take a better history and examine better."

"It has helped me understand what patients and society expect of us and where we fail to live up to those expectations. Reflective medicine will help me adopt more of the ‘core competencies’ in my daily life, including my professional life."

"This activity helped me to realise that a doctor’s job is not only to treat a patient’s body, but also to heal the mind and soul."

"There is greater care and a heightened sense of empathy towards my patients when I am communicating with them. I never forget to greet my patients with a smile."

"It made me more observant. I think it taught me more of what NOT to do than what to do."

"Instilled in me the ability to reflect on my experiences; helped develop a patient-centred, rather than disease-centred approach to medical situations."

I did not like the following things about this activity:

"This activity was close to our examination dates, so we could not participate much."

"For a pilot programme, it was splendid. Loved the way it was conducted. I am glad I was a part of it. I would have incurred a huge loss as a physician had I not participated."

"Could have had more interactive sessions like the one we had recently (debriefing session). We don’t end up discussing these things on our own unless there’s a stimulus."

"The limitation of our narratives to just doctor–patient interactions."

"The duration was very brief and the number of participants was limited. A more elaborate activity involving a large group and spanning a longer period would have been better."

"I really did not have enough time to read what other people had written."

I would change the way this activity is conducted. Here are my suggestions:

"Conduct it during the start of the year. Students are more relaxed then."

"Make it a part of the regular activities in medical college."

"This activity should be conducted for students of all years, from the 3rd semester onwards. Also, the narratives and comments should not be anonymous."

"More face-to-face, interactive sessions"

"I’d like to ensure that everyone reads the narratives, so that at least some kind of message goes through – this is better than none – so that the desired change is induced."

"Every debriefing session should be attended by two to three seniors (postgraduates, residents and consultants) from different departments, so that they can also learn from our experiences, because everyone needs this reflective nature inculcated in them."

"I don’t want to change anything about it. My teachers made it as interesting and fun as it could have been."

"It’s a good activity and should be extended to as many people as possible, and not just to students. Including the stakeholders in discussions like this would make the real difference. For example, while discussing an example of a bad interaction, if senior doctors get to hear what we think of the incident, it would be possible to make a greater difference."
in the competencies desired for an Indian medical graduate (3); however, the current curriculum in universities around the country continues to be very heavily biased in favour of cognitive and, to a lesser extent, psychomotor competencies (17). The MCI’s move to introduce a longitudinal Attitude and Communication (ATCOM) module from the first semester of MBBS is apparently a step to promote the desired competencies (18). The module proposes innovative methods to train students in an attempt to develop ethical and professional attitudes and good communication skills. Specifically, pre-designed case scenarios are to be discussed with students. We used a different approach: students wrote their own narratives to serve the same purpose, with some added advantages. First, the scenarios narrated in our study were based on the actual lived experiences of the students and, possibly, the fact that they had ownership of and interest in the stories would make for better engagement (7). Second, the students were exposed to the nuances of reflective writing. These are the strengths of our study, as the following discussion will show.

We will first consider the affective competencies. The students’ narratives abounded in themes pertaining to the affective domain. As Table 1 shows, many issues related to ethical and unethical behaviour, success and failure in communication, respect or lack of respect for diversity, and empathy or the lack of it. This is a critical finding of the study. Others have also shown how the writing of narratives offers a different way of learning as opposed to usual medical writing, such as the writing of case notes: while both are non-fictional in character, the former allows discussion around topics that may be difficult to consider in a traditional classroom or ward (9). In addition, a space such as the one we provided gives students an opportunity to learn more about themselves, to challenge their assumptions and to appreciate other perspectives (9). These are useful gains when we consider that students are future medical practitioners who must work in teams and thus need to learn the importance of remaining open to and respectful of diversity, and to be sensitive to diverse viewpoints (3).

Feedback from the students provided corroborative evidence of the benefits of narrative writing (Table 2). For one, this exercise introduced them to other roles, like communicator and professional, and they learned that they needed to be more than just ethical clinicians. Two, they reported that they became more observant and patient-centric, and tried harder to communicate with patients in an empathetic manner. Third, they learned how to reflect on issues that they encountered in clinical practice. This last benefit is borne out by the promising level of reflection revealed in the submitted narratives. The students instinctively noticed what was right and what was wrong about a doctor–patient interaction, and were open to writing about it. Reflection helped them to understand these issues, and to make plans on how to modify their attitudes and behaviour so as to enhance patient-centred care. These are important attributes of a good doctor. As stated by a global community of educators, the writing of reflective narratives is a source of learning and can even be used for the assessment of the affective domain (1,4–6). We did not specifically study the use of narratives for the purpose of assessment; however, seeing the rich quality of the content of the submitted narratives, it is not difficult to imagine that assessments could be made. Since most of the work on the use of narratives in medical education is being reported from the West, with only the occasional report from India (10), clearly more work needs to be done in this promising field in India.

Despite their tight academic schedules and other constraints, the participating medical students could be trained to critically analyse an interaction with a patient. Part of the exercise, which was online, allowed the students to work at their own convenience, outside of the regular curriculum, since the latter places time constraints on students and is content-heavy. While the students enjoyed writing narratives and reported having learnt a few things as a result of the exercise, our study had certain limitations. Students self-selected – the quality of the narratives and the reflections may have been different if we had used random sampling instead of enrolling motivated volunteers. It is likely that only those with good language skills, or like-minded students who were interested in writing about their experiences, volunteered. Thus, our sample is unlikely to be truly representative of the entire population of medical students. Nevertheless, this sample served the purpose for which the study was designed – it allowed us to determine that reflective narratives could be used as a means to hone affective (ABCDE) attributes among medical students. A random sample may not have achieved this purpose. There is a need to consider how one can apply this exercise, with the potential learning associated with it, to all students across the board. Recognising the importance of such interventions, Columbia University has made it mandatory for medical students to enrol in one or the other narrative medicine course for half a semester prior to the beginning of their clinical postings, besides offering a month-long elective in the fourth year. These courses are assessed (9). The Ohio State University has a different approach: it requires all fourth-year medical students to write at least one narrative based on their clinical experiences during their posting in a particular department (8). In India, curriculum designers could consider ways in which a learning activity as promising as this one can be mainstreamed in our context. They could also consider using it as an assessment tool. Since assessment drives learning, it might be one way to ensure participation by all students.

Another limitation of this study is that the submission of narratives was anonymous, and it is possible that some of the experiences described may have been exaggerated. Also, the study sample was small, considering that the institution admits 150 students every year. This is a matter of some concern, particularly if the activity is to be mainlined into the curriculum. The timing of the study may have been a primary contributory factor. The study clashed with the terminal examinations, send-ups and professional examinations of some batch or the other; perhaps if it had been implemented right after these
examinations, more students would have taken part and more narratives submitted. The participants also found that they had other academic responsibilities that did not allow them to devote time to an activity that was voluntary and asynchronous. The study suffered from an important drawback of participation by a relatively small number of students: the students’ observations reported in this paper may reflect only a fraction of the entire gamut of issues encountered by them. Thus, some issues may have been missed and would never get discussed in real time. The participants indeed felt that this was the case. During feedback, they reported that they should not have been restricted to reflecting on “just doctor–patient interactions”. Apparently, there were other issues they wanted to share and discuss.

Despite our study's limitations, and going by the self-reported experiences of the students who participated and the quality of their narratives, we can use the narratives to strengthen the training of medical students’ ABCDE attributes. The process includes encouraging open discourse on many issues which they come across in their day-to-day interactions with patients, but which are seldom discussed in the frenetic rush of academic activities. By also promoting reflection, this exercise could hone the affective dimensions of learning. It was moving to hear students talk about their experiences in clinics and a little unnerving to be reminded that students minutely observe what their teachers and peers do. Teachers should be made aware of the need to behave appropriately to serve as role models for their students lest the latter inadvertently adopt practices that are neither ethical, nor professional (19).

This study had an interesting offshoot, which arose from the fact that we invited narratives in Hindi. Our reasoning was that many of our students have studied in Hindi-medium schools. In addition, Hindi is the language that many speak at home and, therefore, they are more expressive when using this language. Only one student chose to write in Hindi. All three authors felt that this narrative was by far the most detailed and reflective of all the narratives submitted. This could have been a coincidence. However, it does beg the question of whether training in communication skills should be offered to medical students in the vernacular – the language in which the students are expected to communicate with patients who visit this hospital – rather than English alone. Other authors have suggested that it may be fallacious to assume that learning communication skills in English will effectively enable doctors to communicate with patients who do not know the language (20). In India, there is a very real possibility that in the future, training in medical colleges will be conducted in regional languages. This is particularly likely in view of the recent amendment that legitimises the conduct of the national entrance examination (for admission to undergraduate and postgraduate medical courses) in English, Hindi and several regional languages (21).

On the basis of the student feedback, we plan to introduce more face-to-face time in future sessions. The post-narrative debriefing will be staggered over many sessions, during which we will discuss 2–3 narratives at a time with the whole group. We will invite reflections on whatever issue the students choose to write about and not just on doctor–patient interactions. We shall look for an opportunity to share these narratives with first-year medical students to make them aware of issues that they should be prepared to come across during practice. Mainstreaming the activity into the curriculum should be helpful in the long run, as it will then be available to more than just volunteer students.

In conclusion, the writing of narratives using Gibbs’ reflective cycle is an unconventional, innovative method to teach and assess competencies in the affective domain. Our findings support the use of reflective narratives to help medical students learn the necessary competencies, with particular reference to empathetic clinician, communicator and professional, and those described in the ABCDE paradigm. Over a period of time, this activity has the potential to transform the institutional climate into one characterised by a frank discussion of issues pertaining to ethics and professionalism. In addition, the effort to teach and acquire communication skills, empathy, and respect for diversity are likely to become a routine matter. The long-term outcomes – effect on the care of patients - may be addressed through a follow-up study. It might be worthwhile to revisit the students who participated in this initiative at different stages of their evolution as medical practitioners, after they have been practising for a few years, to assess how much they still retain of their self-reported learning. This qualitative study could be the basis for future studies that can investigate the influence of narratives on medical students’ actions in practice.

Competing interests and funding support: None declared

Acknowledgements: The authors acknowledge the guidance and help provided during the phase of the conceptualisation of the project by Dr Bharti Uppal and Dr Ciraj Ali Mohammad, CMCL-FAIMER faculty. They are also extremely grateful to the medical students who willingly participated in this project.

Note: The project was presented by Dr UD as an oral paper at “A Palpable Thrill – an Introduction to Medical Humanities”, held on May 7 and 8 (2016) at Hamilton, Canada.

References
Participation in randomised controlled trials: perspectives of psychiatric patients and key relatives

DONAE ELIZABETH GEORGE, SAUMIL DHOLAKIA, PRATHAP THARYAN

Abstract
This study assessed the perspectives of adults who had acute non-organic psychiatric disorders and were admitted in a private, not-for-profit medical college hospital, and also of their key relatives, on randomised controlled trials (RCTs). Structured questionnaires and audio-recorded interviews were used for the purpose. We explored their willingness and motivation to participate in two hypothetical RCTs with different risks and burdens. The transcripts of the interviews were analysed using the principles of grounded theory and framework analysis. Of the 24 consenting participants (12 patient and key-relative dyads), the 20 who completed the interviews had largely positive attitudes towards research and RCTs. However, 50% of those interviewed declined to participate in either of the hypothetical RCTs. The refusal to participate seemed to be influenced by a lack of education; forgetfulness, which impeded the process of making informed decisions; unfavourable benefit–risk–burden ratios; practical difficulties; dependence on treating doctors and relatives for decision-making; and the wish to exercise one’s choice regarding treatment options. The factors that motivated the patients and relatives were trust in doctors and organisations, altruism, expectation of personal benefits and favourable risk–benefit ratios. These observations indicate that while the respondents in this study valued research, they were discerning about whether or not to participate in the trials; their decision-making was influenced by individualised assessments of risks and burdens and pragmatic considerations, rather than only by the benefits they would obtain.

Introduction
Informed consent is an ethical and regulatory prerequisite for participation in clinical research. Ethical and regulatory guidelines and directives stipulate the essential elements of the information that must be provided to potential research participants (1–3). These requirements stem from the premise that the provision of adequate information facilitates decision-