

## CLINICAL REPORT

# Insufficient Knowledge Among Psoriasis Patients Can Represent a Barrier to Participation in Decision-making

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**Patient participation in treatment decisions can have positive effects on patient satisfaction, compliance and health outcomes. The objectives of this study were to examine attitudes of psoriasis patients regarding participation in treatment decisions and to evaluate the effect of a decision-aid for discussing treatment options. A “quasi experiment” was conducted in a large dermatological hospital in Italy: a questionnaire evaluating the decision-making process and treatment knowledge was self-completed by 231 consecutive psoriasis patients after routine clinical practice and by a second sample of 171 patients exposed to a decision-board. In routine clinical practice 67.9% of patients wanted to be involved in decision-making, 28.4% wanted to leave decisions entirely to the doctor and 3.7% preferred making decisions alone. 17.9% and 25.3% of the control and decision-board group had good knowledge. At multivariate analysis good knowledge increased the likelihood of preferring an active role (risk ratio (RR) = 2.21; 95% confidence interval (CI) 1.3–3.9;  $p = 0.006$ ). The decision-board only marginally improved patient knowledge and doctor-patient communication. In conclusion, large proportions of psoriasis patients want to participate in decision-making, but insufficient patient knowledge can represent a barrier. Key words: decision-aid; chronic skin diseases; patient participation.**

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In recent years increasing attention is being devoted to the importance of patient involvement in treatment decisions (1). The *paternalistic model* has dominated until recently, but has been challenged by doctors, patients and researchers. It assumes that the doctor can make the best treatment decision for the patient without involving him or her. At the other extreme lies the *informed model*, with the doctor having the sole responsibility for providing information to the patient, while the decision-making is only prerogative of the patient (2). The *shared model*, which is advocated as the preferred approach, is characterized by a partnership between doctor and patient,

based on a two-way exchange of any information that might be relevant for decision-making (3).

Numerous studies, including one survey on psoriasis patients, have shown that there are considerable variations between individual patients and between doctors and patients regarding values placed on benefits and risks of different treatments and health states (3–5).

Psoriasis is a relatively common disease that can have a significant impact on patients' quality of life (6, 7). Each treatment option, including topical and systemic treatments and photo-therapy, is characterized by specific benefits, costs, potential side-effects and practical difficulties, i.e. time required for applying topical agents or availability of photo-therapy equipment. Because of the chronic nature of psoriasis and because trade-offs between benefits and risks may vary between patients and between patients and doctors it might be particularly valuable to adopt a shared approach in treatment decisions. Some studies suggest that this might have positive effects on treatment compliance and health outcomes (8–11). Improved doctor-patient communication can also increase patient satisfaction (8), which has been shown to positively influence compliance in dermatological outpatients (12).

Numerous studies have dealt with the problem of facilitating patient participation through the development and implementation of decision aids for various clinical situations, i.e. cancer treatments, ischaemic heart disease, hormone therapy and screening tests (8, 13, 14). Decision aids have been shown to improve patient knowledge about treatment options and outcomes and to stimulate patients to take a more active role (4, 8, 13).

Some studies on dermatological diseases include an assessment of patient preferences when comparing different treatment options (15–17) and one study evaluated preferences for different health outcomes among psoriasis patients (5). However, to our knowledge, no study has performed a systematic evaluation of attitudes concerning participation in treatment decisions among patients with skin diseases.

We hypothesized that patient participation, satisfaction and knowledge level could be improved by the introduction of a decision-aid that dermatologists could use for discussing treatment options with patients. Thus, the objectives of the study were: (i) to evaluate the decision-making process regarding treatment prescription

for psoriasis patients in routine clinical practice and to examine whether patients perceive the need for greater patient involvement, and (ii) to develop a decision-board for discussing treatment options with patients, and to examine its effects on patient participation, knowledge on psoriasis treatments and satisfaction with care.

## METHODS

### *Study design*

The study was performed at the Istituto Dermopatico dell'Immacolata (IDI-IRCCS), Rome, Italy, the largest dermatological treatment and research facility in Italy, with 122,000 dermatological outpatient visits and 13,668 admissions during 2004.

A "quasi experiment" with two consecutive phases was performed. In the initial (control) phase (September 2003 – January 2004) a consecutive sample of psoriasis patients was interviewed, collecting information on the decision-making process regarding treatment prescription in routine clinical practice, on patients' and physicians' satisfaction with decision-making, and on patient knowledge on treatments.

In the second (experimental) phase (January–April 2004) clinicians were invited to use a specifically developed decision-board for discussing treatment options with a second consecutive sample of psoriasis patients. The introduction of the decision-board as an aid for discussing treatment options was the only intervention characterizing the experimental phase. Two different samples of patients participated in the initial and the experimental phase and there were no patients participating in both phases.

Outpatients and inpatients affected by psoriasis were recruited in the waiting rooms of the outpatient clinic and at hospital admission, respectively. Exclusion criteria were: age < 18 years; having visited IDI during the last 3 months, for excluding patients coming only for a follow-up visit.

After the outpatient visit and at discharge for inpatients, patients and dermatologists self-completed a questionnaire evaluating the patient-physician interaction and the decision-making process. Patients and physicians were also asked to indicate how much time was spent during the visit discussing treatments. The same questionnaires were used in the two phases of the study, except for some questions on the decision-board regarding only the experimental phase. Dermatologists reported diagnosis and disease severity for each patient. Disease severity was scored on a five-point scale, according to dermatologists' answers to the following question (7, 12): "In your experience, among all patients you have seen with this condition, how severe is this patient's condition?"

Five dermatologists visiting outpatients and 6 dermatologists treating inpatients participated in the study. There were 9 male and 2 female dermatologists, median age was 56 years (range 32–68 years).

The study was approved by the institutional ethical committee and written informed consent was obtained from all participants.

### *Assessment tools*

The questionnaire evaluating patient satisfaction and attitudes regarding decision-making has been designed using as reference already validated questionnaires (8, 18–20). We have adapted the questions for patients attending a dermatological clinic in Italy. Content validity was established by asking 10 patients and 5 dermatologists to review the questionnaire critically,

with particular attention to clarity, completeness and clinical relevance of the questions (21). The questionnaire was then piloted on 30 patients examining ease of comprehension, feasibility and acceptability.

The section on patient satisfaction was based on neutrally worded questions and response formats, in order to minimize acquiescence response bias and unreliability in satisfaction measures (18) and had already been used in a previous study (22). Patients were invited to express their opinion, by choosing their answer on a five-point scale, ranging from totally positive to totally negative opinions. For example: "What is your opinion on the doctor's answers to your questions?" Possible answers: Excellent, Very good, Good, Fair, Poor.

The final version of the patient questionnaire included 25 questions on attitudes and satisfaction regarding the decision-making process. Patient preference for decision-making was assessed using a six-point Likert scale, in agreement with an instrument used in previous studies (8). The Italian version was back translated, in order to assure minimal ambiguity. Response options included: "I prefer to make the final decision myself about which treatment I receive"; "I prefer to make the final decision myself about which treatment I receive, after seriously considering the doctor's opinion"; "I prefer that the doctor and I share the responsibility of deciding which treatment I should receive"; "I prefer that the doctor makes the final decision, but after he has seriously considered my opinion"; "I prefer leaving all decision to the doctor regarding my treatment"; "I am not sure".

Patients' knowledge of psoriasis treatments was evaluated by asking them to identify 9 correct statements among 12 options. The statements regarded simple, clinically relevant information on treatment options. Examples of correct statements were: "Psoriasis treatment can include exposure to UV lamps"; "Psoriasis treatment can include drugs that are taken orally"; "Treatment options can vary according to the severity of psoriasis". An example of a non-correct statement was: "For phototherapy to be effective for treating psoriasis, usually one session every 15 days for a month is sufficient".

### *Decision-board*

A review of the literature regarding treatment options for psoriasis was performed, focusing on efficacy, side-effects, safety and patient attitudes and quality of life related to psoriasis treatments (1, 5, 6, 17, 23) and on decision aids and patient involvement (2–4, 8, 13, 14).

Based on this information a decision-board draft was designed by a group including one dermatologist, one internist, one medical epidemiologist and one physician specialized in public health and preventive medicine. The decision-board draft was then discussed separately with five dermatologists and five patients. Dermatologists suggested corrections regarding the frequency of some potential side-effects. For example, regarding methotrexate, it was specified that cirrhosis can "sometimes occur, in case of long-term treatment". The patients provided comments mainly on the comprehension of the terminology, which was subsequently simplified (e.g. "alopecia" was substituted with "hair loss"). The aim was to present all the important information on different treatment options in a simple easily comprehensible and visually clear manner. The revised decision-board was then piloted on a sample of 30 patients. Minor corrections were made after the pilot study, aiming at further simplifying the decision aid. The final version of the decision-board consisted of an A4-page printed on both sides. The front page described topical treatments and photo-therapy; the back page described systemic therapies. Possible side-effects of each treatment option were reported in three columns of different colours, depending on whether they

occur frequently, sometimes or rarely. A fourth column included additional information that could influence treatment choices, e.g. for photo-therapy it stated that generally it requires three sessions weekly for several weeks.

#### *Statistical analysis and variable definitions*

Satisfaction was grouped into three categories: completely satisfied (including "totally" and "very satisfied"), fairly satisfied and not satisfied (including "not very satisfied" and "absolutely not satisfied"). Overall satisfaction with care was also dichotomized, defining "totally" and "very satisfied" patients as completely satisfied and all others as not completely satisfied.

For evaluating patients' knowledge on psoriasis treatment the mean number of correct answers was compared between control and decision-board group using the *t*-test. Moreover, the knowledge score was divided into tertiles and then grouped into two categories: the upper tertile, corresponding to 6 or more correct items, was defined as good knowledge, the intermediate and lower tertiles were defined as non-good knowledge.

Pearson's  $\chi^2$  test was used for comparing proportions. The significance level was set at  $p < 0.05$ .

Multiple logistic regression was used to examine factors associated with patients preferring an active role in decision-making compared with those preferring a paternalistic doctor-patient relationship. Patients preferring an active role were defined as those wanting to make the final treatment decision alone or after considering the doctor's opinion and those wanting to share the decision with the doctor. Patients preferring a paternalistic approach were defined as those wanting to leave decisions entirely to the doctor and those preferring the doctor make the final decision after considering their opinion. Moreover, logistic regression was used for examining factors associated with good knowledge level.

Sample size calculations were performed hypothesizing that among the control group 30% would have good knowledge on psoriasis treatment vs. 46% among the decision-board group. Thus, a study with 160 unexposed and 160 exposed patients would have 80% power to detect a RR of 1.5, at the 0.05 level of significance.

The computer package STATA-7.0 for Windows was used for statistical analyses.

## RESULTS

### *Baseline attitudes and satisfaction regarding the decision-making process*

Overall, 116 psoriasis outpatients and 115 inpatients were included in the first phase of the study (response rate 88%) and 87 outpatients and 84 inpatients were included in the second experimental phase (response rate 86%). The mean age was 45 years (standard deviation (SD) = 15 years) among the control group and 43 years (SD = 13) among the decision-board group; 68% and 62%, respectively, were men. In both groups 55% of patients had higher educational level (i.e. at least 13 years of school). Disease severity was grouped into three categories: mild (including very low and low severity), moderate and severe (including severe and very severe cases). Disease severity was mild for approximately 28%, moderate for 53% and severe for 18% of patients in both groups.

The main diagnostic categories, in the control and decision-board group, were: diffuse chronic plaque psoriasis (>10% of the body surface area affected (BSA) (47.3% and 42.9%, respectively); localized chronic plaque psoriasis (<10% of BSA) (36% and 33.9%, respectively); psoriatic arthritis (6.8% and 10.7%, respectively). Patient characteristics were not significantly different between control and decision-board group ( $p > 0.05$ ).

In- and out-patients differed significantly regarding educational level (56.3% vs. 43.7% had higher education) and severity of disease: the majority of outpatients had mild (44.6%) and moderated (40.9%) diseases, compared with the majority of inpatients having moderate (65.0%) and severe (22.3%) diseases ( $p < 0.001$ ).

In the control group, i.e. in usual clinical practice, 67.9% of patients would have liked to be involved in discussing treatment options with the doctor; these include 33% of patients preferring to share the decision with the dermatologist, 29.4% preferring the doctor make the final decision, but after seriously considering their opinion, and 5.5% preferring to make the final decision after considering the doctor's opinion. Only 3.7% preferred to make the decision alone, while 28.4% preferred to leave the decision entirely to the doctor. In- and out-patients were not significantly different ( $p = 0.18$ ).

On the question on satisfaction with the decision-making process 33% of patients would have liked to be more involved in decision-making (Table I). The proportion of patients in the control group wanting to be more involved was significantly higher among inpatients than outpatients (42.7% vs. 24.8%;  $p = 0.002$ ). In the control group, satisfaction with all aspects of doctor-patient communication shown in Table I was always significantly higher ( $p < 0.001$ ) for outpatients compared with inpatients, except for overall satisfaction, which was very similar (data not shown).

### *Satisfaction with the decision-board*

Similarly to the control group, also among the decision-board group, 37.6% of patients preferred to share decisions with the dermatologist, 30.9% preferred that the doctor make the final decision after considering their opinion and 7.2% preferred to make the decision after considering the doctor's opinion. No-one preferred to make the decision alone, while 24.3% preferred to leave decisions entirely to the doctor. Among the decision-board group there are no significant differences between in- and out-patients regarding the preferred role in decision-making and the specific aspects of doctor-patient communication (data not shown). The only exception regards the opportunity to express an opinion about treatment, with 61.2% of completely satisfied outpatients compared with 33.8% of inpatients ( $p = 0.002$ ).

Table I. Patient attitudes and satisfaction regarding the decision-making process

	Control group (n=231) (%)	Decision-board group (n=171) (%)	p-value
Satisfaction with decision-making			
Wanted to be more involved	33.0	34.7	0.823
Satisfied	63.2	62.6	
Wanted to be less involved	3.8	2.7	
Opportunity to express opinion/doubts			
Completely satisfied	46.5	48.7	0.707
Fairly satisfied	27.2	26.9	
Not satisfied	14.8	10.9	
Had no doubts	11.5	13.5	
Doctor asked if patient had questions/preferences			
Yes	44.6	44.4	0.976
No	55.4	55.6	
Information on treatment options			
Completely satisfied	54.7	57.1	0.626
Fairly satisfied	35.4	35.9	
Not satisfied	9.9	7.1	
Doctor considered patient's preferences			
Very much	56.2	55.9	0.967
Somewhat	18.6	19.6	
Very little/not at all	25.2	24.5	
Information on treatment side-effects			
Completely satisfied	51.0	56.1	0.059
Fairly satisfied	33.2	36.5	
Not satisfied	15.9	7.4	
Overall patient satisfaction with care			
Completely satisfied	62.5	66.7	0.408
Not completely satisfied	37.5	33.3	

As shown in Table I, comparing satisfaction with specific aspects of doctor-patient communication between the control and the decision-board group, yielded no significant differences. The only difference, that reached borderline significance, regarded a higher proportion of patients satisfied with information on treatment side-effects among the decision-board group compared with the control group.

Patients were asked to indicate how much time the doctor spent informing and discussing treatments with them. In routine clinical practice, 36.9% of inpatients and 17.7% of outpatients reported less than 5 min, 35.9% of inpatients and 53.1% of outpatients reported 5–10 min, and 27.2% of inpatients and 29.2% of outpatients reported more than 10 min ( $p = 0.012$ ). Similar results were found in the decision-board group. Doctors reported in the majority of cases (67.3%) spending 5–10 min discussing treatments with inpatient, while for the majority of outpatients they indicated 11–20 min (68.5%).

Doctors considered the decision-board extremely or very helpful in 50% of cases for inpatients and 22.6% of cases for outpatients; fairly useful in 24.1% and 47.6% of in- and out-patients, respectively, and not useful for 25.9% and 29.8% of in- and out-patients, respectively ( $p = 0.002$ ).

### Patient knowledge of psoriasis treatments

Patients were asked to identify 9 correct statements on psoriasis treatments among 12 possible options. The mean number of correct answers was 3.8 in the control group (range 1–7) and 4.1 in the decision-board group (range 1–8) ( $p=0.087$ ). The percentage of patients with good knowledge (i.e. patients having correctly identified 6 or more items, corresponding to the upper tertile) was 17.9% among the control group compared with 25.3% in the decision-board group ( $p=0.09$ ). We found a higher prevalence of good knowledge for participants exposed to the decision-board compared with the control group also analysing in- and out-patients separately, although no statistically significant values were reached.

Patients with good knowledge reported more frequently complete satisfaction with care (71.2%) compared with patients with poor knowledge (62.6%;  $p=0.039$ ).

Comparing younger dermatologists (<50 years;  $n=6$ ) with older ones ( $\geq 50$  years;  $n=5$ ), has shown that, among patients treated by younger dermatologists, decision-board exposure was significantly associated with better knowledge (42.9% of exposed patients had good knowledge vs. 16.7% of non-exposed patients,  $p=0.008$ ). No association was found among patients seen by older doctors. No significant differences in satisfaction regarding younger vs. older doctors were reported, even though satisfaction was slightly higher for younger doctors (data not shown).

Subgroup analysis was performed for three dermatologists having each visited more than 50 patients. For one dermatologist, no association was found between decision-board exposure and patient satisfaction and knowledge level. For the other two dermatologists, patient satisfaction was higher after decision-board exposure compared with the control group. However, statistically significant values were reached only for patients visited by the youngest dermatologist participating in the study: 100% of his patients exposed to the decision-board reported overall satisfaction vs. 76.9% among his non-exposed patients ( $p=0.02$ ). The proportions of good knowledge level among patients of the youngest dermatologist was also higher after decision-board exposure compared with non-exposed patients (52.6% vs. 24.0%,  $p=0.05$ ).

### Multivariate analysis

Multiple logistic regression was used to examine factors associated with patients preferring an active role compared with preferring a paternalistic doctor-patient relationship. Age, gender, education, duration of disease, disease severity, knowledge regarding psoriasis treatment and decision-board exposure were included in the model. Using two separate models for in- and

out-patients, we found that among outpatients women showed a significantly lower likelihood of preferring an active role than men (RR=0.49; 95% CI 0.3–0.9;  $p=0.04$ ). Good knowledge significantly increased the likelihood of preferring an active role (RR=2.50; 95% CI 1.1–5.8;  $p=0.03$ ). All other variables had no significant effect. Among inpatients only age was somewhat associated with patients' preferences in decision-making: the likelihood of preferring an active role decreased with increasing age (continuous variable), but without reaching statistically significant values (RR=0.56; 95% CI 0.3–1.1;  $p=0.07$ ). Decision-board exposure had no significant effect on decision-making preferences (RR=1.10; 95% CI 0.6–2.1;  $p=0.78$  for outpatients and RR=1.22; 95% CI 0.6–2.4;  $p=0.57$  for inpatients). No significant interactions between variables included in the models were found with the likelihood ratio test.

Including in- and out-patients in one model, only knowledge significantly increased the likelihood of preferring an active role (RR=2.20; 95% CI 1.3–3.9;  $p=0.006$ ).

Finally, multiple logistic regression was used to examine the association between knowledge and age, gender, education, disease severity, duration of disease, in- and out-patient and decision-board exposure. Among inpatients the likelihood of having good knowledge decreased with increasing age (RR=0.39; 95% CI 0.2–0.9;  $p=0.019$ ) and increased with higher educational level (RR=3.81; 95% CI 1.6–9.3;  $p=0.003$ ). Among outpatients, only age was associated with a lower likelihood of good knowledge, but not at statistically significant levels (RR=0.53; 95% CI 0.3–1.0;  $p=0.07$ ). Decision-board exposure was not significantly associated with knowledge level (RR=1.66; 95% CI 0.7–3.7;  $p=0.21$  for inpatients and RR=1.19; 95% CI 0.5–2.7;  $p=0.67$  for outpatients).

## DISCUSSION

This study has shown that, in routine clinical practice, 67.9% of psoriasis patients would have liked to be involved in discussing treatment options with the doctor, while 28.4% of patients wanted to leave treatment decisions entirely to the doctor and only 3.7% preferred to make decisions alone. Studies conducted in different settings reported somewhat higher proportions of patients wanting to play an active role. For example, a study among women with breast cancer found that only 1% of patients wanted to leave treatment decisions entirely to the doctor, 47% preferred a shared decision and 51% wanted to make decisions alone (8). These differences might be related to the different nature of the diseases included in the studies, to patient characteristics and to the cultural context. Unfortunately, we cannot compare our results with other studies on dermatological patients, as no previous survey has evaluated attitudes regarding decision-making among patients with skin diseases.

Multivariate analysis has shown that, in our sample, the main factors associated with outpatients preferring an active role was treatment knowledge and male gender. Knowledge level was, in turn, associated with educational level. These results are in line with a survey on cancer patients in Italy reporting that patient-physician communication and the decision-making process were related primarily to patients' educational level (24).

Knowledge level on treatments in our sample was relatively low. A recent survey on psoriasis patients has shown that also in the USA, there are relevant proportions of patients with substantial knowledge gaps (25). Similarly to our study, also in the US sample, higher knowledge level was associated with greater satisfaction with care.

In our study, decision-board exposure was not significantly associated with knowledge level at multivariate analysis. However, our study had limited power, particularly considering the relatively low prevalence of good knowledge in our sample. A larger sample would have been needed for identifying a significant association. Despite not reaching statistically significant values, patients exposed to the decision-board had a higher prevalence of good knowledge and, for the subgroup of patients visited by younger dermatologists, the decision-board was significantly associated with patient knowledge.

Previous studies using decision-boards in a variety of clinical situations, i.e. for cancer treatments, screening tests, etc., have shown that they are useful instruments for improving patient knowledge and for facilitating communication and shared decision-making (4, 13, 26). For example, women with early breast cancer exposed to a decision-board had better knowledge on the disease and treatment options and greater satisfaction with decision-making compared with non-exposed patients (26). A review on cancer-related decision-aids (4) has shown that they are superior to usual care in improving knowledge and in creating realistic expectations, while they generally have no impact on patient satisfaction. A review on decision-aids for screening or treatment decision (13) found that they produced increased knowledge scores (mean difference 19/100; 95% CI 14–25), more active patient participation (RR 2.27; 95% CI 1.3–4), but no effect on satisfaction with the decision-making process.

Our study is in agreement with previous research regarding a lack of association between decision-board exposure and patient satisfaction. However, contrary to previous reports, we did not find an association between decision-board use and a more active patient participation.

This finding and the finding that knowledge was only marginally improved by decision-board exposure in our study, might in part depend on the design of the instrument, on how it was used and on the general attitudes towards patient participation. Shared decision-making is complex. The decision-board can represent an aid for doctors and patients, but is probably not enough for

significantly modifying the decision-making process, particularly in cases of deep-rooted behaviour and attitudes. Subgroup analysis by dermatologist, has shown that the association between decision-board exposure and patient knowledge and satisfaction with doctor-patient communication varied between dermatologists. In particular, among younger dermatologists, decision-board use was associated with significantly improved patient knowledge. This might be related to a more open and flexible attitude of younger physicians in changing the approach in the doctor-patient interaction. Another possible explanation could be that patients feel more comfortable in discussing treatment options and doubts with younger doctors. A study including a bigger number of dermatologists, each visiting a sufficient number of patients would be necessary, in order to further explore this issue.

Our finding regarding women reporting a lower likelihood of preferring an active role in decision-making, independently of socio-demographic and clinical factors, is in contrast with other studies on patient participation, showing that women were more likely to prefer an active role than men (27, 28). Further studies would be needed, examining specific psychological and personality characteristics of participants.

In our study overall patient satisfaction in routine clinical practice was relatively high (approximately 63%). However, specific aspects of doctor-patient communication would deserve improvement, particularly regarding inpatients. A lower satisfaction among inpatients was somewhat surprising, considering that usually there is more time pressure for outpatient than for inpatient care. However, patients and doctors reported that time spent discussing treatments in a face-to-face encounter was significantly shorter for inpatients than for outpatients. Moreover, differences between in- and out-patients regarding disease severity, age and other characteristics might explain these results.

#### *Potential limitations of the study*

Comparison of our results with previous research is limited almost exclusively to patients with non-dermatological diseases. In fact, only one study among psoriasis patients examined patient preferences for specific psoriasis treatments, showing that individual patients vary widely in their preferences for specific treatments and tolerance for disease burden (5). A survey on members of the US National Psoriasis Foundation showed that 32% of patients felt that treatment was not aggressive enough (6). These findings highlight the need to improve patient involvement in decision-making, in order to determine appropriate treatments for individual patients.

In order to evaluate the impact of the decision-board, the ideal study design would be a randomized controlled

multicentre trial, including sufficient number of doctors randomized to using or not using the decision-board. Randomization of physicians rather than patients would be preferable in order to reduce contamination problems, which could arise if the same physician alternates use and non-use of the decision-board (4). Such a study was, however, beyond our scope. It is possible that our study could have been biased by changes over time in physicians' and patients' behaviour. This is, however, unlikely, because the control and experimental phases were performed over two immediately consecutive and short time periods.

It should be noted that the findings reported here are specific to our institution and the local cultural context. Caution should be used in generalizing our results. However, as shown by studies and initiatives conducted in various countries on different medical conditions, many problems and potential solutions regarding patient participation in decision-making are similar in western healthcare systems.

In conclusion, our study has shown that the majority of patients would like to be involved in decision-making, but insufficient knowledge on treatments can represent a barrier. In order to improve patient participation, various interventions should be considered, in addition to developing improved decision aids. In particular, a greater emphasis should be placed by local healthcare managers and by clinicians on the importance of patient involvement in decision-making. This represents a cultural shift for both patients and doctors, who until relatively recently were used to a more paternalistic doctor-patient relationship (29). Medical education programs can probably be helpful to improve doctors' communication skills regarding decision-making (30). Relatively simple interventions could already improve patient involvement, such as actively inviting patients, during the medical encounter, to express doubts or questions. Doctors are often concerned that addressing patients' clues may increase the length of the interview, however, it has been shown that visits in which a physician responded positively to patient clues (i.e. patients' comments about their emotions, etc.) tended to be shorter than those in which the opportunity was missed (31). Particular attention should be dedicated to patients with lower education, whose knowledge level is worst and who have more difficulties communicating with doctors. Interventions to help patients play a more active role in medical decision-making are also necessary. Besides providing more written information on treatment options, some organisations are launching campaigns to support patient participation (e.g. [www.askaboutmedicines.org](http://www.askaboutmedicines.org) in the UK and [www.partecipasalute.it](http://www.partecipasalute.it) in Italy). Nevertheless, as recently reported in the *British Medical Journal*, much has still to be done to improve the learning and working environment to facilitate shared decision-making (30, 32, 33).

Achieving a balanced doctor-patient relationship might bring benefits in terms of improved quality of care, patient satisfaction, increased treatments adherence and better health outcomes (12, 25, 34).

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