

Does Evidence-Based Information Affect Consent to Care? A Systematic Review of the Literature and Meta-Analysis

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ABSTRACT

BACKGROUND

Patients generally have poor knowledge of the treatments they receive. They overestimate the benefits and underestimate the risks. Today, shared Medical Decision Support Tools (MDTs) exist to provide patients with evidence-based information.

PURPOSE

The primary objective of the study was to assess whether the use of an ADO affected acceptance or intention to accept treatment or screening.

METHOD

A systematic review of the literature with meta-analysis was performed. We searched for randomized controlled trials comparing evidence-based information with usual information in patients undergoing treatment, medication, surgery or screening. The primary outcome was acceptance of treatment or screening. If acceptance was not assessed, intention to accept was used as a surrogate endpoint.

RESULTS

We included 37 studies, totaling 31 399 patients. Acceptance or intention to accept treatment or screening was decreased in patients who received quality information compared with patients who received usual information (Relative Risk (RR)=0.90, CI95% 0.86-0.95). The test for heterogeneity was significant ($p < 0.00001$), with a I^2 at 72%. Screening studies were overrepresented in our synthesis.

CONCLUSION

Our study shows that providing patients with evidence-based information reduces their consent to care. This suggests that patients are undergoing certain treatments or screenings that do not meet their expectations. It is therefore important to promote evidence-based information, particularly through the use of decision support tools.

KEYWORDS

Meta-analysis, Decision making, Patient involvement, Free and informed consent, Decision support techniques

ABBREVIATIONS

OAD: Decision support tool; RR: Relative Risk

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INTRODUCTION

The principle of shared medical decision making is now widely accepted.¹ It responds to patients' demands and is justified by the ethical imperative of autonomy. In France, since 2002, it is also a legal obligation.² However, it does not yet seem to be applied in practice. On the one hand, patients are not sufficiently consulted about their preferences.³ On the other hand, they are poorly informed about the real effectiveness of the treatments proposed to them. Hoffmann, in a recent systematic review of the literature Hoffmann, in a recent systematic review of the literature, showed that patients tend to overestimate the benefits and underestimate the risks of treatments, diagnostic tests and screening.⁴ In other words, patients have unrealistic expectations of medical interventions. For example, women overestimate the benefit of breast cancer screening with mammography by a factor of 10 to 100 depending on the country.⁵ However, there are now ways to better inform patients.⁶ Since the end of the 1990s, Decision Support Tools (DST) have been developed.⁷ In various formats (printed document, website, audio document, video, software), DSTs present to patients the different possible therapeutic options, including the option of not having recourse to a treatment.⁸ They provide information on the benefits and risks of medical interventions; the information should be quantified and as far as possible, individualized; uncertainties should be mentioned.⁹ They must also make the patient aware that his decision is relative to the value he places on the various benefits and risks.¹⁰ These ADOs are of particular interest in situations where the superiority of one treatment over another is not obvious or when the benefits and risks of a treatment appear to be in balance.¹¹ The use of an ADO has been shown to improve the quality of information delivered to the patient, compared to the usual modes of communication. Thus, true evidence-based information is possible.¹² If patients sometimes have unrealistic expectations of medicine, does correcting these expectations with quality information have an impact on their consent to care? To answer this question, we undertook a systematic review of the literature and a meta-analysis of randomized clinical trials comparing evidence-based information with standard information and assessing consent to care.¹³

MATERIALS AND METHODS

In conducting and presenting this study, we followed the PRISMA.

Protocol and Registration

The study protocol was written before the study was conducted and registered in the international PROSPERO database under the number CRD42018085838.¹⁴

Eligibility Criteria

To be included in our review, studies had to be randomized, controlled interventional studies comparing evidence-based information with standard information or no information.¹⁵ The population of interest was anyone who had to make a decision for themselves or for a child, or for another person who was unable to choose.¹⁶ The study had to be about a drug treatment, a surgical intervention or a screening. The information delivered in the intervention group had to contain numerical information and expressed in terms of absolute risks or natural frequencies.¹⁷ This information had to present the most frequent or most serious benefits and risks and be

based on reliable scientific data.¹⁸ Finally, the studies had to assess either acceptance of the medical intervention or intention to accept it. Only articles in English and French were considered.¹⁹ Articles were included until February 14, 2023.²⁰ Studies aimed at increasing or decreasing patient consent were excluded, as were studies in which patients were not in a real clinical situation but in a hypothetical scenario. The same applied to studies where the decision support procedure was not available. Studies concerning dentistry, veterinary medicine, non-conventional medicine or behaviour (dieting, addictive behaviours, etc.) were not included. The initial protocol was to exclude complex procedures. In doing so, we aimed to better control the information that was delivered to patients. However, it seemed to us that the distinction between simple and complex ADOs could lead to arbitrary choices. We chose to abandon this criterion while maintaining the requirement for control of the information.

Judging Criteria

The primary outcome was acceptance of the medical intervention (medication, surgery, screening). This could be acceptance to start or to continue the medical intervention. If this criterion was not assessed in the study, the intention to accept was used as a surrogate criterion.

The secondary endpoints were acceptance and intention to accept. When acceptance and intention were assessed in a study, acceptance was considered for the primary outcome; the two variables were then considered separately for the secondary outcomes. If acceptance or intention to accept was assessed at more than one-time point, we chose the latter time point. If intention was measured by an ordered qualitative variable, it was dichotomized. If only the refusal rate was given, we considered that patients who did not refuse had accepted; in practice this situation never occurred. Secondary endpoints were not included in the original published protocol.

Search and Study Selection Strategy

Studies were identified through the use of two databases, medline and web of science. We also systematically reviewed the bibliography of studies submitted for full reading to identify new articles. We also searched the bibliographies of several meta-analyses related to our topic.

The selection of articles was carried out by three reviewers, EB, SR and SH independently. In case of disagreement, a consensus was sought through discussion. The selection was done in several steps. A first selection was made by reading the titles of the articles. Then, a second selection was made by reading the abstracts. Finally, the remaining articles were subjected to a complete reading, with analysis of the bibliography. If necessary, the authors of the studies were contacted.

Data Extraction

Data were extracted from the studies by the three reviewers. In case of disagreement, consensus was sought through discussion. The data extracted for each study were as follows:

- **General characteristics of the study:** Authors, date, country, type of medical intervention evaluated, primary objective of the study.
- **Characteristics of the population:** Number of participants per arm, criteria for inclusion in the study.

- **Characteristics of the information given in the intervention group:** Scientific basis, format, nature of benefits and risks mentioned, mode of presentation of numerical information.
- Characteristics of the information given in the control group.
- Judgement criteria relevant to the meta-analysis: Acceptance of treatment, intention to accept, duration of follow-up.

No procedure for replacing missing data was used, so as not to unduly extrapolate the results. If there was a significant proportion of missing data, this was reported in the bias assessment as attrition bias. This could affect the final result in the sensitivity analysis.

Risk of Bias Inherent in Each Study

The methodological quality of the included studies was assessed by both reviewers. The assessment was done using the cochrane collaboration tool (Cochrane risk-of-bias tool for randomized trials ROB2).

Evaluation of the Quality of the Information

The quality of information provided to patients in the intervention group was assessed according to five parameters, based on whether the information was:

- Sufficiently evidence-based;
- Complete;
- Clinically relevant;
- Correctly quantified; and
- Accessible for evaluation

Each endpoint was graded on three levels of quality: Poor, uncertain or good. If all parameters were rated as good quality, then the information was considered good. If only one parameter was rated as poor, then the information was rated as low quality. In the other situations, the information was considered of uncertain quality. This analysis was not included in the initial protocol.

Synthesis and Quantification of Results

The analysis was performed with Review Manager version 5.4, a software developed by the Cochrane collaboration. We calculated the Relative Risks (RR) with a 95% confidence interval. If the judgment criterion was a binary qualitative variable (consent/refusal), we calculated the Relative Risks (RR) according to the Mantel-Haenszel statistical method. If some of the judgment criteria were continuous, we planned to analyze them separately, calculating standardized differences in means.

The choice of the analysis model, fixed-effect or random-effect, was not planned a priori. This choice had to be guided by the rate of heterogeneity found.

Heterogeneity was assessed by the *Chi test*², calculated for all outcome measures. The significance level was set at $p=0.05$. If $p \geq 0.05$, the studies could be considered homogeneous among themselves.

The I^2 test, measuring the amount of variability between studies not related to random fluctuations, was performed for each outcome. Values of I^2 equal to 25%, 50% and 75% represent low, moderate and high heterogeneity, respectively.

Additional Analyses

The first additional analysis was a subgroup analysis conducted to explore a clinically relevant variable, namely consent to care by nature of medical intervention.

Further subgroup analyses were performed:

- According to the category to which the medical intervention studied belonged (screening, preventive or curative treatment);
- Taking into account the heterogeneity of the way the different judgement criteria was measured;
- **For the primary judgement criterion:** According to whether acceptance or intention were taken into account;
- **For acceptance:** According to the time when the criterion was recorded;
- **For intention:** According to whether the criterion was strict dichotomous (patients had a choice only between consenting and not consenting) or not (possibility of not choosing, or being uncertain);
- **For type of patients:** Subgroups according to whether the studies included only treatment-naive patients or not;
- For continent where the study was conducted;
- According to whether patients had contact with the examiners or whether the study was conducted entirely remotely.

Sensitivity analyses were also performed to test the robustness of the results found. These analyses were done by:

- Removing the items with the highest risk of bias (containing at least one item with a risk of bias assessed as high);
- Removing the items where the information was estimated to be of poor quality.

Publication bias was not investigated because it seemed to us that the issue of consent to care, which was investigated in our work, was rarely a central issue in ADO studies and therefore unlikely to be subject to publication bias. Instead, we sought to confirm this feeling by systematically recording what the primary outcome of the included studies was.

RESULTS

The study selection process is shown in the flow chart. Of 1455 articles identified in the databases, 37 were included, totaling 31 399 patients. The 37 included studies are described in Table 1.

Authors	Therapeutic studied	Intervention	Population	Information in the control group	Judging criteria relevant to the literature review
Bourmaud	Screening mammography	In the context of organized screening, patients receive an invitation to screening at home+an information booklet, either detailed or standard	16,000 women aged 50 to 74 with no history of breast cancer	Standard information brochure	Participation in screening at 12 months
Dodin	Hormonal treatment of menopause	Patients receiving either a detailed information document or a standard document at home. Evaluation during an interview	101 postmenopausal women aged 40 to 69 years without an IC on HRT	Society of obstetricians and gynaecologists of Canada fact sheet	Favourable to hormone therapy
Gattellari	PSA measurement	MG gives a detailed and quantified information booklet or a standard booklet. Evaluation by questionnaire sent 3 days later	258 men aged 40-70 with no history of prostate cancer	Standard information brochure	Intention to participate in screening within 12 months
Gattellari	PSA measurement	Patients selected from the directory. Received by mail either a standard information booklet, a detailed information booklet or a detailed information video. Telephone evaluation by questionnaire 7 days later	421 men aged 50-70 with no history of prostate cancer	Standard information brochure	Intention to participate in screening within 12 months
Hersch	Screening mammography	Patients receiving in their homes either an AOD containing overdiagnosis information or an AOD not containing this information. Evaluation by phone 1 to 4 weeks later	879 women aged 48-50 years, with no personal or family history of breast cancer, who had not had a mammogram for at least 2 years	AODs that do not contain information on overdiagnosis	Intention to get tested in the next 2-3 years
Hestbech	Cervical cancer screening by smear	Online study. Patients included <i>via</i> Danish civil register. 4 arms: <ul style="list-style-type: none"> No information (control), Information not quantified, Quantified information not taking into account vaccination status, taking into account § 	977 women born between 1993 and 1995 %	No information	Intention to participate in screening
Kasper	Immunotherapy in multiple sclerosis	Patients considering immunotherapy or re-considering existing immunotherapy received either a standard information booklet or an AOD	297 patients ≥ 18 years of age with MS	Standard information booklet	Taking immunotherapy at 6 months
Krist	PSA measurement	Information delivered 2 weeks prior to GP visit. Patients receiving either a paper or electronic AOD at home or no information (control). Assessment immediately after the consultation	497 men aged 50-70 with no history of prostate cancer	Usual information	Prescription of a PSA test after the consultation
LeBlanc	Biphosphonates for fracture prevention	Patients receiving at a primary care consultation either <ul style="list-style-type: none"> An AOD (intervention group) or Standard information or fracture risk estimation (control groups) 	79 women over 50 with untreated osteopenia or osteoporosis	Standard information or fracture risk calculation	Prescription of a biphosphonate at the end of the consultation
Man-Son-Hing	VKA in AF	Patients receiving either standard information or a detailed information brochure on the comparative advantages and disadvantages of VKAs and aspirin before the consultation. Choice made during consultation	287 AF patients at low risk of stroke on aspirin	Usual information	Decision to take a VKA made during consultation
Mathieu	Screening mammography	Patients receiving either a standard information booklet or a detailed information booklet at home on whether to continue screening	734 women in their 70s who had at least 2 mammograms in the previous 5 years and no history of breast cancer	Usual information	Participation in screening at 1 month. Intention to continue screening
Mathieu	Screening mammography	Internet study. Intervention group: Reading an OAD and then answering a questionnaire. Control group: Direct response to a questionnaire	412 never screened women aged 38 to 45 with no personal history of breast cancer	No information	Intention to use screening
Montori	Biphosphonates for fracture prevention	During a consultation with the general practitioner, patients received either an AOD or standard information. The information material was taken home	100 untreated postmenopausal women over 60 with osteopenia or osteoporosis	National Osteoporosis Foundation booklet	Patients who reported starting treatment at 6 months
O'Connor	Hormonal treatment of menopause	Patients received either an AOD (print+audio) or a standard information booklet. They then completed a questionnaire	165 Postmenopausal women aged 50-59 years who have never taken HRT	Standard information booklet	Intention to take the treatment
Reder	Screening mammography	Patients receiving a screening invitation at home with either a standard information booklet or an internet link to an AOD	1206 women aged 50 receiving a screening invitation for the first time	Standard information booklet (containing numerical information)	Participation in screening at 3 months. Intention to participate in 2 weeks
Schapira	PSA and digital rectal examination	In a veterans' consultation, patients received either an AOD or standard information. They were then seen in consultation 2 weeks later	257 patients aged 50 to 80 with no personal history of prostate cancer or other cancer	Information brochure with little detail and no figures	Acceptance of screening at the 2-week visit
Sheridan	PSA measurement	Patients seen prior to consultation with their GP. They either saw an informational video about prostate	130 men aged 40 to 80 with no history of prostate cancer	Information video on road safety	Participation in screening at 9 months. Intention to

		cancer screening and participated in a motivational interview or saw a video unrelated to screening			be screened within 12 months, measured after the intervention
Smith	Search for fecal occult blood	Patients receiving a home occult blood test with either a booklet and DVD of detailed information with or without questions (2 intervention groups) or standard information	572 patients aged 55-64 years, low risk for colorectal cancer, low education level	Institutional information booklet containing information in terms of relative mortality risk reduction	Participation in screening within 3 months
Stacey	Surgery for osteoarthritis of the hip or knee	Patients recruited from an orthopedic center, receiving either detailed information on the benefits and risks of surgery and standard information, or standard information alone	343 patients >18 years of age with severe or moderate hip or knee osteoarthritis on radiological criteria	Standard information	Surgery rate at 2 years. Intention to undergo surgery assessed immediately
Steckelberg	Occult blood testing or colonoscopy	Patients involved in the national screening program receiving either a detailed information booklet or the standard information at home	1577 patients aged 50 to 75 years with no history of colorectal cancer	National screening program information booklet (no quantitative information)	Patients with occult blood test at 6 months post-procedure Patients scheduled for screening at 6 months
Thomson	Warfarin in AF (as an alternative to aspirin)	During a consultation with the treating physician, patients receive either an AOD or standard information	136 patients over 60 years of age with non-valvular atrial fibrillation, treated or not with VKA	Patients were informed of treatment recommendations	Patients who started or continued Warfarin therapy (immediate assessment)
Tran	PSA assay	After consultation with their GP, patients received either an AOD on prostate cancer screening or no information	1170 asymptomatic patients aged 50-74 years with no personal or family history of prostate cancer	No information	Intention to participate in screening (assessed immediately)
Trevena	Search for fecal occult blood	Patients in a general practice received either an AOD or standard information in their homes. Patients recontacted by phone at 1 month	314 Patients aged 50 to 74 years with no personal or family history of colorectal cancer	3-page booklet with screening recommendations for people over 50. No quantitative information	Participation in screening at 1 month. Intention to be screened (assessed immediately)
Watson	PSA measurement	Patients from 11 general practices were mailed either a detailed screening booklet and questionnaire or the questionnaire alone, which had to be returned	997 patients aged 40 to 75 years with no history of prostate cancer	No information (other than the purpose of the PSA test)	Intention to use screening within 12 months
Weymiller	Statin	Diabetic patients receiving either an AOD or standard information before or during a consultation with an endocrinologist	98 patients with type 2 diabetes	Standard information booklet: general information on dyslipidemia	Taking a statin at 3 months
Whelan	Adjuvant chemotherapy for breast cancer	Intervention group: AOD presented by a nurse before consultation with an oncologist. AOD taken home with a standard booklet. Control group: same without the ADO	176 breast cancer patients under 65 years of age who were potential candidates for adjuvant chemotherapy	Standard information booklet	Choice of chemotherapy at 1 week
Wolf	PSA	Patients consulting in general practice. They received either an ADO or standard information	205 patients aged 50 years or older with no personal history of prostate cancer, who had never had a PSA test	A sentence of information about the purpose of the test	Intention to use screening, assessed immediately
Wolf	Fecal occult blood test or sigmoidoscopy	Patients consulting their general practitioner received either standard or detailed information. This was expressed in terms of relative or absolute risk reduction.	399 patients over 65 years of age with no personal history of colorectal cancer	Short description of the screening tests	Intention to start or continue screening (assessed immediately)
Zadro	Decompression surgery in subacromial syndrome	Online trial, patients recruited then OADs sent by email (two subgroups) or standard information. Questionnaire sent by email, answers online	Patients with shoulder pain considering decompression surgery	NHS Shoulder Pain General Information Brochure	Intention to treat, to perform surgery
Schonberg	Breast cancer screening mammography	Receipt of a decision aid or home safety brochure prior to consultation with the general practitioner. Evaluation by questionnaire in interview	Women aged 75-89 years without dementia or breast cancer who had a mammogram within 2 years but not within the last 6 months	Home Safety Information Brochure	Receipt of a screening mammogram within 18 months
Noseworthy	Anticoagulation in atrial fibrillation	Patients receiving either standard care or AOD at the meeting: A website presenting the different treatment options	Patients over 18 years of age with a diagnosis of non-valvular AF, at high risk of thromboembolic events	Routine care: Discussion with the practitioner	Patients with pharmacy records who were prescribed an anticoagulant and filled the first prescription within 30 days
Kostick	Left ventricular assist device	LVAD Coordinator provides the patient with a copy of the AOD and a link to an AOD support website + explanatory videos	Inpatients aged 30 to 85 years considering left ventricular assist therapy	Coordinator provides standard information: including educational brochures	Intention to choose left ventricular assist therapy
Tiedje	Prostate cancer screening by PSA	Patients recruited by general practitioners and urologists in office. Assigned in 4 parallel groups (OAD or not +/- cost compensation or not, factorial design 2*2). Electronic OAD used during the medical consultation	Men aged 55 to 69 years with no history of prostate cancer	Usual information	Participation in screening at 6 months
Rivero-Santana	Arthroplasty in osteoarthritis of the knee	Patients with knee osteoarthritis who are possible candidates for PTG as judged by clinicians, receiving or not receiving computer-based OAD. Telephone interview at 6 months	Patients aged 18 to 90 years with gonarthrosis who are candidates for PTG	Usual information	Knee replacement rate at 6 months

Perez-Lacasta	Breast cancer screening mammography	Pre-intervention questionnaire sent to all patients. Then OAD in the form of a leaflet sent to the intervention group	Women between 49 and 50 years old who will be invited to perform breast cancer screening	Standard flyer	Participation in the screening program at 3 months
Allen	Left ventricular assist therapy	Patients randomized into two groups. Standard care or intervention: decision support training, 26-minute video, and an 8-page decision support brochure	Patients over 18 years of age with end-stage heart failure and active consideration for ventricular assist therapy	Usual information	Rate of left ventricular assist device implantation at 6 months
Ye G	Surgical treatment of cataract	Patients receiving either a detailed information document or a standard document at home. Evaluation during an interview	Cataract patients aged 50 to 80 years	Standard information brochure National Eye Institute US	Intention to undergo the surgical procedure
Note: NR: Not Known; HRT: Menopausal Hormone Therapy; CI: Contraindication; DST: Decision Support Tool; MS: Multiple Sclerosis; KA: vitamin K Antagonist; AF: Atrial Fibrillation LVAD: Left Ventricular Assist Therapy ; PTG: total knee prosthesis § Group 2 was excluded from the analysis. The vaccination program began in 2008 for girls born between 1993 and 1995 £ only the group receiving information in terms of absolute risk reduction was considered					
Table 1. Characteristics of the Included Studies.					

Medical intervention	Endpoint, relative risk (95% CI) n=number of studies		
	Acceptance or intention	Acceptance	Intent
Prostate cancer screening	0.83 (0.74-0.94) n=9	0.82 (0.66-1.01) n=4	0.79 (0.66-0.94) n=6
Breast cancer screening	0.95 (0.89-1.01) n=7	0.96 (0.93-1.00) n=5	0.98 (0.89-1.08) n=6
Colorectal cancer screening	0.94 (0.76-1.17) n=4	0.89 (0.67-1.19) n=3	0.99 (0.94-1.04) n=3
Cervical cancer screening	0.88 (0.80-0.97) n=1	NR	0.88 (0.80-0.97) n=1
Anticoagulation and atrial fibrillation	0.92 (0.81-1.03) n=3	0.92 (0.81-1.03) n=3	NR
Hormonal treatment of menopause	0.78 (0.45-1.35) n=2	NR	0.78 (0.45-1.35) n=2
Biphosphonates for fracture prevention	1.21 (0.83-1.77) n=2	1.21 (0.83-1.77) n=2	NR
Statins and type 2 diabetes	1.01 (0.74-1.36) n=1	1.01 (0.74-1.36) n=1	NR
Immunotherapy and multiple sclerosis	1.08 (0.83-1.41) n=1	1.08 (0.83-1.41) n=1	NR
Hip or knee osteoarthritis surgery	0.91 (0.81-1.02) n=2	0.91 (0.81-1.02) n=2	0.94 (0.74-1.20) n=2
Decompression surgery in subacromial syndrome	1.10 (0.98-1.23) n=1	NR	1.09 (0.97-1.22) n=1
Left ventricular assist therapy	0.81 (0.46-1.43) n=2	0.62 (0.51-0.76) n=1	1.07 (0.84-1.37) n=1
Cataract surgery	0.66 (0.52-0.83) n=1	NR	0.66 (0.52-0.83) n=1
Adjuvant chemotherapy and breast cancer	1.10 (0.92-1.31) n=1	1.10 (0.92-1.31) n=1	NR
Table 2. Subgroup Analysis by Type of Medical Intervention.			

Summary of Results

For the primary endpoint: For the primary endpoint, 37 studies were included, with a total of 33,399 patients: 23 measuring the "acceptance" endpoint and 24 the "intention to accept" surrogate endpoint. The synthesis showed a relative risk of 0.90 (IC95% 0.86-0.95). Thus, there was a decrease in consent in the group receiving evidence-based information compared with the group receiving standard information. The test for heterogeneity was significant (p<0.00001), with an I² at 72%. Because significant heterogeneity was found, the comparison model used was the random-effect model. Of the 37 studies, 13 found a statistically significant result, all in the direction of decreased consent.

For the secondary criterion "acceptance: For the acceptance criterion, 23 studies were included, totaling 25,177 patients. The relative risk was 0.92 (CI95% 0.88-0.97). Heterogeneity was significant (p<0.00001), with an I² at 66%. The randomized model was therefore used. Of the 23 studies, 7 found a significant result, all in the direction of decreased acceptance.

For the secondary criterion "intention to accept: For the intent-to-accept criterion, 24 studies were included. Totaling 11,466 patients. The relative risk was 0.90 (CI95% 0.84-0.96). Heterogeneity was significant (p<0.00001), with

an I²=81%. The randomized model was therefore used. Of the 24 studies, 9 found a significant result, all in the direction of a decrease in intention to accept.

Additional Analyses

Subgroup analysis: Subgroup analysis was performed to explore the outcome by type of treatment or screening (Table 2). Other subgroup analyses were performed to explore the heterogeneity found. These analyses were not able to account for this heterogeneity (results available on request).

Sensitivity Analysis

A sensitivity analysis was performed by removing the 10 articles with the highest risk of bias. This analysis did not change the nature of the results. The RR found for the primary endpoint was 0.89 (0.84-0.94). Another analysis was performed after removing the 2 articles in which the information given to patients was considered low quality. This analysis did not change the nature of the results. The RR for the primary outcome was 0.90 (0.85-0.95).

DISCUSSION

Our study, including 37 articles and totaling 31,399 patients, thus showed that evidence-based information results in a statistically significant decrease in patients' consent to care.

Hoffmann has previously shown that patients have unrealistic expectations. Our work goes a step further. Indeed, if patients were better informed, they could have been disappointed by the effect of the treatments. but continue to choose them, for lack of an alternative. However, this is not what happens. Once informed, a number of patients prefer not to use the recommended treatments. Perhaps they feel that the benefit/risk balance is not favorable, or that the actual benefit is too small and not worth the effort. These questions could be explored in qualitative studies. It has already been shown in a systematic review that more than one third of patients would refuse to take a daily treatment with no side effects if it did not reduce their absolute 5-year risk of cardiovascular events by more than 5%. However, this efficacy threshold is rarely reached in therapy.

Our results run counter to the idea that non-use of care or non-compliance with treatment is necessarily linked to patients' ignorance. In fact, the opposite is suggested in our study: Better-informed patients make less use of the proposed care.

If the use of ADOs therefore leads to a decrease in consent. should the principle of shared medical decision making be questioned? Some authors have claimed that this is the case. On the contrary, it seems to us that patient autonomy is an intangible ethical principle. One can only ask that patients participate in the decision if they end up submitting to the decisions that have been made without them. In other words, if we accept the principle of shared medical decision-making, we must also accept that patients sometimes make decisions that go against our expectations.

Our work shows that evidence-based information decreases intention to accept (RR=0.90) more than acceptance itself (RR=0.92). In other words, patients who would have decided not to take a treatment or undergo a test would have taken or undergone it. This might suggest that there is an incentive to act, which would go against the initial intention.

Limitations of the Study

In our meta-analysis screenings were over-represented. This diminishes the external validity of our work. This overrepresentation of screenings is in part a reflection of the current state of research on shared medical decision making, which seems to have focused on medical interventions that generate dissent within the medical community. But the fact that we set stricter inclusion criteria than has been practiced to date in meta-analyses on the same topic may also explain the low diversity of medical interventions addressed.

The high heterogeneity found also constitutes some limitation to the average estimate of the effect found. Subgroup analyses did not provide a simple account of the existing heterogeneity. We accounted for this heterogeneity in our analysis by using a randomized analysis model. The resulting confidence interval is wider than if we had used a fixed effect model. The use of a random model is therefore more conservative.

Another limitation is the great variability of the included studies: Variability of medical interventions (screenings, primary or secondary prevention treatments, curative treatments), variability of populations, variability of ADOs (from simple brochures to complex interventions).

The Strengths of the Study

Despite the limitations detailed above, our work can claim several significant strengths.

On the one hand, our study is the first truly general meta-analysis of the impact of information on consent. Synthesis work has already been done on this subject. However, the

answers provided so far seemed unsatisfactory to us, for several reasons. On the one hand, these studies were not general in scope but often concerned a specific medical intervention, such as prostate cancer screening. breast cancer or colorectal. On the other hand, the only general review, that of the Cochrane collaboration mentioned above, only assessed the issue of consent in a secondary way. Moreover, this Cochrane review, although general in its exploration, did not produce a general synthesis, but grouped the results according to the type of intervention. Finally, the last shortcoming in our opinion of the reviews carried out to date is that they do not seem to be sufficiently restrictive in terms of the studies included. In particular, they did not strictly enough exclude interventions whose aim was to increase or decrease consent to care, which is what our study did.

Our study also boasts a substantial number of patients included.

In addition, the great variability of studies, mentioned above, makes it possible to account for the diversity of real situations.

Another strength of our work is that the information provided to patients has been monitored to ensure completeness and fairness.

Similarly, we included only studies in true clinical settings and excluded studies that offered patients hypothetical scenarios. Finally, our work shows a high degree of qualitative homogeneity in the results (although there is considerable statistical heterogeneity). Thus, for the main criterion "acceptance or intention to accept", out of the 13 studies that found a statistically significant result, all pointed in the direction of a decrease in consent. The same was true for the secondary criteria. None of the included studies showed a significant increase in consent, regardless of the outcome.

Practical Consequences

Our study suggests that providing patients with quality information had practical consequences for their choice to be or not to be treated or screened. This finding provides further support for our efforts to improve patient education. ADOs are now well evaluated. They have been shown to improve patient understanding. Recently, simplified forms of ADO have been proposed, the facts boxes. These are single-page cards that summarize the main benefits and risks of treatments or screening. These easy to use ADOs can be given to patients during a consultation or sent to them at home with an invitation to participate in a screening.

The use of such tools is already being promoted in some countries. For example, the main German health insurance system (AOK) has made Facts Boxes available to doctors and patients concerning, among other things, flu vaccination, ovarian cancer screening or vitamin D supplementation. These tools are still too rare in France, but projects have been launched to produce information sheets based on solid clinical evidence. It is therefore important to multiply these initiatives in order not only to create these ADOs but also to implement them in daily practice.

It is also important to integrate the shared medical decision into the recommendations of good practice issued by national health authorities or learned societies. These recommendations are usually formulated as incentives or disincentives: They say what is good to do and what is not good to do. It would be entirely conceivable that in a certain number of situations, which would have to be defined, these recommendations would leave more room for the choice of the patient, informed by his or her physician, as has been proposed by certain authors. It could even be proposed that these bodies themselves draft ADOs for patients and

physicians, which would be consistent with the position of the Haute Autorite de Sante in favour of shared medical decisions.

Our work seems to highlight a certain contradiction between the real expectations of patients and the public health objectives that aim to increase patient participation, particularly in screening campaigns. These objectives should therefore be revised to better coincide with the expectations of the populations whose interests they are supposed to serve.

Finally, it would be important to question the factors behind the unrealistic expectations of patients, without which the effect we found might have been even greater.

CONCLUSION

Our systematic review of the literature with meta-analysis showed that quality information had a negative impact on consent to care, particularly in prevention or screening situations. Patients who receive evidence-based information are less likely to accept or intend to accept treatment or screening than patients who receive routine information. This means that some patients receive treatments or screenings that do not necessarily meet their expectations. This raises broader questions about the conflict that may exist between individual and population-based care.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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