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ORIGINAL RESEARCH

Comprehensive Implementation of Shared Decision Making in a Neuromedical Center Using the SHARE TO CARE Program

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Purpose: SHARE TO CARE (S2C) is a comprehensive, multi-module implementation program for shared decision making (SDM). It is currently applied at the University Hospital Schleswig-Holstein in Kiel, Germany, and among general practitioners at the Federal State of Bremen. This study examines the results of the full implementation of S2C in terms of effectiveness within the Kiel Neuromedical Center comprising the departments of neurology and neurosurgery.

Method and Design: The S2C program consists of four combined intervention modules: 1) multimodal training of physicians; 2) a patient activation campaign including the ASK-3 method; 3) digital evidence-based patient decision aids; and 4) SDM support by nurses, e.g., as decision coaches. The SDM level before and immediately after implementation was retrospectively assessed in consecutively selected patients on the subscale "Patient Decision Making" of the Perceived Involvement in Care Scale ($PICS_{PDM}$). Mean scores were compared with t-tests.

Results: Eighty-nine percent of all physicians (N = 56) completed the SDM training. We developed a total of 12 evidence-based digital decision aids in the center, educated two decision coaches to support patients' decision processes by using decision aids. Physicians adjusted patients' pathways to incorporate the use of decision aids. Patients (n = 261) reported a significant increase in participation ($p<0.001$; Hedges' g = 0.49) in medical decision making.

Conclusion: The S2C program has been successfully implemented within the entire Neuromedical Center. Patients reported a medium to small increase of perceived involvement in decision making demonstrating the effectiveness of the implementation. For future research, it might be interesting to investigate the sustainability of the effects of S2C. In addition, it seems useful to complement the patient-based evaluation with observer-based data.

Keywords: shared decision making intervention, decision aids, physician training, patient activation, neurology, neurosurgery, SDM

Introduction

Shared decision making (SDM) describes the process of information exchange between patients and physicians based on the best available evidence about different treatment options and patient's preferences aiming for an informed and shared decision.[1] In Germany, participation of patients in their medical decision making is mandated by law.[2] Additionally, several advantages support implementation of SDM compared to the use of informed consent only in medical decision making: there is evidence that a large number of complaints occur because of patients' lack of participation in decision processes and

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a resulting lack of understanding of potential benefits and harms. That is, patients receive information about potential risks of the treatment choice but do not necessarily understand individual consequences for their life when side-effects occur.[3] SDM offers a chance to fill this information gap as the exchange between physician and patient focuses on patient's preferences and life circumstances, which fosters the patient's deeper understanding of different therapy options, their benefits and harms, and probability of occurrence.[4] As a result, patients are better informed, feel more satisfied with their treatment choice, show greater treatment adherence and self-efficacy during conduction of therapy.[4,5] Furthermore, patients feel more trust in treatment and experience greater satisfaction with their physician, and their care in general.[6] In addition, patient's deep understanding leads to a more realistic expectation of treatment outcomes[7] and in consequence to less complaints and decisional regret.[8] In sum, SDM meets patients' needs for better information and involvement in medical decision making at an individual level. Furthermore, SDM can improve health care regarding safety and cost-effectiveness.[9]

These issues lead to the question of how to successfully implement SDM in healthcare. Several programs aiming to foster SDM in medical decision making either focus on patient information using decision aids or training of health care professionals. In addition, many programs are limited to specific populations or healthcare sectors. Légaré et al (2018) give an overview about different methods and starting points on how to increase SDM in health care summing up that only few programs follow a holistic approach of combining information and training involving patients, physicians and other medical staff.[4] The aim of the present study was to examine the feasibility of the multicomponent and holistic SHARE TO CARE program (S2C) and its effectiveness regarding the increase of the SDM level in hospitals.[10] The S2C program involved physicians, health care professionals and patients and was implemented in a large-scale, hospital-wide setting including 22 departments of the University Hospital Schleswig Holstein (UKSH) in Kiel, Germany. To address the complexity of the intervention, the program implementation and evaluation was designed as a triangulated qualitative and quantitative evaluation based on CFIR as framework. In this paper, we focus on the effectiveness from a patient perspective and present the quantitative patient reported outcome measures at the Neuromedical Center of UKSH.[10]

Methods

Design and Setting

To examine effectiveness of the S2C-program we collected data at the Neuromedical Center (Department of Neurology and Department of Neurosurgery) at University Hospital Schleswig Holstein (UKSH), Campus Kiel, in 2018 prior to (baseline t_0) and in 2020 immediately after implementation of the S2C program (t_1) as part of the hospital-wide implementation. The baseline survey was conducted at a time when neither medical staff nor patients had been informed about the upcoming SDM implementation. At t_1, medical staff was informed that the S2C program would be evaluated. However, they were not aware of evaluation measures, the sampling period and, hence, the patients to be included as patients received questionnaires only after their discharge. They had no influence on inclusion of patients as the data for patient inclusion was provided by the hospital management independently of the individual departments. During their consultations, neither medical staff nor patients were aware that they might be invited to participate in a survey about SDM later.

Participants

We included adults (age 18 and older) who recently had a consultation at the Neuromedical Center at the UKSH in Kiel. During their hospital treatment potential participants signed informed consent to be contacted for medical research. After their discharge, patients were contacted by mail to fill out a questionnaire. Both outpatients and inpatients were covered by the intervention modules and covered by the evaluation. There were no a priori exclusion criteria regarding the diagnosis. The questionnaire can be found in Appendix A. The study was approved by the Ethics Committee of the Faculty of Medicine at Kiel University (reference number A111/18).

Intervention

The multicomponent S2C program consists of four intervention modules addressing physicians, medical staff and patients. Each module had been separately tested previously in randomised controlled trials and shown effectiveness and feasibility.[10]

1) A minimum of 80% of all physicians within each clinical department ought to complete a multimodal training composed of an online-training[11] and two individual feedback sessions based on videotaped patient consultations: The online training (one hour approx.) provided basic SDM knowledge and several simulations of physician-patient-interactions to demonstrate Dos and Don'ts in SDM. Subsequently, physicians received an individual SDM coaching session in a peer group setting (2–5 participants) based on their own videotaped patient consultations. Interaction of increased self-reflection through video excerpts and feedback from colleagues and experienced SDM coaches aimed to create an encouraging and constructive learning atmosphere. Later, physicians recorded another consultation and participated in a second small group training to further increase and consolidate their SDM skills. After successful training completion, physicians received a certificate and education credits by the Physicians Chamber of the Federal State of Schleswig-Holstein.

2) To increase patients' participation and involvement in medical decision making, every patient received information why and how to actively take part in their physician-patient interaction. By distributing various material inside the Neuromedical Center (e.g., SDM clips on screens, roll ups, posters, flyers, promotional items, SDM content on the department websites, paper postcards and screen-based messages and media) we encouraged patients to ask more questions during their consultation to gain deeper understanding of their treatment opportunities. The core element of this campaign was the ASK-3 approach.[12]

3) To foster patients' understanding of their condition and treatment opportunities indication-specific digital evidence-based Patient Decision Aids (EbPDA) were implemented. They were developed in cooperation with local physicians following the International Patient Decision Aids Standards.[13,14] Experts for evidence-based medicine within the study group conducted a systematic review of best available evidence for all treatment options. They also performed needs assessment interviews with patients to align with needs and preferences of patients in the specific decision situations. Methods were based on the German guidelines for evidence-based patient information and the methods of systematic reviews in patient information.[15,16] Conceptualizing EbPDA as a user-oriented interface, we enhanced text information with graphics and video clips featuring the local clinical experts explaining interventions as well as patients who shared their experience facing the same decision as the EbPDA user. Each EbPDA underwent external review. More information regarding structure of the EbPDA can be found in Appendix B.

Decision Aids cannot cover all decisions that are regularly made in a university hospital. Therefore, we selected topics together with clinical experts in the departments based on frequency of their occurrence and the physicians' appraisal of the expected benefit in daily clinical practice. We expected a spill-over effect from the decisions made with the help of decision aids to others, where no EbPDA is available.

4) We educated at least 80% of all nurses by a videoclip how to integrate SDM in patient care and how to support patients and physicians to apply the abovementioned modules. Additionally, selected nurses (or physiotherapists, study nurses etc.) were trained as decision coaches to facilitate patients' decision processes with physicians. The training is designed in a similar way as physicians' face-to-face feedback sessions: During 2 workshop days, healthcare professionals gained further knowledge about SDM, deep insight in the DAs of their specific department or section and skills to support patients' decision making. Accompanied by the S2C trainer team, nurses completed decision coach training by recording coaching conversations with a patient twice and received individual feedback. Decision coaches function as emotional assistance to sensitize patients to unanswered questions and treatment preferences. The decision aids could be filled out either at home or in the company of a decision coach at the hospital in preparation for an improved physician-patient-consultation.

By completing all four modules a department meets the criteria to be awarded with the S2C certificate.

Data Collection and Outcome Measures

Outcome data was collected in a pre-post-design using mailed patient questionnaires before (t_0) and after (t_1) intervention. Baseline measurement was conducted from July until September 2018 at the Department of Neurology and from August until October 2018 at the Department of Neurosurgery. Post intervention measurement (t_1) took place from January until March 2020 at the Department of Neurology and from November 2020 until January 2021 at the Department of Neurosurgery. Patients received up to two mailed reminders if they failed to answer within 4 weeks. Post intervention measurement was launched as soon as the four intervention modules were completed.

Sampling was performed as a retrospective and consecutive sample at a certain key date. The overall sample size within the hospital-wide SDM implementation was prescribed by the study protocol (N>1.600 pre and post each).[10] The sample size within each of the 22 included departments was determined by its proportion of cases compared to the overall hospital, with a minimum of N>30 per measurement and department. This resulted in a minimum of N>60 in this study in the Neuromedical Center (2/22 departments).

The primary outcome was the "Patient Decision Making" ($PICS_{PDM}$) subscale of the Perceived Involvement in Care Scale (PICS), a patient-reported outcome instrument translated and validated in Germany.[17,18] The SDM level was measured on a scale from 1 = `do not agree at all´ to 4 = `totally agree´. $PICS_{PDM}$ can be seen as a key indicator of SDM-based physician-patient interaction and has proven applicable in retrospective studies by mail.[19]

As secondary outcome, SDM level was assessed using the patient questionnaire collaboRATE (COLL; 3 items; 5 point scale).[20] The Preparation for Decision Making Scale (PrepDM; 10 items; 5 point scale) was used as an indicator of decision-specific health literacy.[21] In addition, data of the other two subscales of PICS, doctor facilitation scale ($PICS_{DFS}$) and patient information scale ($PICS_{PIS}$), were collected.

Statistical Analyses

For descriptive purposes, data are expressed as mean with standard deviation (SD) and/or 95% confidence interval (CI), unless stated otherwise. Analysis was conducted as an intention-to-treat approach. A questionnaire was declared evaluable if all questions of the respective subscale were answered. Missing data mechanism was assumed to be missing not at random (MNAR). To avoid possibly biased and misleading results using multiple imputation under the MNAR assumption, a complete case analysis has been performed. We used Z-score normalization before pooling the two departments. An independent two-sided *t*-test was used to determine if there were significant differences between t_0-baseline and t_1-post-intervention data for $PICS_{PDM}$, COLL and PrepDM. Effect size was judged using Hedge's g.

To analyse sociodemographic factors as potential effect modifiers, we performed a multiple regression analysis examining the effect of age, education gender and the intervention itself on $PICS_{PDM}$.

To conduct a responder analysis, a threshold value of >2.5 points on the $PICS_{PDM}$, which ranges from 1 to 4 points, was set a priori as an indicator of SDM. Associations between and among baseline and post-intervention groups and $PICS_{PDM}$ threshold value of <2.5 were assessed using chi-square-test. A score above 2.5 indicated a good level of SDM. All analyses were performed using STATA 16.1 with a p-value < 0.05 considered to indicate statistical significance.

Results

Feasibility of the Intervention

The 4 modules of S2C were successfully implemented at the Neuromedical Center: when the t_1-post intervention measurement was initiated, a total of 89% of all physicians completed training (N = 56) and 12 decision aids had been developed (topics e.g., epilepsy medication, advanced Parkinson disease, neuropathic pain, severe tremor, vestibular schwannoma) and were in use. A current list of all DA-topics of the program can be found at (https://share-to-care.de). We approached the whole nursing staff by an education video and reached > 80%. We educated 2 decision coaches, and launched the patient activation campaign as planned within the entire center. Implementation took approximately 1.5 years in Neurology and 2 years in Neurosurgery where it was temporarily interrupted by the COVID19 pandemic. Further measures of feasibility (e.g., a qualitative evaluation) will be reported elsewhere.

Patients' Characteristics

During the previously defined sampling period, 109 of 182 all contacted patients at t_0 mailed back a survey (response rate: 60.5%). At t_1 due to organizational reasons 267 patients were contacted. One hundred fifty two of them (56.9%) sent back their questionnaire. Therefore, both response rates were close to the predefined range as described in the study protocol (60–70%).[10]

Details of patients' characteristics are shown in Table 1.

Table 1 Sample Description

	t_0		t_1		Total
	n	%	n	%	
Number of patients	109		152		261
Age					
Total responses	107		152		259
18–40 years	6	5.6%	22	14.5%	
41–60 years	40	37.4%	54	35.5%	
61–80 years	53	49.5%	66	43.4%	
Over 80 years	8	7.5%	10	6.6%	
Gender					
Total responses	99		147		246
Female	45	45.5%	74	50.3%	
Male	54	54.5%	73	49.7%	
Education					
Total responses	102		152		254
Lower than secondary school certificate	38	37.3%	46	30.3%	
Secondary school certificate	32	31.3%	53	34.8%	
Higher education entrance qualification	28	27.4%	48	31.6%	
Other school qualification	4	4.0%	5	3.3%	

Effectiveness

The perceived SDM level increased significantly after the intervention (z-score standardized $PICS_{PDM}$: M_{t0}= −0.29 (SD = 1.10); M_{t1}= 0.19 (SD = 0.88); $p < 0.001$; see Table 2). The effect size Hedges' g = 0.49 indicates a medium effect.[22]

Patients reported significantly increased health literacy in preparation for treatment decisions (PrepDM: M_{t0}= −.19 (SD=1.04); M_{t1}= 0.13 (SD = 0.95); p = 0.002; Hedges' g = 0.32) and reported a greater collaboration with physicians (Coll: M_{t0}= −0.15 (SD= 0.97); M_{t1}= 0.11 (SD = 1.01); p = 0.005; Hedges' g = 0.26). Following Cohen (1977), effect sizes vary from medium to small effects.[22]

To examine potential influence of age, gender or education on the primary endpoint $PICS_{PDM}$, we performed a multiple regression analysis. Results indicated that apart from the intervention itself ($p<0.001$), no other variable had a significant impact (see Table 3).

In the responder analysis at t_0, 58% of all consultations exceeded 2.5 (our pre-defined cutpoint for $PICS_{PDM}$ for "good SDM"); at t_1, the quota of conversation with high SDM level was enhanced to 77% (p = 0.001). The two additional subscales $PICS_{DFS}$ and $PICS_{PIS}$ had descriptively positive, nonsignificant results (data not reported).

Table 2 Endpoints Before and After Implementation (z-Score Standardized Values)

	Original Values				z-Score Standardized Values					
	t_0		t_1		t_0		t_1			
	M	SD	M	SD	M	SD	M	SD	p	Hedges' g
$PICS_{PDM}$	2.65	0.92	3.06	0.75	−0.29	1.10	0.19	0.88	<0.001	0.49
COLL	3.63	1.12	3.93	1.18	−0.15	0.99	0.11	1.01	0.05	0.26
PrepDM	3.15	1.29	3.55	1.19	−0.19	1.04	0.13	0.95	0.02	0.32

Table 3 Multiple Linear Regression Analysis of the Effect of Time Point of Measurement, Age, Sex and Educational Level on the Primary Endpoint "Patient Participation in Decision Making" ($PICS_{PDM}$)

	Regression Coefficient	SD	95% CI
Time point of measurement			
Baseline t_0 (reference group)			
Post intervention t_1	0.43**	0.13	0.15 to 0.67
Age (years)			
18–40 (reference group)			
41–60	−0.20	0.23	−0.57 to 0.30
Over 60	−0.37	0.22	−0.73 to 0.12
Sex			
Female (reference group)			
Male	−0.04	0.13	−0.29 to 0.21
Highest educational level attained			
Lower than secondary school certificate (reference group)			
Secondary school certificate	0.21	0.16	−0.08 to 0.53
Higher education entrance qualification	0.15	0.16	−0.13 to 0.49
Regression constant	−0.09	0.25	−0.63 to 0.33
R^2	0.08		
R^2 adj.	0.05		
n (t_0)	85		
n (t_1)	140		

Note: ** $p<0.01$.

Discussion and Conclusion

To our knowledge this is the first study exploring the center-wide implementation of SDM in Neuromedicine. Results from the Neuromedical Center in Kiel indicate that the multicomponent S2C program significantly increases SDM from the patients' point of view according to both $PICS_{PDM}$ and CollaboRATE. Patients also report being better informed and prepared for their medical decisions. As patient participation plays an important role in medical encounters regarding patient's adherence, trust and collaboration between physician and patient,[23,24] and satisfaction with the decision itself,[6] these are promising results for the improvement of healthcare quality in general. There is no evidence in our data that the program works better – or solely – for patients with certain sociodemographic characteristics, namely age, gender or educational level. This is an important finding as it is sometimes argued that SDM is not applicable to poorly educated or elderly patients.[25]

The high number of trained physicians (89%) is a strong indication for good feasibility and acceptance of the intervention. To the best of our knowledge, there is no other large-scale SDM implementation program with comparable values. The high level of training participation was positively influenced by various factors: On the one hand, the implementation was supported by SDM motivated chief and senior physicians, who themselves completed the training and acted as role models. One physician in each department was designated as the central key figure and contact person for all physicians and health care professionals for the topic of SDM. On the other hand, structural support was provided so that physicians completed the training in paid working hours whenever possible. In addition, the simultaneous implementation of S2C program not only in the Neuromedical Center but in many other departments of the UKSH led to the fact that SDM could also be applied in interdisciplinary patient cases e.g., in the development of decision aids. In this context, it is important to stress that there were no strong incentives for physicians and patients to be part of the program.

Across the whole hospital, we intended to train approximately 150 nurses. In the end, we were only able to train significantly fewer (2 at the Neuromedical Center). This can be explained by the shortage of nursing staff in Germany that was even exacerbated by the COVID pandemic so that there were not enough resources available to enable nurses to receive further training as decision coach. There is further research needed to create a better framework for decision coaching in a hospital-wide implementation of SDM.

The validity of our findings might be limited by the lack of a randomization. However, as we enrolled the entire center with an organization-focused implementation program, an analysis randomizing physicians or patients to different experimental arms was not applicable. Due to the size of the departments, a cluster-randomized study was neither affordable nor implementable Hence, a consecutive cohort study provided the best experimental quality. As we obtained the data through the hospital administration, the organizational burden for prospective data collection was too high, so that a larger recall bias may have resulted from the retrospective survey. Because of the consistent survey process, we expect a similar recall bias at both survey time points. Therefore, the effect measured should only minimally be biased. However, data protection regulation did not allow us to capture the exact times of discharge and survey administration for each patient separately. Representativity might be reduced by self-selection of consenting and of responding patients. However, response rates of around 60% are to be viewed rather high. Even more, neither physicians nor the study group had any influence on the selection of patients enrolled in the study or were aware of the sampling period and the evaluation measures. Restrictively, it might be added that we assumed an independent sample as the probability that a patient was included twice in the survey is very low, but never excluded. As another possible limitation, all outcome data on effectiveness reflect the patient's point of view using PICS and CollaboRATE as retrospective patient-reported outcome instruments. It is indisputable, that the patient's experience is of major importance, especially when other patient-related variable like adherence are discussed. Nevertheless, the evaluation within other departments at the UKSH in Kiel also includes observer-based analyses of videotaped consultations using MAPPIN'SDM[26,27] and data on costs and quality of care as a result of the SDM implementation.[10] With those future findings, it will be possible to further underscore the conclusions from the current study.

Due to pre-post design of the study the results may be biased by the COVID19 pandemic – pre-intervention data collection took place in regular operation of the Neuromedical Center whereas post-intervention data was collected in the first year of the pandemic. The survey period in the Department of Neurosurgery coincided with an increased number of COVID infections and hospitalized patients during winter season. As a consequence, elective treatments and surgeries were postponed such that our sample of patients might differ from pre- to post-intervention survey. However, with a reduction of elective treatments at t_1, the proportion of decisions qualified for SDM is lower. Therefore, if all patients are included in a consecutive sample under these conditions, regardless of whether they come as emergency treatment or as a planned procedure, the measured SDM level after the intervention t_1 can rather be regarded as underestimated.

Furthermore due to the pre post design of the study a general effect of time might have biased the results. Our 10 year experience in observative studies with PICS did not find strong trends in perceived involvement.[19] Therefore, a bias by time in 2.5 years seems to be rather small.

For future research it might be interesting to evaluate qualitative and quantitative data from additional departments of UKSH Kiel to gain a more comprehensive insight in a hospital-wide implementation. In addition, another post-intervention measurement at Neuromedical Center is scheduled at least 6 months after t_1 so that we can judge the sustainability of the S2C intervention.

In conclusion, this study provided convincing evidence for an increase of perceived involvement of patients in their medical decision making from a center-wide multi-module implementation of SDM in neuromedicine. Future studies on the application of the multicomponent S2C program in other departments in Kiel as well as in other hospitals beyond Kiel will show if the S2C program will live up to the expectations of being a universally applicable program for large-scale implementation of SDM.

Abbreviations

SDM, Shared decision making; UKSH, University Hospital Schleswig Holstein; EbPDA, evidence-based Patient Decision Aids.

Ethics Statement

The study was approved by the Ethics Committee of the Faculty of Medicine at Kiel University (reference number A111/18). The study is aligned with the Helsinki declaration.

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Disclosure

FG, FS and KW are co-founders, JUR is CEO and co-founder of SHARE TO CARE Patientenzentrierte Versorgung GmbH (Cologne/Germany). JUR is also CEO of TakePart Media + Science GmbH, Cologne, Germany. KHS reports personal fees from Hoffmann La-Roche AG, Sanofi Genzyme, Merck KGaA, Biogen Idec, Bayer AG, and Bristol-Meyer-Squibb. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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