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Patient-reported effects of hospital-wide implementation of shared decision-making at a university medical centre in Germany: a pre–post trial

Fülöp Scheibler ,[1] Friedemann Geiger,[2,3] Kai Wehkamp,[4] Marion Danner,[5] Marie Debrouwere,[6] Constanze Stolz-Klingenberg,[2,6] Anja Schuldt-Joswig,[2,6] Christina Gesine Sommer ,[2,6] Olga Kopeleva,[6,7] Claudia Bünzen,[2,6] Christine Wagner-Ullrich,[2,6] Gerhard Koch,[8] Marie Coors ,[9] Felix Wehking ,[10] Marla Clayman ,[11,12] Christian Weymayr,[2,6] Leonie Sundmacher,[9] Jens Ulrich Rüffer[13]

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For numbered affiliations see end of article.

Correspondence to:
Dr Fülöp Scheibler, National Competency Center for Shared Decision Making, University Hospital Schleswig Holstein, Köln 24105, Germany;
Fueloep.Scheibler@uksh.de

FS and FG contributed equally.

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Abstract

Objectives To evaluate the feasibility and effectiveness of the SHARE TO CARE (S2C) programme, a complex intervention designed for hospital-wide implementation of shared decision-making (SDM).

Design Pre–post study.

Setting University Hospital Schleswig-Holstein (UKSH), Kiel Campus.

Participants Healthcare professionals as well as inpatients and outpatients from 22 departments of the Kiel Campus of UKSH.

Interventions The S2C programme is a comprehensive implementation strategy including four core modules: (1) physician training, (2) SDM support training for and support by nurses as decision coaches, (3) patient activation and (4) evidence-based patient decision aid development and integration into patient pathways. After full implementation, departments received the S2C certificate.

Main outcome measures In this paper, we report on the feasibility and effectiveness outcomes of the implementation. Feasibility was judged by the degree of implementation of the four modules of the programme. Outcome measures for effectiveness are patient-reported experience measures (PREMs). The primary outcome measure for effectiveness is the Patient Decision Making subscale of the Perceived Involvement in Care Scale ($PICS_{PDM}$). Pre–post comparisons were done using t-tests.

Results The implementation of the four components of the S2C programme was able to be completed in 18 of the 22 included departments within the time frame of the study. After completion of implementation, $PICS_{PDM}$ showed a statistically significant difference ($p<0.01$) between the means compared with baseline. This difference corresponds to a small to medium yet clinically meaningful positive effect (Hedges' g=0.2). Consistent with this, the secondary PREMs (Preparation for Decision Making and collaboRATE) also showed statistically significant, clinically meaningful positive effects.

Conclusions The hospital-wide implementation of SDM with the S2C-programme proved to be feasible and effective within the time frame of the

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Shared decision-making (SDM) is the recommended way for patients and doctors to make decisions together. While many studies have shown beneficial effects of SDM on patient knowledge, decision conflict and decision quality, successful large-scale implementation in healthcare organisations is still scarce.

WHAT THIS STUDY ADDS

⇒ This study aimed to implement SDM throughout the Kiel campus of the University Hospital of Schleswig, Holstein (UKSH), 1 of the 10 biggest university medical centres in Germany. We developed a multimodule complex intervention, the SHARE TO CARE programme. It proved to be feasible in everyday clinical settings. The results of this study show a small sized to medium sized, clinically relevant effect on a validated patient-reported experience measure (PREM). This is in line with the other PREMs documented within the project. As a further result of this study, compulsory health insurance companies have agreed to reimburse for SDM at UKSH. Further, the German Federal Joint Committee has recommended making SDM the national standard of care.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Further studies should examine the effect of this or similar complex interventions in other healthcare settings and improve the effectiveness and resource requirements of implementation. Politically, the decisive course will now have to be set to implement the program - as originally envisaged in the Innovation Fund - across the board in German healthcare.

project. The German Federal Joint Committee has recommended to make the Kiel model of SDM a national standard of care.

Introduction

Shared decision-making (SDM) is considered the apex of patient-centred, evidence-based healthcare. Much has been written about the benefits of SDM in doctor–patient interactions.[1–14] Numerous intervention studies have been published reporting on the effects of different SDM interventions. Such studies have been summarised in systematic reviews at regular intervals.[12 15 16] However, the implementation and scaling up of SDM remain challenging. To our knowledge, no SDM implementation has yet been demonstrated in a rigorous and quantitative evaluation to be successful and sustainable across an entire hospital or healthcare organisation.[3 10 17–20]

The project 'Making SDM a Reality' was funded from October 2017 to September 2021 (ref. 01NVF17009) by the German Innovation Fund and the Medical Faculty of Kiel University. One goal of the German Innovation Fund is to test scalability of new forms of care that have been proven effective in smaller studies. If such testing is successful, then they can be recommended for national implementation.[21 22] Here, we present the feasibility and effectiveness results of the funded demonstration project.

Design and setting

The four modules of the SHARE TO CARE (S2C) programme were implemented at the entire Kiel campus of the University Hospital Schleswig-Holstein (UKSH). The Kiel campus has 25 departments, roughly 620 doctors, 1100 nurses and treats around 220 000 patients annually. This makes it 1 of the 10 largest university medical centres in Germany. The study protocol was published prospectively.[1]

To examine feasibility and effectiveness of the S2C programme (described in the Intervention section) we collected data from 2018 until 2021, with a baseline measurement (T_0) prior to the implementation of the S2C programme in the 20 eligible departments, and T_1 and T_2 measurements after completion of programme implementation in these departments. Departments were enrolled consecutively, with T_0 occurring between December 2018 and April 2020. Outcome measurement (for T_1) was completed in December 2021. Outcome measurement for T_2 was only reached for two departments by the end of the study (see online supplemental table 1). Data for T_2 only for neurology and neurosurgery are published elsewhere.[14]

Participants

We included all adult patients (age 18 and older) who in the past few weeks had an outpatient or inpatient visit to 1 of the 20 eligible departments of USKH at the Kiel campus. Three of the 25 departments were ineligible for implementation, as all decisions with patients are made in other departments (Radiology) or were undergoing leadership changes, making participation infeasible (otolaryngology and neuropaediatrics). Two other departments were ineligible for patient-reported experience measure (PREM)-evaluation as they only treat paediatric patients (<18 years; general paediatrics and paediatric cardiosurgery). Two of the 20 eligible departments were too late for T_2 measurement due to COVID-19 delays in project schedule (orthodontics and haematology). Independent cross-sectional patient samples were included for the measurements before (T_0) and after (T_1) programme implementation. All patients who consented to research activities at their intake were included and consent was implied by the patient by returning the questionnaire.

Intervention

The multicomponent S2C programme consists of four intervention modules targeting physicians, other medical staff (nurses, medical technical assistants, physiotherapists, etc) or patients. Each module had shown effectiveness and feasibility in previously conducted randomised controlled trials.

Module 1

A minimum of 80% of all physicians of each clinical department completed a multimodal training composed of an online-training session and two consecutive individual feedback sessions based on videotaped real patient consultations. First, physicians underwent a 1-hour online training session teaching basic SDM skills, including viewing of simulated physician–patient interactions to demonstrate the dos and don'ts in SDM. Second, a real life consultation video from each physician was analysed and rated by the S2C trainer team using the MAPPIN' SDM rater manual. In small group training sessions, physicians then received individual feedback based on their own video recordings. To complete the training module, physicians recorded a second patient consultation and participated in a second small group training to view their, hopefully improved, performance and further develop their SDM skills.[7 23] After completion physicians received their SDM certificates from the S2C programme and continuing education credits by the Physicians Chamber of Schleswig-Holstein.

Module 2

To increase patients' participation and involvement in decision-making, every patient received information how to actively take part in their physician–patient interaction using the 'Ask 3 Questions' approach.[11] Besides that, a comprehensive patient activation campaign across the hospital incorporated video clips (eg, on websites, bedside screens and in waiting rooms) and printed materials (flyers, roll ups, etc).

Module 3

To facilitate understanding of their health condition and available treatment options, patients received evidence-based online patient decision aids (EbPDA) in 80 different treatment decisions. To ensure content quality each EbPDA is based on a needs assessment, validated by user testing and external peer review. Clinicians at UKSH and the S2C staff collaborated to develop the list of specific decisions for which EbPDAs were developed. The evidence research team conducted a systematic review of best available evidence for all treatment opportunities available. They also

performed needs assessments with patients to align with needs and preferences of patients in the specific decision situations.

Methods of content development were based on the German Standard of Evidence-Based Patient Information and the methods of evidence generation in patient information.[24–27] The process of DA development follows the International Patient Decision Aids Standards criteria.[25 27] EbPDAs should be designed to be as user-friendly as possible. Therefore, we included video sequences with UKSH physicians explaining interventions and patients sharing their experiences facing the same decision as the EbPDA users.[28 29] Patients did not report on their individual experiences with the interventions presented to avoid influence on users of the EbPDAs. An example-EbPDA can be found here: https://eh-epilepsie.share-to-care.de.

Module 4

All nurses were educated to help patients find relevant EbPDAs, encourage them to actively engage in decision-making, and to be aware if physicians seemed to overlook patient preferences. In addition, nurses or other healthcare professionals were trained as decision coaches to facilitate patients' decision processes in selected clinical pathways.[3 30] Decision coaches function as emotional assistance to sensitise patients to unanswered questions and treatment preferences improving physician–patient consultation.

Training has been designed in a similar way as physicians' face-to-face feedback sessions. However, in addition to gaining basic knowledge about SDM, decision coaches also receive detailed information about the EbPDAs of their specific department and skills to support patients' decision-making. Nurses completed decision coach training by recording two coaching conversations with different patients at different time points and received individual feedback. Decision coaching training has an emphasis on the EbPDAs of the specific departments.

Certification

Once a department has met implementation and training metrics for each of the four modules, it receives a department-wide S2C certificate. Continued certification requires annual documentation by the department that the criteria has been maintained (eg, new staff have been trained).

Data collection and outcome measures

Detailed explanations of the study methods are published elsewhere.[1] Outcome data were collected in a pre–post design via mailed patient questionnaires. Baseline measurements were conducted from July to September 2018 and immediate postintervention completion within each department (T_1) from February 2020 to December 2021. Due to the COVID-19 lockdowns, implementation and evaluation were delayed for several months. This also affected the timeline and available funding for the planned evaluation. The primary intervention outcome was whether and to what degree patients were involved in clinical decisions. To cover different perspectives, we focused on two types of outcome measures, one from the patient perspective (PREM) and one from an observer perspective (Observer-Reported Outcome Measure).[31] This paper focuses on the patient- perceived involvement in care (PREM). The observer-based perspective and the intermediate term outcomes (T_2) are published elsewhere.[32 33] We used a validated SDM measurement instrument, the Perceived Involvement in Care Scale (PICS).[34 35] The PICS is translated and validated in Germany and consists of three subscales with 4–5 items each. The subscales are (1) Doctor Facilitation Scale ($PICS_{DFS}$; five items) (2) Patient Information Scale ($PICS_{PIS}$; four items) and (3) Patient Decision-making Scale ($PICS_{PDM}$; five items). Each item is measured on a scale from 1 (='do not agree at all') to 4 ('totally agree'). The $PICS_{PDM}$ subscale was prospectively defined as the primary outcome of interest.

Sampling for outcome measurement was conducted in a retrospective, consecutive index date method.[1] Patients who had been discharged from the hospital before a defined date (index date) were enrolled consecutively from the index date backward until the required sample size was achieved. At T_1 index, dates were set for each department separately with at least 2 months gap between finalisation of interventions and start of sampling.

As the main aim of the study was to enhance patient's perceived involvement in SDM, we focused on the ($PICS_{PDM}$) subscale of the PICS.[1] However, data of the other two subscales of PICS, the ($PICS_{DFS}$) and the ($PICS_{PIS}$), were also collected. Difference in PICS scores of 0.4 comparing T_0 and T_1 measurement (or Hedges' g>0.5, which corresponds to a medium size effect) were used to calculate the sample size. Sample size calculation was based on expected effect size and number of returned questionnaires (attrition rates of 40% were expected).[1]

Additional secondary outcomes were two validated and widely used questionnaires, the Preparation for Decision Making Scale (PrepDM: 10 items; 5-point scale; preparedness for decision-making)[36] and collaboRATE (three items; 5-point scale; brief generic SDM-measure).[37]

Statistical analyses

Data analysis was conducted by independent evaluators of the Technical University München. For descriptive purposes, data are expressed as mean with SD and/or 95% CI. Subscales were only included in the analyses if all items were filled out. Cases were excluded entirely if >95% of all items of the overall questionnaire were missing. Z-score normalisation within departments across both measurement points was used to account for heterogeneity in 'naturally' occurring SDM levels within each department before and after the intervention. An independent two-sided t-test was used to determine if there were significant differences between baseline and postintervention data. A score above 2.5 indicated a good level of SDM. In addition, we performed a multiple regression analysis examining the effect of age, education and gender on $PICS_{PDM}$. Effect size was reported using Hedges' g. All analyses were performed using STATA 16.1 with a $p<0.05$ considered statistically significant. We performed all analyses in two different data sets: data set A was the subset of all departments with at least 30 patient questionnaires returned. Data set B included the full sample of all departments as defined in the study protocol.

Results

Feasibility

As described above (see the Participants section), 20 departments were eligible for this evaluation with 18 that completed T_1 measurement. Eighteen of the 22 included departments have successfully implemented the full S2C programme indicating good feasibility (see online supplemental table 1 for details). Also the process evaluation gave mainly positive feedback on the different components and some suggestions for improvements.[32] Fourteen departments completed the implementation and both measurements and were, therefore, suitable for the per protocol (PP) analysis.

Table 1 Sample characteristics (T_0 and T_1 summarised)

Sample characteristic	Subgroup	n	%
Age	18–40	314	11.7
	41–60	808	30.2
	61–80	1325	49.6
	›80	223	8.3
Gender	Female	1168	46.5
	Male	1337	53.2
	Gender diverse	6	0.2
Highest school-leaving qualification	Without qualification	42	1.6
	Elementary school leaving certificate	718	27.5
	Secondary school leaving certificate/ equivalent	931	35.6
	Vocational baccalaureate/A-levels	841	32.2
	Ther qualification	81	3.1
Vocational training	No vocational training	287	11.4
	In vocational training	49	2.0
	Basic vocational training year completed	19	0.8
	Vocational training	1718	68.4
	Master craftsman/technician/technical college diploma	290	11.5
	Ther qualification	148	5.9
University degree	No university degree	1546	65.1
	In studies	90	3.8
	Bachelor	74	3.1
	Master/magister/diploma/state examination	388	16.3
	Doctorate/PhD	81	3.4
	Ther degree	193	8.1
Current professional situation (main job)	Employed	809	30.7
	Self-employed	125	4.7
	Studying/training	66	2.5
	Unemployed	89	3.4
	Retired	1421	53.9
	Ther	127	4.8
Current marital status	Single	433	16.3
	Married	1693	63.7
	Divorced	283	10.6
	Widowed	242	9.1
Health insurance	Compulsory	1889	72.7
	Compulsory/voluntary	269	10.4
	Private	437	16.8
Mother tongue	German	2546	95.6
	Ther	115	4.3
Who filled out the questionnaire?	Patient	2542	95.4
	Someone else (family member, etc)	117	4.4

Meanwhile, as a result of this project, SDM according to the S2C programme is reimbursed at the UKSH by all large compulsory health insurance companies. Also, the German Federal Joint Committee has issued a positive recommendation to make the S2C programme a national standard of care.[38] These developments can also be regarded as indicators of feasibility and sustainability.

Effectiveness

Sample sizes for T_0 and T_1 are summarised in online supplemental table 1. Overall return rates were 65% at T_0 and 48% at T_1. Participants' characteristics are displayed in table 1. About half of the patients were older than 60, 46.5% female, 35% had a secondary school leaving certificate, 68.4% had completed professional vocational training (beyond secondary school), 34.9% had a university degree, 53.9% were retired, 63.7% were married, 83.1% had a compulsory health insurance plan and more than 95% had German as their mother tongue and had filled out the questionnaire themselves. We did not find relevant differences in these characteristics in the T_0 and T_1 subsamples (data not shown).

Descriptive results

Table 2 contains the analyses for $PICS_{PDM}$, PrepDM and collaboRATE for the 14 departments included in the final sample. In data set A, only those departments were included that had at least 30 questionnaires at both time points T_0 and T_1 (n=7 departments). Data set B included all departments that had at least one questionnaire at each point in time (n=14 departments).

For $PICS_{PDM}$, an overall difference in the mean values of 0.29 (data set A) and 0.20 (data set B) between T_0 and T_1 was shown. This difference was statistically significant and corresponded to a small to medium positive effect (Hedges' g=0.3 data set A/0.2 data set B). If, instead of the PP analysis for the primary endpoint, an intention-to-treat (ITT) analysis with including the four not fully implemented departments that also collected data at T_1(urology, cardiology, nephrology and orthopaedics/traumatology; see dashed line in online supplemental table 1), the effect remains significant but, as expected, becomes smaller (p=0.006; Hedges' g=0.13).

Consistent with this, the secondary endpoints (PrepDM and collaboRATE) also showed statistically significant, small but relevant positive effects (see table 2).

The responder analysis with a threshold of 2.5 on the $PICS_{PDM}$ showed an increase in responders feeling involved in decision-making from 58.7% to 70.0% (= 11.3%; data set A) and from 71.8% to 77.8% (= 6.0%; data set B), respectively (see table 1).

Subgroup analyses

Beyond the analyses prespecified in the study protocol, explorative subgroup analyses were conducted for individual departments. However, only those who fulfilled the criteria of data set A (ie, ≥30 patients) were included in these analyses. The department with the most returned questionnaires at both time points was ophthalmology with 64 in T_0 and 80 in T_1. The departments with the fewest were neurosurgery in T_0 (n=37) and nuclear medicine in T_1 (n=37). Table 3 displays the subgroup effects for the primary endpoint ($PICS_{PDM}$). Similar effects were shown in the secondary endpoints (data not presented).

The $PICS_{PDM}$ analysis of individual departments showed a significant mean increase (mean difference greater than zero, p value significant) for the departments of cardiac and vascular surgery, neurology, neurosurgery and ophthalmology. The greatest increase and the greatest effect size (Hedges' g: 0.67) was shown in cardiac and vascular surgery. Of those with a significant effect size, neurology showed the smallest effect (Hedges' g=0.48, medium effect size). Effect sizes for non-significant means are not to be considered and are therefore shown in grey in table 2.

Linear regression

A simple linear model with the variable 'time of measurement' (model 1) was calculated in both data sets (see table 4). To control for sociodemographic differences (age, gender and school-leaving qualification), a linear regression of a correspondingly extended model was calculated (model 2).

The change in the coefficient for T_1 was measured in a stepwise regression with covariables (age, gender and school-leaving

Table 2 SDM effect for the entire hospital (PICS, PrepDM and collaboRATE)

Outcome	$PICS_{PDM}$		PrepDM		collaboRATE	
Data set	A	B	A	B	A	B
n (T_0)	361	706	348	675	374	733
n (T_1)	440	581	414	551	445	588
No of departments	7	15	7	15	7	15
Mean (T_0)	0.16	0.09	0.12	0.08	0.12	0.07
SD (T_0)	1.02	1.01	1.01	1.00	1.00	1.01
Mean (T_1)	0.13	0.11	0.10	0.10	0.10	0.09
SD (T_1)	0.96	0.96	0.98	0.98	0.98	0.97
MD (T_1–T_0)	0.29	0.20	0.22	0.18	0.22	0.16
P value	0.00	0.00	0.00	0.00	0.00	0.00
Threshold T_0	58.7%	71.8%	n.s.	n.s.	n.s.	n.s.
Threshold T_1	70.0%	77.8%	n.s.	n.s.	n.s.	n.s.
Hedges' g	0.2993	0.1995	0.2291	0.1836	0.2187	0.1612

Data set A: only departments that had at least 30 valid questionnaires at both time points T_0 and T_1 were included; Data set B: all departments that had at least one valid questionnaire at each time point were included.

MD, mean difference; n.s, not specified; PICS, Perceived Involvement in Care Scale; PrepDM, preparation for decision-making.

qualification). Even after adding all the control variables, the coefficient of T_1 remained significant.

By adding departments with fewer than 30 returned questionnaires per measurement point (data set B), the effect (=size of T_1) was reduced but remained statistically significant (see table 4).

Discussion

In this 4-year implementation study, the complex intervention programme S2C with its four modules was fully implemented in 18 departments of UKSH, Kiel campus. This was achieved despite the fact that most departments moved to newly erected buildings during this period and that the COVID-19 pandemic repeatedly interrupted implementation efforts.

Significant and clinically meaningful effects were observed regarding patients' perceived involvement in treatment decisions. These effects were consistent across all instruments measuring SDM with a focus on patient involvement in this project. These patient-reported results (PREMs) are also consistent with the results from the observer perspective using the MAPPIN'SDM instrument.[32] As we were able to demonstrate statistically significant, positive effects on patients' perceived involvement even after 6–18 months (ie, T_2) in two of the departments (neurology and neurosurgery),[14] we are optimistic that these are lasting effects. Our results suggest that SDM can be implemented in entire hospitals, across different types of departments. The observed effects are smaller than predicted in the protocol. Nevertheless, results greater than Hedges' g=0.2 indicate a clinically meaningful positive effect of the intervention.

We are aware of other large-scale SDM implementation studies in Germany and other countries. The special issue of ZEFQ in 2022 summarises international developments.[4] However, to our knowledge, only one of these has been evaluated in a quantitative and controlled way, comparable to this study.[10 39] That study could not show an effect of the SDM intervention. The reasons for this are varied and cannot be clearly identified by directly comparing the interventions of the two studies.[39] Overall, we think that for an SDM implementation to be successful, an organisation-wide cultural change is required, which is very likely to be reached only with a certain fidelity to and duration of the intervention.

Methodological aspects

Within the framework of this study, it was not possible to differentiate among the effects of the four individual components separately. Since all components were implemented simultaneously and interact synergistically with each other (eg, participation in the creation of the decision aids influences the clinicians'

Table 3 SDM effect in individual departments: PICS (data set A)

Outcome	$PICS_{PDM}$							
Department	General surgery	Cardiac and vascular surgery	Internal medicine	Neurosurgery	Neurology	Nuclear medicine	Ophthalmology	Urology
n (T_0)	49	51	49	38	57	53	64	48
n (T_1)	66	62	51	74	70	37	80	70
Mean (T_0)	2.91	2.21	2.71	2.62	2.68	2.94	2.32	2.92
SD (T_0)	0.89	0.8	0.95	1	0.86	0.78	0.84	0.85
Mean (T_1)	2.8	2.79	2.91	3.07	3.05	2.67	2.75	2.76
SD (T_1)	0.89	0.91	0.73	0.81	0.68	0.95	0.84	0.91
MD (T_1–T_0)	0.11	0.58	0.20	0.45	0.37	0.27	0.43	0.16
P value	0.54	0.00	0.25	0.01	0.01	0.14	0.00	0.33
Hedges' g	0.1148	0.6662	0.2297	0.5164	0.4758	0.3138	0.5074	0.1830

Not significant effects in grey font. Urology department=waitlist control department.

MD, mean difference; $PICS_{PDM}$, Patient Decision Making subscale of the Perceived Involvement of Care Scale; SDM, shared decision-making.

Table 4 Representation of the SDM effect in the entire hospital via linear regression

Instrument	$PICS_{PDM}$			
	A		B	
Data set	Model 1 coeff. (SE)	Model 1 coeff. (SE)	Model 1 coeff. (SE)	Model 1 coeff. (SE)
Timepoint (T_0=reference)				
T_1	0.30 (−0.07)***	0.27 (−0.07)***	0.20 (−0.06)***	0.20 (−0.06)***
Age (18–40 years=reference)				
41–60		0.21 (−0.14)		0.06 (−0.10)
>60		0.28 (−0.14)*		0.13 (−0.09)
Gender (female=reference)				
Male		0.00 (−0.07)		0.03 (−0.06)
Highest school-leaving qualification (elementary school leaving certificate or lower=reference)				
Secondary school leaving certificate		0.13 (−0.09)		0.12 (−0.07)
Vocational baccalaureate/A-levels		0.04 (-0.09)		0.13 (-0.07)
Constant	0.16 (−0.05)**	0.03 (−0.15)	0.09 (−0.04)*	0.10 (−0.10)
R^2	0.022	0.031	0.010	0.018
Adjusted R^2	0.021	0.023	0.009	0.013
n T_0	361	329	706	646
n T_1	440	400	581	527
n overall	801	729	1.287	1.173

*p<0.05, **p<0.01, ***p<0.001.

$PICS_{PDM}$, Patient Decision Making subscale of the Perceived Involvement of Care Scale; SDM, shared decision-making.

communication with the patients), it is not possible to clearly distinguish between the effects of individual SDM intervention modules. A National Institute for Health and Care Excellence(NICE) guideline on SDM yields inconsistent results regarding the desired effect size of different interventions and their combinations.[40] However, there is a tendency towards intervention intensity and number of intervention components being positively correlated with effects on SDM.

Little is known about the responsiveness to change of patient-reported SDM measurement instruments.[41] In our study, three PREM-instruments were used in parallel (PICS,[35] PrepDM[36] and collaboRATE).[37] The instruments measure slightly different facets of SDM but are all suitable for a generic use across conditions and decision-making situations. The instruments provided mainly consistent results, with PrepDM and collaboRATE providing somewhat smaller effects than $PICS_{PDM}$ (see table 2). It should be mentioned here that the collaboRATE instrument was not used in its final German version, as this was not yet available at the time of the measurements.

The COVID-19 pandemic was likely a confounder, as it led to massive management changes in the hospital soon after the baseline survey and a significant decrease in elective procedures. While it is possible that COVID-19 biases the PREM positively (social desirability) or negatively (omission of elective interventions, increased stress of staff due to COVID measures and less time for conversations with patients), other departments that did not start SDM implementation (eg, urology) do not seem to indicate any such effect. In addition, the fact that the T_2 measurements, which were largely carried out under conditions later in the pandemic, show a positive effect in two departments[14] mitigates serious concerns about confounding by COVID-19.

The move of many departments to a new building during the project could have similar confounding effects. This also led to considerable additional organisational and logistical burdens. Here, we assume that it could have tended to bias the results downwards, as the intervention could have been seen as less urgent or important. Therefore, our measured effects on SDM may be an underestimate of how SDM could improve under more typical conditions.

Most studies on SDM to date have been conducted in selected patient populations who were immediately facing a preference-sensitive decision. In this study, the intervention was carried out and measured without selectively removing clinical conditions, decisions or populations. It can be assumed that a significant proportion of patients did not face a relevant decision (eg, check-up) or had an emergency admission (eg, stroke) that did not allow for SDM. In addition, many elective interventions that are typical candidates for SDM have been omitted or postponed due to the pandemic. These may also have led to an underestimate of the effect size of SDM on the PREMs we included.

Advantages of a large-scale implementation

It is evident that implementation of this magnitude leads to economies of scale in many ways. These include decision aid production, learning curves for trainers and processes to support implementation. For example, in the production of the 80 decision aids in this project, it was possible to improve efficiency by adjusting our processes, adding checklists and developing templates.[29] While only one decision aid was completed in the first year of the project, by the end of the project we managed to complete three per month. The situation is similar for the trainings. Once an online training is in place, the individual costs for the training become lower with each additional participant. The trainers concurrently experienced a significant learning curve. At an administrative level, implementation strategies that were developed for the first departments and proved to be ineffective could be omitted in the subsequent departments. Effective implementation strategies, on the other hand, could be replicated across departments and used with only slight adjustments.

At least seven additional German hospitals will begin implementation of the S2C programme in 2023. In these hospitals, the implementation is expected to be both cheaper and faster. This is

because intervention components and implementation strategies (eg, online trainings, decision aids, patient activation materials, processes) will not need to be developed from scratch. Moreover, with each successfully implemented hospital, we hope that other hospitals will want to be seen as innovating along with their peers. Meanwhile, we also have health economic analyses that indicate that SDM can also save costs.[32]

Limitations

In 4 of the 20 eligible departments, the SDM interventions could not be carried out within the original project schedule. One of these, urology department did not even start with the implementation. This was due to temporary staff bottlenecks and the acute COVID-19 pandemic. However, as shown in the additional ITT analysis the overall effect stayed significant and meanwhile two of the four have also finished implementation.

This study has a pre–post design. It has neither a control group nor is it randomised. This carries the risk of several forms of bias. However, randomisation was not feasible at the level of an entire university hospital. Another possible design would have been a stepped wedge or a waiting-list control group design. The sheer size of the study, the unexpected delays in implementation schedules in the different departments and the expected heterogeneity of baseline levels of the primary outcome would also have made evaluation difficult here. According to the Medical Research Council's scheme for evaluating complex interventions,[42 43] the present project is in phase VI (long-term implementation), which is concerned with the question of whether results of interventions that proved effective in randomised trials can be replicated in non-randomised trials in the longer term or in larger scale.

Only 14 of the 20 eligible departments were included in the primary PREM analysis according to the study protocol (PP analysis). However, we additionally conducted an ITT analysis with 18 of the 20 eligible departments included, that had survey data for T_1. The results stayed significant, although smaller.

Conclusion

This large-scale implementation study demonstrated the feasibility and effectiveness of implementing SDM in an entire university hospital within 4 years. Effects of individual intervention modules have been reproduced in a significantly larger way, despite a move of many departments to a new building and the COVID-19 lockdowns. Meanwhile, as a result of this project, SDM is reimbursed at the Kiel campus by all major compulsory health insurance companies. In addition, the German Federal Joint Committee has issued a recommendation to make the S2C programme a national standard of care.

Author affiliations
[1]National Competency Center for Shared Decision Making, University Hospital Schleswig Holstein, Köln, Germany
[2]Department of Paediatrics I, University Hospital Schleswig-Holstein, Kiel, Germany
[3]Department of Psychology, MSH Medical School Hamburg, Hamburg, Germany
[4]Department of Internal Medicine I, University Medical Center Schleswig-Holstein, Kiel, Germany
[5]DARUM Marion Danner und Anne Rummer GbR, Cologne, Germany
[6]National Competency Center for Shared Decision Making, University Hospital Schleswig Holstein, Kiel, Germany
[7]Department of General Surgery, University Hospital Schleswig Holstein, Kiel, Germany
[8]Department for Orthodontics, University Hospital Schleswig Holstein, Kiel, Germany
[9]Department of Health Economics, Technical University of Munich, München, Germany
[10]Department of Emergency Medicine, University Hospital Jena, Jena, Germany
[11]Center for Healthcare Organization and Implementation Research (CHOIR), Veterans Administration, Bedford, Massachusetts, USA
[12]Department of Population and Quantitative Health Sciences, University of Massachusetts Chan Medical School, Worcester, Massachusetts, USA
[13]TAKEPART Media + Science, Köln, Germany

Correction notice Since this paper was first published, an author surname has been updated to Bünzen. A second affiliation for Marie Debrouwere was also removed.

Twitter Marla Clayman @marlaclayman

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ORCID iDs
Fülöp Scheibler http://orcid.org/0000-0002-4983-7253
Christina Gesine Sommer http://orcid.org/0009-0001-5446-8894
Marie Coors http://orcid.org/0000-0002-6800-3326
Felix Wehking http://orcid.org/0000-0002-7554-1851
Marla Clayman http://orcid.org/0000-0001-8491-3672

References

1 **Danner M**, Geiger F, Wehkamp K, *et al*. Making shared decision-making (SDM) a reality: protocol of a large-scale long-term SDM implementation programme at a northern German University hospital. *BMJ Open* 2020;10:e037575.
2 **Arterburn D**, Wellman R, Westbrook E, *et al*. Introducing decision AIDS at group health was linked to sharply lower hip and knee surgery rates and costs. *Health Aff (Millwood)* 2012;31:2094–104.
3 **Berger-Höger B**, Liethmann K, Mühlhauser I, *et al*. Nurse-led coaching of shared decision-making for women with ductal carcinoma in situ in breast care centers: a cluster randomized controlled trial. *Int J Nurs Stud* 2019;93:141–52.
4 **Bravo P**, Härter M, McCaffery K, *et al*. Editorial: 20 years after the start of international shared decision-making activities: is it time to celebrate. *Z Evid Fortbild Qual Gesundhwes* 2022;171:1–4.
5 **Elwyn G**, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implementation Sci* 2015;11.
6 **Elwyn G**, Price A, Franco JVA, *et al*. The limits of shared decision making. *BMJ Evid Based Med* 2023;28:218–21.
7 **Geiger F**, Hacke C, Potthoff J, *et al*. The effect of a Scalable online training module for shared decision making based on flawed video examples - a randomized controlled trial. *Patient Educ Couns* 2021;104:1568–74.
8 **Montori V**, Kunneman M. Caring without boundaries: delimiting shared decision-making. *BMJ Evid Based Med* 2023;28:226–7.
9 **Montori VM**, Ruissen MM, Hargraves IG, *et al*. Shared decision-making as a method of care. *BMJ Evid Based Med* 2023;28:213–7.
10 **Scholl I**, Hahlweg P, Lindig A, *et al*. Evaluation of a program for routine implementation of shared decision-making in cancer care: results of a stepped wedge cluster randomized trial. *Implement Sci* 2021;16:106.
11 **Shepherd HL**, Barratt A, Trevena LJ, *et al*. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns* 2011;84:379–85.
12 **Stacey D**, Légaré F, Lewis K, *et al*. Decision AIDS for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4:CD001431.
13 **Stiggelbout A**, Griffioen I, Brands J, *et al*. Metro mapping: development of an innovative methodology to co-design care paths to support shared decision making in oncology. *BMJ Evid Based Med* 2023;28:291–4.
14 **Stolz-Klingenberg C**, Bünzen C, Coors M, *et al*. Sustainability of large-scale implementation of shared decision making with the SHARE TO CARE program. *Front Neurol* 2022;13:1037447.
15 **Légaré F**, Adekpedjou R, Stacey D, *et al*. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database Syst Rev* 2018;7:CD006732.
16 **Wehking F**, Debrouwere M, Danner M, *et al*. Impact of shared decision making on healthcare in recent literature: a scoping review using a novel taxonomy. *J Public Health (Berl)* 2023.
17 **Berger-Höger B**, Liethmann K, Mühlhauser I, *et al*. Implementation of shared decision-making in oncology: development and pilot study of a nurse-led decision-coaching programme for women with ductal carcinoma in situ. *BMC Med Inform Decis Mak* 2017;17:160.
18 **Joseph-Williams N**, Lloyd A, Edwards A, *et al*. Implementing shared decision making in the NHS: lessons from the MAGIC programme. *BMJ* 2017;357:j1744.
19 **Kasper J**, Stensdal L-A, Kienlin S, *et al*. New status report from Norway: implementation of patient involvement in Norwegian health care. *Z Evid Fortbild Qual Gesundhwes* 2022;171:105–12.
20 **Steffensen KD**, Vinter M, Crüger D, *et al*. Lessons in integrating shared decision-making into cancer care. *J Oncol Pract* 2018;14:229–35.
21 **Blettner M**, Dierks M-L, Donner-Banzhoff N, *et al*. Überlegungen des expertenbeirats zu Anträgen Im Rahmen des Innovationsfonds. *Zeitschrift Für Evidenz, Fortbildung Und Qualität Im Gesundheitswesen* 2018;130:42–8.
22 **Gemeinsamer Bundesausschuss (Federal Joint Committee**. Innovationsausschuss (innovation committee) Berlin. 2022. Available: https://innovationsfonds.g-ba.de/innovationsausschuss/ [Accessed 28 Dec 2022].
23 **Geiger F**, Liethmann K, Reitz D, *et al*. Efficacy of the doktormitSDM training module in supporting shared decision making - results from a multicenter double-blind randomized controlled trial. *Patient Educ Couns* 2017;100:2331–8.
24 **Deutsches Netzwerk Evidenzbasierte Medizin**. Gute praxis gesundheitsinformation (good practice health information) Berlin. 2015. Available: http://www.ebm-netzwerk.de/gpgi
25 **Holmes-Rovner M**. International patient decision aid standards (IPDAS): beyond decision aids to usual design of patient education materials. *Health Expect* 2007;10:103–7.
26 **Lühnen J**, Albrecht M, Hanßen K, *et al*. Guideline for the development of evidence-based patient information: insights into the methods and implementation of evidence-based health information. *Z Evid Fortbild Qual Gesundhwes* 2015;109:159–65.
27 **Stacey D**, Volk RJ, Leads IEU. The International patient decision aid standards (IPDAS) collaboration: evidence update 2.0. *Med Decis Making* 2021;41:729–33.
28 **Danner M**, Debrouwere M, Rummer A, *et al*. A scattered landscape: assessment of the evidence base for 71 patient decision aids developed in a hospital setting. *BMC Med Inform Decis Mak* 2022;22:44.
29 **Rummer A**, Weik K, Danner M. Online-entscheidungshilfen für patient:Innen. In: **Scheibler F**, Geiger F, Rüffer J, eds. *Eine praktische anleitung für mehr shared decision making im klinischen alltag*. Köln: atp-Verlag, 2023.
30 **Schuldt A**, uch C. Projekt Im Hohen Norden: Pflegekräfte ALS decision coaches. *Pflegez* 2020;73:10–2.
31 **Clayman ML**, Scheibler F, Rüffer JU, *et al*. The six steps of SDM: linking theory to practice, measurement and implementation. *BMJ Evid Based Med* 2023:bmjebm-2023-112289.
32 **Franke S**, Coors M, Kropp S, *et al*. MAKING SDM A REALITY - evaluationsbericht: gemeinsamer bundesausschuss - innovationsausschuss; 2023. 2023. Available: https://innovationsfonds.g-ba.de/downloads/beschluss-dokumente/375/2023-02-23_MAKING-SDM-A-REALITY_Evaluationsbericht.pdf [Accessed 09 Mar 2023].
33 **Geiger F**. Quebec 2019 – evaluation of online training module. ISDM; 2019.
34 **Lerman CE**, Brody DS, Caputo GC, *et al*. Patients' perceived involvement in care scale: relationship to attitudes about illness and medical care. *J Gen Intern Med* 1990;5:29–33.
35 **Scheibler F**, Freise D, Pfaff H. Die einbeziehung von patienten in die behandlung - validierung der deutschen PICS Skalen. *J Public Health (Bangkok)* 2004;12:199–209.
36 **Bennett C**, Graham ID, Kristjansson E, *et al*. Validation of a preparation for decision making scale. *Patient Educ Couns* 2010;78:130–3.
37 **Hahlweg P**, Zeh S, Tillenburg N, *et al*. Translation and psychometric evaluation of collaboRATE in Germany – a 3-item patient-reported measure of shared decision-making. 10th International shared decision-making conference; Quebec City, Canada, 2019
38 **Gemeinsamer Bundesausschuss**. Beschluss des innovationsausschusses beim Gemeinsamen Bundesausschuss Gemäß § 92B Absatz 3 SGB V Zum

Abgeschlossenen Projekt MAKING SDM A REALITY (01Nvf17009) 2023. 2023. Available: https://innovationsfonds.g-ba.de/downloads/beschluss-dokumente/373/2023-02-23_MAKING-SDM-A-REALITY.pdf [Accessed 01 Mar 2023].

39 **Hahlweg P**, Lindig A, Frerichs W, *et al*. Major influencing factors on routine implementation of shared decision-making in cancer care: qualitative process evaluation of a stepped-wedge cluster randomized trial. *BMC Health Serv Res* 2023;23:840.

40 **National Institute for Health and Care Excellence**. Shared decision making - NICE guideline. 2021. Available: https://www.nice.org.uk/guidance/ng197 [Accessed 13 Dec 2022].

41 **Gärtner FR**, Bomhof-Roordink H, Smith IP, *et al*. The quality of instruments to assess the process of shared decision making: a systematic review. *PLoS One* 2018;13:e0191747.

42 **Campbell NC**, Murray E, Darbyshire J, *et al*. Designing and evaluating complex interventions to improve health care. *BMJ* 2007;334:455–9.

43 **Skivington K**, Matthews L, Simpson SA, *et al*. A new framework for developing and evaluating complex interventions: update of medical research council guidance. *BMJ* 2021;374:n2061.