

1 **Sustainability of large-scale implementation of shared decision making**
2 **with the SHARE TO CARE program**

3 **Constanze Stolz-Klingenberg¹, Claudia Bünzen¹, Marie Coors², Charlotte Flüh³, Nils G**
4 **Margraf⁴, Kai Wehkamp^{5,6}, Marla L Clayman^{7,8}, Fueloep Scheibler¹, Felix Wehking⁹, Jens**
5 **Ulrich Rüffer¹⁰, Wiebke Schüttig², Leonie Sundmacher², Michael Synowitz³, Daniela Berg⁴,**
6 **Friedemann Geiger^{1,11}**

7 ¹National Competency Center for Shared Decision Making, University Hospital Schleswig-Holstein,
8 Kiel, Germany

9 ²Chair of Health Economics, Technical University of Munich, Munich, Germany

10 ³Department of Neurosurgery, University Hospital Schleswig-Holstein, Kiel, Germany

11 ⁴Department of Neurology, University Hospital Schleswig-Holstein, Kiel, Germany

12 ⁵Department of Internal Medicine I, University Hospital Schleswig-Holstein, Kiel, Germany

13 ⁶Department of Medical Management, MSH Medical School Hamburg, Hamburg, Germany

14 ⁷Center for Healthcare Organization and Implementation Research (CHOIR), Veterans Administration,
15 Bedford, Massachusetts, USA

16 ⁸Department of Population and Quantitative Health Sciences, University of Massachusetts Chan
17 Medical School, Worcester, Massachusetts, USA

18 ⁹Department of Emergency Medicine, University Hospital Jena, Jena, Germany

19 ¹⁰TakePart Media+Science GmbH, Cologne, Germany

20 ¹¹Department of Psychology, MSH Medical School Hamburg, Hamburg, Germany

21

22 *

23 **Correspondence:**

24 Constanze Stolz-Klingenberg

25 Constanze.Stolz-Klingenberg@uksh.de

26 **Keywords: Shared decision making (SDM)¹, sustainability², SDM implementation³, decision**
27 **aids⁴, training of physicians⁵, patient activation⁶ (Min.5-Max. 8)**

28 **Abstract**

29 Introduction:

30 SHARE TO CARE (S2C) is a comprehensive implementation program for shared decision making
31 (SDM). It is run at the University Hospital Schleswig-Holstein (UKSH) in Kiel, Germany, and consists
32 of four combined intervention modules addressing healthcare professionals and patients: (1)

33 multimodal training of physicians (2) patient activation campaign including the ASK3 method, (3)
34 online evidence-based patient decision aids (4) SDM support by nurses.

35 This study examines the sustainability of the hospital wide SDM implementation by means of the
36 Neuromedical Center comprising the Departments of Neurology and Neurosurgery.

37 Methods:

38 Between 2018 and 2020, the S2C program was applied initially within the Neuromedical Center: We
39 implemented the patient activation campaign, trained 89% of physicians (N=56), developed 12 patient
40 decision aids and educated two decision coaches. Physicians adjusted the patients' pathways to
41 facilitate the use of decision aids.

42 To maintain the initial implementation, the departments took care that new staff members received
43 training and decision aids were updated. The patient activation campaign was continued.

44 To determine the sustainability of the initial intervention, the SDM level after a maintenance phase of
45 6-18 months was compared to the baseline level before implementation. Therefore, in- and outpatients
46 received a questionnaire via mail after discharge. The primary endpoint was the 'Patient Decision
47 Making' subscale of the Perceived Involvement in Care Scale (PICS_{PDM}). Secondary endpoints were
48 an additional scale measuring SDM (CollaboRATE), and the PrepDM scale, which determines
49 patients' perceived health literacy while preparing for decision making. Mean scale scores were
50 compared using t-tests.

51 Results:

52 Patients reported a significantly increased SDM level (PICS_{PDM} p=.02; Hedges' g=.33; CollaboRATE
53 p=.05; Hedges' g=.26) and improved preparation for decision making (PrepDM p=.001; Hedges'
54 g=.34) 6-18 months after initial implementation of S2C.

55 Discussion:

56 The S2C program demonstrated its sustainability within the Neuromedical Center at UKSH Kiel in
57 terms of increased SDM and health literacy. Maintaining the SDM implementation required a fraction
58 of the initial intensity. The departments took on the responsibility for maintenance. Meanwhile, an
59 additional health insurance-based reimbursement for S2C secures the continued application of the
60 program.

61 Conclusion:

62 SHARE TO CARE promises to be suitable for long-lasting implementation of SDM in hospitals.

63

64 **1. Introduction**

65 Patients' satisfaction, successful treatment of diseases and cost-effectiveness are three of the main goals
66 in healthcare, which in some cases are difficult to reconcile. Shared decision making (SDM) as a
67 process of information exchange and negotiation can contribute as an essential lever to achieve these
68 ambitious goals simultaneously (Coulter 1999). To successfully reach a shared decision, a positive and
69 productive collaboration between physician and patient is needed (Bieber et al. 2006). Physicians act

70 as medical experts with their expertise in causes of disease, symptoms, treatment options with possible
71 advantages and disadvantages. Based on the best available evidence they provide the information base
72 for a meaningful physician-patient-conversation (Stiggelbout et al. 2012). The patient acts as an expert
73 on himself, his preferences and his personal circumstances. Patients enrich the information exchange
74 with their thoughts, experiences of disease, risk behavior and expectations – information that is not
75 evident from any medical record (Coulter 1999). The active participation of both leads to a shared
76 decision that is medically justifiable and provides the best fit for the individual patient.
77 Such an exchange on equal terms meets patients need for better information, understanding and
78 involvement in their medical decision making (Timmins und Kaliszer 2003; Oterhals et al. 2006;
79 Richter et al. 2011). In a study with more than 1.500 cancer patients in Germany over 80% of the
80 participants preferred to take a collaborative or active role in decision making underlying the need for
81 increased SDM-practice (Grabbe et al. 2022).

82 In addition to the arguments from the patient's point of view, SDM also offers advantages for
83 physicians as well as the healthcare system: SDM strengthens patients' self-responsibility and
84 knowledge of their disease, so that well-informed patients more rapidly recognize and communicate
85 side-effects. This can be a protective factor against serious treatment complications, especially in
86 complex decision-making situations with a multitude of treatment options, such as in the treatment of
87 multiple sclerosis in neurology (Heesen et al. 2011). Complementary, patients perceive themselves as
88 more self-efficacious (Richter et al. 2011). In particular through the application of SDM, patients
89 develop more realistic outcome expectations leading to increased patient satisfaction, greater treatment
90 adherence, less decisional regret and less complaints (Whittle et al. 2007; Davison und Goldenberg
91 2003; Légaré et al. 2018; Clayman et al. 2016).

92 In sum, there are many arguments in favor of SDM. This raises the question: How can SDM be
93 successfully implemented in the hospital initially, and how can it be maintained so that SDM remains
94 a matter of course in daily healthcare?

95 Only a limited number of SDM-interventions follow a comprehensive approach involving all relevant
96 stakeholders, i.e. patients, physicians, nurses and other healthcare professionals (Légaré et al. 2018).
97 The SHARE TO CARE program (S2C) addresses each of these groups with a dedicated intervention
98 module. Integrating four modules into a comprehensive implementation strategy, the S2C program
99 aims to implement SDM within entire hospitals. The four S2C modules are:

100 *1) Training of all physicians.* A minimum of 80% of physicians within each clinical department
101 has to complete a multimodal training composed of an online-training session (Geiger et al.
102 2021a) and two individual feedback sessions based on videotaped patient consultations.
103 Physicians first complete a one-hour online session presenting basic SDM knowledge and
104 several simulations of physician-patient-interactions to demonstrate Do's and Don'ts in SDM.
105 Subsequently, physicians take part in an individual SDM coaching session in a peer group
106 setting (2-5 participants) based on their own videotaped patient consultations. Interaction of
107 increased self-reflection through video excerpts and feedback from colleagues and experienced
108 SDM coaches shall create an encouraging and constructive learning atmosphere. Later,
109 physicians record another consultation and participate in a second small group training to
110 further increase and consolidate their SDM skills. After successful training completion,
111 physicians receive a certificate and education credits by the Physicians Chamber of the Federal
112 State of Schleswig-Holstein.

113 2) *Activation of patients.* To increase patients' participation and involvement in medical
114 decision making, every patient receives information how to actively take part in their physician-
115 patient consultations using the ASK-3 approach (Shepherd et al. 2016). By distributing various
116 promotion/information material (e.g. SDM video clips on screens, roll ups, posters, flyers,
117 promotional items, SDM web page, paper postcards and screen-based messages and media)
118 inside each department, patients are encouraged to ask specific questions during their
119 consultation to gain deeper understanding of their treatment opportunities.

120 3) *Implementation of evidence-based decision aids.* Fostering patients' understanding of their
121 condition and treatment opportunities is also done through online evidence-based Patient
122 Decision Aids (EbPDA). These are developed within each department based on a literature and
123 guideline review, in cooperation with physicians and patients. The evidence research team
124 conducts a systematic review of best available evidence for all treatment opportunities available
125 at the hospital. They also perform needs assessment interviews with patients to align with needs
126 and preferences of patients in the specific decision situations. Methods are based on the German
127 Standard of evidence-based patient information and the methods of evidence generation in
128 patient information (Lühnen et al. 2017; Institut für Qualität und Wirtschaftlichkeit im
129 Gesundheitswesen 2017). Considering EbPDA as a user-oriented interface, text information is
130 complemented with video clips featuring local physicians explaining interventions and local
131 patients who share their experience facing the same decision as the DA user. The process of
132 DA development follows the International Patient Decision Aids Standards (Elwyn et al. 2006;
133 Holmes-Rovner 2007; Stacey und Volk 2021). Each EbPDA undergoes external review. The
134 process of EbPDA development for the S2C program is described in detail elsewhere (Danner
135 et al. 2022).

136 As decision aids will never cover every relevant decision within a hospital, clinical experts are
137 to choose topics that are of relevance from a clinical perspective, preference-sensitive as well
138 as sufficiently frequent. These topics are expected to induce a spill-over effect to decisions
139 where no EbPDA is available in terms of a systematic consideration of benefits and harms of
140 each treatment as well as the patient's preferences.

141 4) *Integration of nurses as SDM supporters.* At least 80% of the nurses are educated how to
142 integrate SDM within their own work and how to support patients and physicians regarding the
143 application of the abovementioned modules. Beyond this, selected nurses (or physiotherapists,
144 study nurses etc.) are trained as decision coaches to facilitate patients' decision processes with
145 physicians. Training is designed in a similar way as physicians' coaching sessions: During 2
146 workshop days, healthcare professionals gain further knowledge about SDM, deep insight in
147 the DAs of their specific department or section, and skills to support patients' decision making.
148 Accompanied by the S2C trainer team, nurses complete decision coach training by recording
149 coaching conversations with a patient twice and receiving individual feedback. Decision
150 coaches function as emotional assistance to sensitize patients to unanswered questions and
151 treatment preferences improving the physician-patient-consultation.

152 By completing all four modules, a department meets the criteria to be awarded with the S2C
153 certificate. The fulfilment of the criteria is reviewed annually.

154 Initial findings from the hospital-wide implementation of SDM at the UKSH in Kiel indicate that the
155 S2C program is feasible and effective (Geiger et al. 2021b).

156 Beyond the short-term effectiveness of SDM interventions, it is crucial that the effects are long-lasting,
157 or can be maintained with reasonable effort. However, there is very limited research on the
158 sustainability of SDM interventions. In a sample of patients with fibromyalgia, Bieber et al. (2006)
159 were able to show a diminished but still significantly enhanced SDM level one year after their SDM
160 intervention. In a review by Martínez-González et al. (2019), only outcome parameters related to SDM
161 – but not the SDM level itself – were reported, e.g. knowledge or perceived information level. No study
162 was found with long-term effects (>3 months). Another study in outpatient asthma practices included
163 data 1 year after implementation, but with poor comparability due to lack of a baseline survey (Tapp
164 et al. 2014).

165 In summary, there is no conclusive evidence on the sustainability of hospital wide implemented SDM
166 interventions such as the S2C program. Although – given the substantial effort required for large-scale
167 implementation of SDM – such evidence is particularly relevant as only a long-term effective
168 intervention is cost-effective and reasonable for a hospital. To fill this research gap, the aim of this
169 study was to examine the sustainability of the large-scale implementation of SDM with the S2C
170 program at the UKSH in Kiel (Danner et al. 2020).

171 **2. Methods**

172 **2.1 Design and Setting**

173 To assess the sustainability of the S2C program in terms of a long-lasting increase of the SDM level,
174 we collected data at the Neuromedical Center (Department of Neurology and Department of
175 Neurosurgery) at UKSH in Kiel. Patients were included in 2018 prior to the SDM implementation
176 (baseline t_0), in 2020 immediately after the implementation (t_1) and in 2021 at the end of the funding
177 period of the implementation project, i.e. 6-18 months after implementation (t_2). In this study, data
178 from t_2 and t_0 were compared.

179 The baseline survey was conducted at a time when neither medical staff nor patients had been informed
180 about the upcoming SDM implementation. At t_1 and t_2 , medical staff was informed that the S2C
181 program would be evaluated. However, they were not aware of evaluation measures, the sampling
182 period and, hence, the patients to be included. They had no influence on inclusion of patients. During
183 their consultations, patients were not aware that they might be invited to participate in a study about
184 SDM later.

185 **2.2 Participants**

186 We included adult patients (age 18 and older) who recently had a consultation at the Neuromedical
187 Center at the UKSH in Kiel (inpatients and outpatients). After their discharge, patients were contacted
188 by mail to fill out a questionnaire (see section 2.4 for details). The study was approved by the Ethics
189 Committee of Faculty of Medicine of Kiel University (reference number A111/18).

190 **2.3 Intervention**

191 **2.3.1 Initial implementation**

192 Between 2018 and 2020, the S2C program had been applied successfully within the Neuromedical
193 Center: The patient activation campaign had been rolled out, 89% of physicians (N=56) had completed
194 SDM training. 12 patient decision aids had been developed. 2 decision coaches had been educated.
195 Patients' pathways had been adjusted to facilitate the use of decision aids. Implementation took ca. 1.5

196 years in Neurology and 2 years in Neurosurgery where it was temporarily interrupted by the Covid19
 197 pandemic. Both departments were awarded the S2C certificate indicating full SDM implementation,
 198 which is valid 12 months. At t_1 immediately after implementation, the SDM level had significantly
 199 increased, as reported elsewhere (Geiger et al. 2021b).

200 **2.3.2 Maintenance of the implementation**

201 After successful initial implementation, step by step the departments were asked to take on the
 202 responsibility for maintenance of the SDM implementation: New physicians should be consecutively
 203 trained, and all physicians should participate in further SDM education (twice a year). Other healthcare
 204 professionals should be regularly educated. The decision aids should be kept up to date and the patient
 205 activation campaign be continued.

206 **2.4 Data collection and outcome measures**

207 Outcome data was collected in a pre-post-design via mailed patient questionnaires before (t_0),
 208 immediately after (t_1) intervention and at follow-up 6-18 months after (t_2) intervention. Baseline
 209 measurements were conducted from July until September 2018 at the Department of Neurology and
 210 from August until October 2018 at the Department of Neurosurgery. Long-term post intervention data
 211 collection (t_2) took place from May until July 2021 for both departments, shortly before the end of the
 212 funding period to cover the longest possible follow up-period. This explains the different time periods
 213 between t_1 and t_2 at the Department of Neurology vs. the Department of Neurosurgery.
 214 Patients received two mailed reminders if they failed to answer within 4 weeks.

215 Both inpatients and outpatients were included without exclusion criteria regarding diagnosis or other
 216 parameters. Sampling was done as a retrospective and consecutive sample at a certain key date. The
 217 overall sample size within the hospital-wide SDM implementation was prescribed by the study protocol
 218 ($N > 1.600$ pre and post each) (Danner et al. 2020). The sample size within each of the 22 departments
 219 included within the hospital-wide implementation was determined by its proportion of cases compared
 220 to the overall hospital, with a minimum of $N > 30$ per measurement and department. This resulted in a
 221 minimum of $N > 60$ in this study in the Neuromedical Center with its two constituting departments.

222 The primary outcome was the ‘Patient Decision Making’ (PICS_{PDM}) subscale of the Perceived
 223 Involvement in Care Scale (PICS), a patient reported outcome instrument translated and validated in
 224 German (Scheibler et al. 2004; Lerman et al. 1990). It was measured on a scale from 1= ‘do not agree
 225 at all’ to 4= ‘totally agree’. PICS_{PDM} can be seen as a key indicator of SDM-based physician-patient
 226 interaction and has proven applicable in retrospective studies by mail (Scheibler et al. 2019).
 227 As secondary outcome, SDM level was assessed using the patient questionnaire collaboRATE (Forcino
 228 et al. 2018) (COLL; 3 items; 5 point scale). The Preparation for Decision Making Scale (Bennett et al.
 229 2010) (PrepDM; 10 items; 5 point scale) was used as an indicator of decision-specific health literacy.

230 In addition, the process of maintaining the SDM implementation was monitored and documented.

231 **2.5 Statistical analyses**

232 For descriptive purposes, data are expressed as mean with standard deviation (SD) and/or 95 %
 233 confidence interval (CI), unless stated otherwise. A questionnaire was declared evaluable if all
 234 questions of the respective subscale were answered. We used z-score normalization before pooling the
 235 two departments. t_0 -baseline and t_2 -post-intervention data were compared using independent two-sided
 236 t-test to examine whether there were significant differences in PICS_{PDM}, PrepDM and COLL. In

237 addition, we performed a multiple regression analysis testing the effect of age, education and gender
 238 on PICS_{PDM}, PrepDM and COLL. Effect size was reported using Hedges' *g*. All analyses were
 239 performed using STATA 16.1 with a *p*-value < 0.05 considered to indicate statistical significance.

240 **3. Results**

241 3.1 Patients' characteristics

242 During the previously defined sampling period, 109 (63%) of all eligible patients at *t*₀ mailed back a
 243 survey. The sampling period at *t*₂ happened to contain more eligible patients. 142 of them (59%) sent
 244 back their questionnaire. Therefore, both response rates were in the predefined range as described in
 245 the study protocol (Danner et al. 2020).

246 Details of patients' characteristics are shown in table 1.

247 3.2 Transfer to "maintenance mode"

248 The Neuromedical Center successfully switched into "maintenance mode" regarding the four S2C
 249 modules: Until submission of this manuscript, 17 additional physicians completed training and 14 more
 250 physicians have entered the training process. Each ward management conducted internal SDM
 251 education for nurses at least annually. As a complement to the continued patient activation campaign
 252 via ASK 3 (flyers, posters, cards), a short video encouraging patients to engage in decision making was
 253 made available on the screen at the patient's bedside. The decision aids were regularly reviewed by
 254 clinical experts which led to an update of the decision aid for Parkinson's disease.

255 Beyond the maintenance of the standard S2C modules, the Neuromedical Center proactively expanded
 256 its SDM activity: an additional SDM consultation service by specifically trained staff was introduced
 257 at the epilepsy outpatient ward. Complementary, the Center engaged in scientific and public relations
 258 activity featuring the patient-centeredness as proven by the certified SDM implementation.

259 3.3 Sustained effects

260 The newly obtained long-term data from this study revealed a significant increase of the SDM level 6-
 261 18 months after the intervention (*z*-score standardized PICS_{PDM}: *M*_{*t*0} = -.19 (SD=1.04); *M*_{*t*2} = .14 (SD=
 262 .95); *p* = .02). The effect size Hedges' *g* = .33 indicates a small effect (Cohen 1977).

263 Patients reported an improved preparation for their treatment decision (PrepDM: *M*_{*t*0} = -.20 (SD= 1.00);
 264 *M*_{*t*2} = .14 (SD= .96); *p* = .001; Hedges' *g* = .34). In addition, patients experienced a better collaboration
 265 with physicians (Coll: *M*_{*t*0} = -.15 (SD= .98); *M*_{*t*2} = .11 (SD= 1.00); *p* = .05; Hedges' *g* = .26).

266 To examine potential influence of age, gender or education on the primary endpoint PICS_{PDM}, we
 267 performed a multiple regression analysis. Results indicated that apart from the intervention itself
 268 (*p* = .05), younger patients reported significantly higher levels of SDM (see table 3). Table 3 displays
 269 results of additional multiple regression analysis on the potential impact of age, gender and educational
 270 level on the secondary endpoints COLL and PrepDM.

271 **4. Discussion and Conclusion**

272 It had already been shown that the S2C program is feasible and can have positive effects on the SDM
 273 level right after full implementation: Immediately after the end of implementation, patients felt

274 significantly more involved and better informed and prepared for decision-making (Geiger et al.
275 2021b). At that time, the healthcare professionals were trained recently and the learning content was
276 fresh in their minds, the decision aids had been newly developed with a great deal of commitment from
277 physicians, and patient activation had just been set up. In short, SDM was on everyone's agenda.

278 This new study is the first exploring the sustainability of a full S2C implementation in a hospital. The
279 question was, how does the SDM level evolve months after the end of the initial implementation? Do
280 departments deliberately invest resources to maintain the implementation, and does the effect on
281 patient-reported SDM level and health literacy persist?

282 The results of this study show: Even 6-18 months after the end of the initial implementation of the S2C
283 intervention, i.e. 2.5-3 years after the first physician has been trained, the SDM level is still
284 significantly increased. Patients continue to perceive themselves as significantly more involved than
285 before the intervention as indicated coherently by two different SDM measures, PICS and
286 CollaboRATE. In addition, patients reported a higher health literacy while preparing for a decision. As
287 patients were recruited regardless of their diagnosis, from acute and aftercare, from inpatient and
288 outpatient care, in neurology and neurosurgery, these results seem exceptionally representative.

289 The sustained intervention effects can be attributed to at least two factors. On the one hand, it may be
290 assumed that the effects from the initial intervention in terms of skills and attitudes have persisted
291 among the healthcare professionals, and that they adhered to the procedures and pathways that were
292 adapted to allow for SDM. In line with Légaré et al. (2018), the comprehensiveness and intensity of a
293 multifaceted program like S2C in combination with the fact that nearly all departments at the hospital
294 in Kiel were transformed into SDM clinics simultaneously is supposed to have had enough impact to
295 stimulate a cultural change that is more robust than a rather superficial adoption of SDM-related
296 communication skills. On the other hand, the maintenance activity from the Neuromedical Center is
297 regarded as important to secure sustainability. Within every hospital, let alone a university hospital,
298 the turnover within the healthcare personnel requires constant introduction of new colleagues. The
299 decision by the departments to continuously invest resources into SDM training and education, updates
300 of decision aids etc. is both an important factor and a sign of appreciation of SDM. The intrinsic
301 motivation to maintain SDM is further illustrated by the activities within the departments that exceeded
302 the basic criteria required to renew the S2C certificate, such as ongoing scientific activity and public
303 communication in cooperation with the National Competency Center for Shared Decision Making as
304 well as the development of additional support models for patients regarding decision making.

305 Apart from the efforts within the hospital, an additional factor was established on the system level. In
306 collaboration with the largest health insurance company in Germany, the Techniker Krankenkasse
307 (TK), we managed to put in place a reimbursement scheme triggering an additional fee for every patient
308 case within a department that is awarded with the S2C certificate at University Hospital Schleswig-
309 Holstein. The motivation of the TK was to increase patient safety through enhancement of SDM, as it
310 is recommended by the WHO (World Health Organization 2021). The reimbursement partly covers
311 the costs for the professional SDM trainers, the updates of the decision aids etc. It is important to know
312 that currently the departments have no financial benefits from this reimbursement; on the contrary,
313 they invest own resources in terms of working hours of their staff. This corroborates their intrinsic
314 motivation to maintain SDM by continuation of the S2C program. The amount of time needed to
315 maintain SDM on a level that is sufficient for regular recertification is, however, much smaller than
316 during the initial implementation phase.

317 Some possible limitations of this study have to be discussed. Firstly, the question may arise whether
318 the results sustainability within two departments are sufficiently representative for the entire hospital.
319 On the one hand, the Neuromedical Center is a large-volume center within the hospital, with a broad
320 variety of diseases, treatments and patient characteristics. On the other hand, the S2C program has been
321 successfully implemented in 15 other departments at the University Hospital Schleswig-Holstein
322 simultaneously also using the standardized S2C approach (publications in preparation). There were no
323 cues indicating that the implementation process in the Neuromedical Center was considerably different
324 compared to the other departments. The reason the Neuromedical Center was chosen for examination
325 of sustainability is that it was the first entire center that had started and fully completed the intervention.
326 This allowed for the longest follow-up period during the overarching implementation project (Danner
327 et al. 2020). Hence, it seems justified to interpret the results as proof of the sustainability of the S2C
328 program in general. However, future results from other departments, and from other hospitals, should
329 be gathered to underscore this conclusion.

330 Secondly, data might be biased by self-selection of responding patients. However, response rates of
331 around 60% are to be viewed as comparably high indicating a rather low risk of selection bias. In
332 addition, neither physicians nor the study group had any influence on the selection of patients enrolled
333 in this study.

334 Thirdly, all outcome data on sustainability reflect the patients' point of view using PICS, PrepDM and
335 CollaboRATE as retrospective patient reported outcome instruments. It is indisputable, that the
336 patient's experience is of major importance, especially when other patient-related variables like e.g.
337 adherence are discussed. Nevertheless, the evaluation within other departments at the UKSH in Kiel
338 also includes observer-based analyses of videotaped consultations using MAPPIN'SDM (Kasper et al.
339 2012) and data on costs and quality of care as a result of the SDM implementation (Danner et al. 2020).
340 With those future findings available, it will be possible to further corroborate the conclusions drawn
341 from the current study.

342 Fourthly, data might also be biased by the occurrence of the Covid19 pandemic. While the pre-
343 intervention data (t_0) were collected during regular hospital operation, the long-term (t_2) data collection
344 took place from May 2021 on, immediately after a multi-week lockdown for the majority of the German
345 population. During this period, elective procedures and treatments were restricted or postponed, so that
346 the patient sample must be expected to be different from the pre-intervention sample. However, a
347 reduction of elective treatments at t_2 should result in a *lower* level of perceived SDM, not a higher one.
348 Therefore, the positive effect in this study can hardly be explained by the influence of the pandemic.
349 On the contrary, the pandemic in general made it even harder for all departments to adhere to the
350 intervention program. Nevertheless, in view of the major influence of the pandemic on all levels of
351 healthcare, post-pandemic replications of these findings are welcome.

352 Fifthly, in subsequent analyses of this study, we found a potential impact of age on both indicators of
353 the SDM level indicating a smaller long-term effect among older patients. However, the size of some
354 of the compared subgroups is very small. As such effects had not been found in previous data from the
355 same population (Geiger et al. 2021b), the slightly differential effect among the subgroups should be
356 interpreted cautiously until more long-term data are available.

357
358 In conclusion, this study is valuable as it provides long-term results from a hospital wide SDM
359 implementation effort. It shows that the comprehensive, multifaceted S2C program has significant
360 long-term effects on patient reported SDM and health literacy by inducing sustained intervention
361 effects and the willingness among health professionals to actively maintain the SDM implementation.
362 Future results from the ongoing S2C program in Kiel and in other hospitals will further broaden the
363 knowledge on the sustainability of the program.

364 **table 1. sample description**

	t ₀		t ₂		overall
	n	%	n	%	
number of patients	109		142		251
age					
Total responses	107		142		249
18-40 years	6	5.6%	17	12.0%	
41-60 years	40	37.4%	46	32.4%	
61-80 years	53	49.5%	69	48.6%	
over 80 years	8	7.5%	10	7.0%	
gender					
Total responses	99		126		225
female	45	45.5%	74	58.7%	
male	54	54.5%	52	41.3%	
education					
Total responses	102		140		242
Lower than secondary school certificate	38	37.3%	42	30.0%	
Secondary school certificate	32	31.3%	52	37.2%	
higher education entrance qualification	28	27.4%	44	31.4%	
other school qualification	4	4.0%	2	1.4%	

365 **table 2. endpoints before and after implementation (original and z-score standardized values)**

	original values				z-score standardized values					
	t ₀		t ₂		t ₀		t ₂		p	Hedges' g
	M	SD	M	SD	M	SD	M	SD		
PICS _{PDM}	2.65	.92	2.92	.85	-.19	1.04	.14	.95	.02	.33
COLL	3.15	1.29	3.59	1.26	-.15	.98	.11	1.00	.05	.26
PrepDM	3.63	1.12	3.92	1.16	-.20	1.00	.13	.96	.01	.34

367 **table 3. multiple linear regression analysis of the effect of time point of measurement, age, sex**
 368 **and educational level on the primary endpoint “patient participation in decision making”**
 369 **(PICS_{PDM}) and on secondary endpoints CollaboRATE and PrepDM**

	Dependent variables		
	PICS _{PDM}	COLL	PrepDM
	Regression coefficient (SD)	Regression coefficient (SD)	Regression coefficient (SD)
Time point of measurement			
baseline t ₀ (reference group)			
follow up t ₂	.29* (.14)	.26 (.14)	.39** (.15)
Age (years)			
18 – 40 (reference group)			
41 – 60	-.62* (.25)	-.61* (.25)	-.50 (.26)
over 60	-.62** (.24)	-.43 (.24)	-.38 (.25)
Sex			
Female (reference group)			
male	-.11 (.14)	-.14 (.14)	-.07 (.15)
Highest educational level attained			
Lower than secondary school certificate (reference group)			
Secondary school certificate	.09 (.17)	-.10 (.16)	-.10 (.18)
Higher education entrance qualification	-.05 (.17)	-.15 (.18)	-.22 (.18)
Regression constant	.44 (.26)	.42 (.27)	.26 (.28)
R²	.08	.06	.07
R² adj.	.05	.04	.04
n (t₀)	85	88	83
n (t₁)	112	115	110

370 * p < 0,05; ** p<0,01; **** p<0,001

371

372 1 Literaturverzeichnis

- 373 Bennett, Carol; Graham, Ian D.; Kristjansson, Elizabeth; Kearing, Stephen A.; Clay, Kate F.;
374 O'Connor, Annette M. (2010): Validation of a preparation for decision making scale. In: *Patient*
375 *education and counseling* 78 (1), S. 130–133. DOI: 10.1016/j.pec.2009.05.012.
- 376 Bieber, Christiane; Müller, Knut Georg; Blumenstiel, Klaus; Schneider, Antonius; Richter, Angelika;
377 Wilke, Stefanie et al. (2006): Long-term effects of a shared decision-making intervention on
378 physician-patient interaction and outcome in fibromyalgia. A qualitative and quantitative 1 year
379 follow-up of a randomized controlled trial. In: *Patient education and counseling* 63 (3), S. 357–366.
380 DOI: 10.1016/j.pec.2006.05.003.
- 381 Clayman, Marla L.; Bylund, Carma L.; Chewning, Betty; Makoul, Gregory (2016): The Impact of
382 Patient Participation in Health Decisions Within Medical Encounters: A Systematic Review. In:
383 *Medical decision making : an international journal of the Society for Medical Decision Making* 36
384 (4), S. 427–452. DOI: 10.1177/0272989X15613530.
- 385 Cohen, Jacob (1977): *Statistical Power Analysis for the Behavioral Sciences*: Routledge.
- 386 Coulter, A. (1999): Paternalism or partnership? Patients have grown up-and there's no going back. In:
387 *BMJ (Clinical research ed.)* 319 (7212), S. 719–720. DOI: 10.1136/bmj.319.7212.719.
- 388 Danner, Marion; Debrouwere, Marie; Rummer, Anne; Wehkamp, Kai; Rüffer, Jens Ulrich; Geiger,
389 Friedemann et al. (2022): A scattered landscape: assessment of the evidence base for 71 patient
390 decision aids developed in a hospital setting. In: *BMC medical informatics and decision making* 22
391 (1), S. 44. DOI: 10.1186/s12911-022-01777-x.
- 392 Danner, Marion; Geiger, Friedemann; Wehkamp, Kai; Rueffer, Jens Ulrich; Kuch, Christine;
393 Sundmacher, Leonie et al. (2020): Making shared decision-making (SDM) a reality: protocol of a
394 large-scale long-term SDM implementation programme at a Northern German University Hospital.
395 In: *BMJ open* 10 (10), e037575. DOI: 10.1136/bmjopen-2020-037575.
- 396 Davison, B. J.; Goldenberg, S. L. (2003): Decisional regret and quality of life after participating in
397 medical decision-making for early-stage prostate cancer. In: *BJU international* 91 (1), S. 14–17.
398 DOI: 10.1046/j.1464-410x.2003.04005.x.
- 399 Elwyn, Glyn; O'Connor, Annette; Stacey, Dawn; Volk, Robert; Edwards, Adrian; Coulter, Angela et
400 al. (2006): Developing a quality criteria framework for patient decision aids: online international
401 Delphi consensus process. In: *BMJ (Clinical research ed.)* 333 (7565), S. 417. DOI:
402 10.1136/bmj.38926.629329.AE.
- 403 Forcino, Rachel C.; Barr, Paul J.; O'Malley, A. James; Arend, Roger; Castaldo, Molly G.; Ozanne,
404 Elissa M. et al. (2018): Using CollaboRATE, a brief patient-reported measure of shared decision
405 making: Results from three clinical settings in the United States. In: *Health expectations : an*
406 *international journal of public participation in health care and health policy* 21 (1), S. 82–89. DOI:
407 10.1111/hex.12588.
- 408 Geiger, Friedemann; Hacke, Claudia; Potthoff, Judith; Scheibler, Fueloep; Rueffer, Jens Ulrich;
409 Kuch, Christine; Wehkamp, Kai (2021a): The effect of a scalable online training module for shared
410 decision making based on flawed video examples - a randomized controlled trial. In: *Patient*
411 *education and counseling* 104 (7), S. 1568–1574. DOI: 10.1016/j.pec.2020.11.033.
- 412 Geiger, Friedemann; Novelli, Anna; Berg, Daniela; Hacke, Claudia; Sundmacher, Leonie; Kopeleva,
413 Olga et al. (2021b): The Hospital-Wide Implementation of Shared Decision-Making–Initial Findings

- 414 of the Kiel SHARE TO CARE Program. In: *Deutsches Arzteblatt international* 118 (13), S. 225–226.
415 DOI: 10.3238/arztebl.m2021.0144.
- 416 Grabbe, Pia; Gschwendtner, Kathrin M.; Gaisser, Andrea; Kludt, Evelyn; Wild, Beate; Eich,
417 Wolfgang et al. (2022): Preferred and perceived participation roles of oncological patients in medical
418 decision-making: Results of a survey among users of the German Cancer Information Service. In:
419 *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*. DOI:
420 10.1016/j.zefq.2022.04.026.
- 421 Heesen, Christoph; Solari, Alessandra; Giordano, Andrea; Kasper, Jürgen; Köpke, Sascha (2011):
422 Decisions on multiple sclerosis immunotherapy: new treatment complexities urge patient
423 engagement. In: *Journal of the neurological sciences* 306 (1-2), S. 192–197. DOI:
424 10.1016/j.jns.2010.09.012.
- 425 Holmes-Rovner, Margaret (2007): International Patient Decision Aid Standards (IPDAS): beyond
426 decision aids to usual design of patient education materials. In: *Health expectations : an international*
427 *journal of public participation in health care and health policy* 10 (2), S. 103–107. DOI:
428 10.1111/j.1369-7625.2007.00445.x.
- 429 Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (2017): Allgemeine Methoden
430 (Version 5.0). Köln. Online verfügbar unter [https://www.iqwig.de/papierkorb/general-](https://www.iqwig.de/papierkorb/general-methods_version-5-0_alt.pdf?rev=194835)
431 [methods_version-5-0_alt.pdf?rev=194835](https://www.iqwig.de/papierkorb/general-methods_version-5-0_alt.pdf?rev=194835), zuletzt geprüft am 24.08.2021.
- 432 Kasper, Jürgen; Hoffmann, Frauke; Heesen, Christoph; Köpke, Sascha; Geiger, Friedemann (2012):
433 MAPPIN´SDM - The Multifocal Approach to Sharing in Shared Decision Making. In: *PLoS ONE*
434 (7(4):e34849.). DOI: 10.1371/journal.pone.0034849.
- 435 Légaré, France; Adekpedjou, Rhéda; Stacey, Dawn; Turcotte, Stéphane; Kryworuchko, Jennifer;
436 Graham, Ian D.; Lyddiatt, Anne (2018): Interventions for increasing the use of shared decision
437 making by (7).
- 438 Lerman, C. E.; Brody, D. S.; Caputo, G. C.; Smith, D. G.; Lazaro, C. G.; Wolfson, H. G. (1990):
439 Patients' Perceived Involvement in Care Scale: relationship to attitudes about illness and medical
440 care. In: *Journal of general internal medicine* 5 (1), S. 29–33. DOI: 10.1007/BF02602306.
- 441 Lühnen, J.; Albrecht, M.; Mühlhauser, I.; Steckelberg, A. (2017): Leitlinie evidenzbasierte
442 Gesundheitsinformation. Hamburg. Online verfügbar unter
443 <http://www.leitliniegesundheitsinformation.de/>, zuletzt geprüft am 24.08.2021.
- 444 Martínez-González, Nahara Anani; Plate, Andreas; Markun, Stefan; Senn, Oliver; Rosemann,
445 Thomas; Neuner-Jehle, Stefan (2019): Shared decision making for men facing prostate cancer
446 treatment: a systematic review of randomized controlled trials. In: *Patient preference and adherence*
447 13, S. 1153–1174. DOI: 10.2147/PPA.S202034.
- 448 Oterhals, Kjersti; Hanestad, Berit R.; Eide, Geir E.; Hanssen, Tove A. (2006): The relationship
449 between in-hospital information and patient satisfaction after acute myocardial infarction. In:
450 *European journal of cardiovascular nursing* 5 (4), S. 303–310. DOI: 10.1016/j.ejcnurse.2006.01.004.
- 451 Richter, M.; Schmid-Ott, G.; Leicht, R.; Muthny, F. A. (2011): Wahrgenommene
452 Informationsvermittlung und Partizipation von Patienten in der kardiologischen Rehabilitation –
453 Ausprägung und Zusammenhänge mit Reha-Outcome und Selbstwirksamkeit. In: *Physikalische*
454 *Medizin Rehabilitationsmedizin Kurortmedizin* (21), S. 126–130. DOI: 10.1055/s-0031-1277143.
- 455 Scheibler, Fülöp; Pfaff, Holger; Kowalski, Christoph; Ansmann, Lena (2019): Shared Decision
456 Making in Brustzentren in NRW: Ergebnisse einer 10-Jahres-Trendanalyse. In: *Zeitschrift für*

- 457 *Evidenz, Fortbildung und Qualität im Gesundheitswesen* 147-148, S. 97–102. DOI:
458 10.1016/j.zefq.2019.09.003.
- 459 Scheibler Fülöp; Freise D.; Pfaff H. (2004): Die Einbeziehung von Patienten in die Behandlung -
460 Validierung der deutschen PICS Skalen. In: *Patient education and counseling* (12), S. 199–209.
- 461 Shepherd, Heather L.; Barratt, Alexandra; Jones, Anna; Bateson, Deborah; Carey, Karen; Trevena,
462 Lyndal J. et al. (2016): Can consumers learn to ask three questions to improve shared decision
463 making? A feasibility study of the ASK (AskShareKnow) Patient-Clinician Communication
464 Model® intervention in a primary health-care setting. In: *Health expectations : an international*
465 *journal of public participation in health care and health policy* 19 (5), S. 1160–1168. DOI:
466 10.1111/hex.12409.
- 467 Stacey, Dawn; Volk, Robert J. (2021): The International Patient Decision Aid Standards (IPDAS)
468 Collaboration: Evidence Update 2.0. In: *Medical decision making : an international journal of the*
469 *Society for Medical Decision Making* 41 (7), S. 729–733. DOI: 10.1177/0272989X2111035681.
- 470 Stiggelbout, A. M.; van der Weijden, T.; Wit, M. P. T. de; Frosch, D.; Légaré, F.; Montori, V. M. et
471 al. (2012): Shared decision making: really putting patients at the centre of healthcare. In: *BMJ*
472 *(Clinical research ed.)* 344, e256. DOI: 10.1136/bmj.e256.
- 473 Tapp, Hazel; Kuhn, Lindsay; Alkhazraji, Thamara; Steuerwald, Mark; Ludden, Tom; Wilson, Sandra
474 et al. (2014): Adapting community based participatory research (CBPR) methods to the
475 implementation of an asthma shared decision making intervention in ambulatory practices. In: *The*
476 *Journal of asthma : official journal of the Association for the Care of Asthma* 51 (4), S. 380–390.
477 DOI: 10.3109/02770903.2013.876430.
- 478 Timmins, Fiona; Kaliszer, Michael (2003): Information needs of myocardial infarction patients. In:
479 *European journal of cardiovascular nursing* 2 (1), S. 57–65. DOI: 10.1016/S1474-5151(02)00089-0.
- 480 Whittle, Jeff; Conigliaro, Joseph; Good, Chester B.; Kelley, Mary E.; Skanderson, Melissa (2007):
481 Understanding of the benefits of coronary revascularization procedures among patients who are
482 offered such procedures. In: *American heart journal* 154 (4), S. 662–668. DOI:
483 10.1016/j.ahj.2007.04.065.
- 484 World Health Organization (2021): Global patient safety action plan 2021–2030: towards eliminating
485 avoidable harm in health care. Geneva: Online available at
486 <https://apps.who.int/iris/rest/bitstreams/1360307/retrieve>.
- 487