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# Making Shared Decision Making (SDM) a Reality: protocol of a full SDM implementation program at a Northern German University Hospital



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# TITLE PAGE

**Making Shared Decision Making (SDM) a Reality: protocol of a full SDM implementation program at a Northern German University Hospital**

**Running title**: Protocol of a full SDM implementation program

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# ABSTRACT

**Introduction:** Shared Decision Making (SDM) is not yet the standard way to make decisions in German hospitals. Making SDM a reality is a complex task. It involves training health care professionals in SDM communication and enabling patients to actively participate in communication, in addition to providing sound, easy to understand information on treatment alternatives in the form of evidence-based patient decision aids (EbPDAs). SDM needs to be designed together with relevant stakeholders to make implementation a simultaneous reality. This project funded by the German Innovation Fund aims at designing, implementing, and evaluating a multicomponent, large-scale and integrative SDM program - called SHARE TO CARE (S2C) - at all departments of a University Hospital Campus in Northern Germany within a 4 year time period.

**Methods and Analysis:** S2C tackles the above mentioned components of SDM at a time: (1) training clinicians in SDM communication (2) activating and empowering patients (3) developing EbPDAs in the most common/relevant diseases, and (4) training health care professionals in SDM coaching. S2C is designed together with patients and providers. The clinician training program is based on an online and a brief in situ training module. The decision coach training is based on a similar but less comprehensive approach. The development of online EbPDAs follows the International Patient Decision Aid Standards (IPDAS) and includes written, graphical and video-based information. Validated outcomes of SDM implementation are measured in a pre-post-intervention evaluation design. Health economic impact of the intervention is investigated using a propensity-score approach based on SDM-sensitive hospital cases.

**Ethics and Dissemination:** Ethics committee review approval has been obtained from Medical Ethics Committee of the Medical Faculty of the Christian Albrecht University (CAU) Kiel. Project information and results will be disseminated at conferences, on project-hosted websites at UKSH and by S2C and in peer-reviewed and professional journals.

**KEYWORDS (max. 6):** Shared Decision Making (SDM), SDM training, Evidence-based Patient Decision Aid (EbPDA), patient activation, decision coaching

## STRENGTHS AND LIMITATIONS

- This study is the first full implementation of SDM in an entire University Hospital setting involving all stakeholders in patient care at a time.
- This study aims to make any patient encounter at the UKSH a better, more informed and more appreciating experience to patients and their clinicians.
- Project implementation is based on sound strategies and highly professional EbPDA development, training and implementation teams, but implementation barriers are nevertheless expected to be manifold in a busy and primarily profit-oriented hospital setting.
- A clear limitation of the study is that clinicians' and patients' contribution is not mandatory and there is no financial remuneration planned for their contribution.
- A clear advantage, however, is that patients are involved at several stages of the project and it is known from previous research that involving patients makes interventions more feasible and improves their quality.
- It might be initially very difficult to convince clinicians of how they will profit from more SDM in daily patient communication.

# INTRODUCTION

Shared Decision Making (SDM) between clinician and patient is currently no standard in German hospitals. (1, 2) SDM has rather been implemented sporadically in individual indications and health care settings. (3, 4) This lack of SDM in routine settings might be due to a range of provider, patient, organizational, economic, and/or contextual factors. (1, 2, 5) On the other hand, German legislation with the Patients' Rights Act in 2013 gave SDM and the patient a more prominent role in German health care. (6) The act implies that clinicians and patients follow SDM communication rules in preference-sensitive treatment situations. For example, clinicians have to comprehensively inform their patients about relevant treatment alternatives (§630e). (6) In this context, the law also points out that written material like patient decision aids might support the clinician in meeting these legal requirements. While legislation in Germany therefore seems to be ready for SDM and supporting instruments such as evidence-based Patient Decision Aids (EbPDAs), daily practice is not or not yet routinely implementing it.

For SDM to be effective, the patients' and the health care providers' ability and willingness to participate in SDM are crucial. (2, 7) To make SDM a reality in any health care setting is an ambitious endeavor and a complex multi-level task. (5) It involves training clinicians and other health care staff in SDM communication skills as well as enabling and motivating patients to actively participate in communication, in addition to providing evidence-based, easy to understand information on treatment alternatives to patients and their doctors. (8) To be effective in daily practice, SDM also should be co-designed with all involved stakeholders to gain acceptance and recognition. (3) It needs an inner (i.e., within the institution that wants to do SDM) and an outer (concerning the external conditions in which the institution works) setting, in which program implementation is possible – as defined e.g. by the Consolidated Framework for Implementation Research (CFIR). (9) The Norwegian approach (DA factory of the University Hospital North Norway), in which researchers and developers of SDM components – so-called "knowledge producers" - work in close cooperation with the clinicians and patients – so-called "knowledge users" – strongly inspired implementation processes in this project. (10)

Individual components of SDM such as SDM training for health care professionals, complex patient activation/empowerment programs or decision aids have all been previously tested in specific indications, populations and using different study designs. (11-15) For each component, effectiveness and impact on decision processes have been assessed. For example, according to a recent systematic review of 115 RCT with about 35.000 patients altogether, the use of only EbPDAs to inform patients in specific indications led to improved health education/literacy, more active participation and value congruent choices, more accurate expectations regarding course of disease and risk perceptions, more treatment satisfaction and better adherence to treatment. (14) This finding has been reinforced by reviews in other specific populations. (16) However, most of the EbPDAs previously tested in RCTs are not subsequently used in the settings they were developed in. (3) A recent study therefore concluded that "To improve subsequent use, researchers should codesign EbPDAs with end users to ensure fit with clinical practice and develop an implementation plan". (3) In this study, the lack of clinicians supporting and agreeing with the DAs hindered successful implementation. Training clinicians in SDM in theory and practice has equally demonstrated to be effective in some settings and to some degree, but the certainty of this evidence is low and limited to specific treatment settings. (15, 17-19) While there may still be a lack of evidence regarding the effectiveness of SDM on patient-relevant clinical endpoints, there is growing agreement and consensus that SDM is a necessity, a patients' and a citizen's right, and an ethical imperative. (7)

While individual SDM components might be effective to a more or lesser degree, it has become clear that effectiveness to a large extent will depend on effective implementation strategies and consistent stakeholder involvement. (3, 5) No program until now has addressed the simultaneous implementation of a range of SDM components at the same time. Therefore, in this publicly funded project the objective was to design, implement and evaluate a multicomponent, large-scale and integrative SDM program - called SHARE TO CARE (S2C) - at the University Hospital Medical Center Schleswig Holstein (UKSH), Campus Kiel, within a 4 year time period - from October 2017 until September 30, 2021. The project is

designed and implemented in cooperation between the UKSH, Kiel, Germany, and the University Hospital of Northern Norway, Tromsø, Norway.

# METHODS AND ANALYSIS

## Study design

This study implies the full implementation of SDM at the University Hospital Campus Kiel within a 4 year time period based on the S2C intervention program. It also implies a comprehensive evaluation, which will include (1) measuring the SDM level based on patients' and external observers' perceptions before and after S2C implementation and (2) measuring the impact of the S2C intervention on health care use and costs in comparison to a propensity-score matched comparison population not exposed to S2C.

The term "multicomponent" in the S2C program refers to four different interventions (components) designed and implemented simultaneously in individual clinics. This includes SDM training for clinicians, SDM qualification as "decision coach" for other health care staff like nurses or physiotherapists, a program that aims at patient activation and empowerment, and development of online EbPDAs. These components and the respective S2C project teams are depicted in Figure 1.

*Insert here:* Figure 1

The term "large-scale" means that the program will sequentially be implemented at the UKSH Campus in Kiel involving all 27 clinics with more than 650 clinicians. 83 EbPDAs will be developed - contacting new clinics every 6 months and identifying between one and eight EbPDA topics at each clinic in collaboration with the clinicians (Figure 2). At the same time, each clinician in the respective clinic has to undergo SDM training. A clinic-based patient activation program is implemented simultaneously. In addition, in selected clinics up to 150 decision coaches will be trained to facilitate EbPDA use in specific patient target groups.

*Insert here:* Figure 2

The term "integrative" in S2C means that from the very beginning, patients and clinicians will be actively involved in the decision aid structure and content generation inspired by the DA factory approach (10). The integrative approach begins with identifying new topics together with the clinicians as well as doing needs assessments with patients for each EbPDA topic. It follows through the program and ends with having clinicians do the final review and distribution of the decision aids in their clinic. Sample patients will also user-test the EbPDAs before being used in daily practice.

**Patient and Public Involvement**

No patient was involved in the development or design of this study.

**Theoretical Framework**

The S2C program is designed and implemented on the grounds of the Theory of Planned Behavior suggesting behavior is a result of motivation (intention) and ability (perceived behavior control) (20, 21). The S2C program accordingly aims to induce attitude and perception-changes by training clinicians and other health care providers in SDM and by informing patients to enable simultaneous behavior change at the level of patients and health care providers at UKSH. The implementation of the S2C program and respective evaluation strategies are guided by the concept of Normalization Process Theory (NPT). The four components of the NPT are coherence (does the program make sense to those who are involved?), participation (how do relevant stakeholders participate in implementation?), collective action (what to do to make implementation successful?) and reflexive monitoring (how do the involved individuals judge implementation processes?). (22) As part of a complementary formative evaluation, these questions/constructs will be addressed with key stakeholders at specific points in time throughout the 4 year project time to continuously monitor implementation processes.

The complexity of this project is documented using the implementation criteria of the Consolidated Framework for Implementation Research (CFIR) (https://cfirguide.org/). This framework comprises five domains (intervention characteristics, outer setting, inner setting, characteristics of individuals, and

process) and 39 related constructs. (9, 29, 30) CFIR helped to better structure planning and implementation needs in the early stages of project development. An outline of the program and its components was transferred into a CFIR format and is provided in Table 1. CFIR provides constructs that are used to address the five domains of each intervention included in the implementation program: its characteristics, the outer setting of the intervention, the inner setting if the institution that hosts the program, characteristics of individuals involved in each intervention and processes related to the interventions.

*Insert somewhere here:* Table 1.

**Setting and Study population**

Campus Kiel as part of the UKSH Medical Center is a tertiary care hospital with more than 200.000 cases each year. 27 clinics with more than 650 clinicians and more than 150 decision coaches in other professions will be part of either training modules or development and use of decision aids or both. Health professionals will be sequentially enrolled in the study each time new clinics are started, which happens in 6 month cycles (Figure 2). Since clinicians are requested to get involved in DA topic generation, there will be one responsible SDM clinician coordinating SDM activities in the clinic and one to three clinicians will be responsible for each selected topic.

**S2C Intervention components**

*Intervention "SDM training for clinicians"*

This module aims to provide structured SDM training in three steps to a minimum of 80 % of clinicians working at the UKSH (i.e., at least 500 clinicians should receive training). The module is based on a pretested and validated training approach that has previously been demonstrated to be effective and lead to an increased patient, clinician and observer perception of involvement in decision making. (17, 18) Preceding training sessions, each clinician has to first take a baseline video of him or herself in a typical patient-clinician decision making interaction. The clinicians then undergo an online video tutorial which

contains general information on SDM and its application in clinical practice. It also contains fictional interactions between clinician and patient actors teaching clinicians to differentiate "good" from "bad" SDM communication. For the subsequent video-based small group training sessions, the baseline videotape and a second videotape of a patient-physician interaction (following online training) are rated by the S2C trainer team for their SDM suitability using an SDM evaluation criteria catalogue. In subsequent group discussion each clinician receives video-based trainer and group feedback. The aim of the group sessions is to provide an interactive and common SDM learning experience. To increase clinicians' motivation to participate in training sessions, their participation is rewarded by continued medical education credits by the German Medical Associations.

*Intervention "Activation of patients"*

The "Ask 3 questions" program has originally been developed and tested in Australia. (31, 32) The patients are instructed and motivated to actively participate in communication by asking their doctors questions regarding the specific treatment situation. This concept is the basis for activation of patients in the S2C project communicating the message "Ask three questions - decide together" using various distribution channels: paper postcards, posters/stand-up displays at the clinics, screen-based messages inside UKSH. It will be embedded in several other interventions, like a patient homepage within the UKSH-homepage, information screens and special SDM-days in the central lobby, a bedside infotainment system and other awareness interventions.

*Intervention "(Online) Evidence-Based Patient Decision Aids (EbPDAs)"*

83 Online EbPDAs will be developed in all clinics at UKSH within the four year project time. Inspired by the DA factory approach, implementation starts with the identification of topics for EbPDAs together with clinicians. Relevant topics should be important for clinicians, involve at least two preference-sensitive treatment alternatives and ideally occur frequently. Each topic is then specified by defining the target population for the EbPDA (in-/exclusion criteria), the relevant treatment options, and potential

outcomes of each treatment. Topic specification is done based on preliminary searches of the literature, review of national and international guidelines, and in continuous exchange with the responsible clinician(s). Once a topic is specified, needs assessments are done with about 4-8 patients per topic to gather information on sensitive disease-, treatment- or outcome-related issues. This information is used to guide and structure DAs and to develop patient questions that are answered as part of the EbPDA. Development of EbPDAs involves a systematic search and assessment of best available evidence for all relevant interventions, focusing on systematic reviews and evidence-based clinical practice guidelines. The methods are based on the German standards of evidence-based patient information and the methods of evidence generation in patient information. (33, 34) Text information on the disease and the pros and cons of treatment will be accompanied by video sequences that are done with UKSH clinicians and patients. In these sequences clinicians will explain treatments and patients will share their experience in decision making with other patients. The latter is to motivate users of the online DAs to actively participate in decision-making. To avoid bias by testimonials, patients do not rate the different interventions in their video sequences but limit themselves to talking about their experience with the disease and their individual decision process. The entire process of DA development follows the International Patient Decision Aids Standards (IPDAS) criteria (www.ipdas.ohri.ca (26, 27)) and will undergo external review.

*Intervention "Qualification of Decision coaches"*

This qualification module provides SDM training to about 150 nurses or other health care professionals in specific preference-sensitive indications, where patients most likely will need support in using EbPDAs. Training principles are based on previous research and decision coaching application in specific settings. (12, 13, 24, 35) The goal is to train health care staff like nurses or physiotherapists to act as "decision coaches" for their patients when using EbPDAs, i.e., to simultaneously provide emotional, psychological and technical support. The qualification consists of two workshop days communicating the principles of SDM and EbPDAs and including two individual decision coaching sessions for each participant. As for

the clinician training, each decision coach will be asked to videotape a coaching communication with a patient twice and each time will receive individual SDM trainer feedback.

**Study Outcomes**

To cover different perspectives, one primary outcome providing the patient perspective and one providing an observer-based perspective on the S2C intervention effect will be assessed. The first is based on a validated SDM measurement instrument, the Patient Involvement in Care Scales (PICS). (36, 37) It is a patient-reported outcome instrument and consists of three subscales. The subscales are (1) patient activation by doctors, (2) active information seeking behavior and (3) perceived patient participation in decision making. Each item is measured on a scale from 1 = „do not agree at all“ to 4 = „totally agree”.

The second primary outcome consists in an observer rating of patient-clinician interaction before and after intervention, using the MAPPIN'SDM-O-dyad instrument. (17, 18, 23) MAPPIN'SDM-O-dyad measures the degree of SDM performance realized by the doctor-patient dyad (i.e., by the unit made up of patient and clinician) as rated by independent observers. The instrument consists of 9 items assessing the process and quality of SDM. Each item is scored from "0" ("the indicator is not present") to "4" ("the indicator is present at an excellent standard"). The observer ratings are provided by independent but trained raters who rate videotapes of patient-clinician-interactions before and after the intervention (see data collection). All observers are blinded to the measurement objects and time points of video recordings.

Additional secondary outcomes assessing patient-clinician-interaction from the patient perspective are based on two validated and widely-used questionnaires, the Preparation for Decision Making Scale (PrepDM: 10 items; 5-point scale) (38) and collaboRATE (39) (3 items; 5-point scale). All patient-reported outcome instruments will be administered to patients at the scheduled points in time within a combined patient questionnaire.

**Data collection and analysis plan**

The first part consists of a pre-post data collection within UKSH assessing SDM implementation from the patient (PICS/patient questionnaire assessements) and the observer perspective (MAPPIN'SDM-O-dyad assessments). The second part consists of a health economic evaluation comparing UKSH patient data following the S2C intervention to a propensity-score matched insurance-based comparison group regarding use of specific health care services and costs. A complementary formative evaluation of implementation processes within UKSH using structured qualitative interviewing techniques is planned.

The data collection and evaluation schedule is depicted in Figure 3.

*Insert here:* Figure 3

**Patient-based S2C evaluation**

Patient questionnaires are administered to patients at three points in time throughout the 4 year study period. The first measurement ($T_0$) is scheduled at study initiation and is based on the entire UKSH campus population. The second measurement ($T_1$) is taken after completion of the S2C intervention at each individual clinic to assess immediate intervention effect. The intervention is considered complete at the clinic level when at least 80% of clinicians have undergone training, clinic-specific EbPDAs are developed and in use, and the patient activation program is in place. The last campus-level measurement ($T_2$) is scheduled at study completion. It aims to appraise the sustainability of the S2C intervention.

The patient questionnaire is mailed to 1600 randomly selected patients that were hospitalized within the preceding weeks at each of the three measurement time points with a return envelope included in each mailing. Patients who do not return the questionnaire within a 2 or 4 week time frame, respectively, will get a reminder either once or twice. Using this procedure based on the Total Design Method approach by Dillmann et al. (40)., final response rates of at least 60% are expected.

It is hypothesized that the measured pre-post intervention effect, i.e., the mean difference in PICS patient involvement scale score, is significant (with $\alpha$=0.05) and relevant (considered relevant if Hedges g > 0.5 – which is considered a medium size effect). If the distribution doesn't allow the assumption of normality, appropriate non-parametric tests will be applied in the data anlaysis.

**Observer based SDM (S2C) evaluation**

The observer assessment via MAPPIN'SDM-O-dyad is performed twice throughout the 4 year study period. It is once performed directly before the intervention and once following completion of the intervention in each clinic as defined above. To minimize workload for UKSH clinicians, who have to videotape encounters with patients to facilitate the MAPPIN'SDM-O-dyad evaluation, these assessments will be limited to specific clinical entities. Clinical entities will include surgery, internal medicine, radiotherapy, oncology, orthopedics, and gynecology.

It is hypothesized that in 80% of patient-clinician-interactions patients will receive satisfactory SDM treatment at the second clinic-wide measurement ($T_1$). To answer the latter study hypothesis, a Mappin-SDM-O-dyad mean value of greater or equal to 1.5 was defined as satisfactory basic patient involvement in decision making based on previous validation research. (18)

**Sample size calculation**

Sample size calculation for the patient-based primary outcome is based on previously published PICS data. (37, 41) An assumed difference of 0.4 in the PICS outcome at $T_1$ vs. $T_0$ and an assumed standard deviation of 0.7 yields a sample size of about 40 for each group/clinic at each measurement (assuming a power of 80% and a level of significance of 5%, (one-sided, assuming positive effect). A presumed response rate of 60% to the patient questionnaire mailings leads us to target about 1600 patients at each measurement point (T0, T1, T2) to finally have at least about 950 to 1000 patient questionnaires returned, yielding on average between 30-60 returned questionnaires per clinic. These numbers will allow to measure significant differences in the primary endpoint not only at the campus but also at the individual

clinic level (at least in the larger clinics). For the primary observer-based outcome (Mappin'SDM) no sample size calculation is needed since no changes in effect are measured. Instead, our objective is to reach a satisfying level of SDM in more than 80% of patients undergoing evaluation. Sample size is given by number of clinicians at each involved clinic, and will be 200 to 240 in total. This includes general surgery (n=34 clinicians), internal medicine (n=62), radiotherapy (n=16), oncology (n=21), orthopedics (n=27), gynecology (N=34), and urology (N=13).

**Health Economic Evaluation**

In addition to the pre-post SDM evaluation, an economic evaluation will be conducted. This analysis will be based on insurance claims data provided by the largest German Health Insurance provider (Techniker Krankenkasse (TK)). In Germany, approximately 86 % of the population is covered under the comprehensive statutory health insurance system. The TK provides health insurance for approximately 9.8 million people and routinely collects data for reimbursement purposes on hospital stays, clinician visits, medical procedures, medication and medical diagnoses. In the economic evaluation, incremental costs and use of specific services of patients admitted to the UKSH with preference-sensitive conditions (intervention group) will be compared to a matched population (control group) drawn from the administrative dataset from the TK. The control group includes patients with a hospital admission to another German University or Educational hospital. From this sample population, patients will be matched to the intervention group using exact matching, propensity score matching or a combination of exact and propensity score matching. (42, 43) Matching criteria will include patient characteristics like age and sex, the main diagnosis of the hospital admission as well as measures of morbidity within 12 months preceding hospital admission. In line with previous research (28), variables that are compared across groups include preference-sensitive surgery rates, imaging rates, inpatient costs, total medical costs and hospital and emergency department admissions within 12 months after the admission to the hospital. To account for systematic differences between intervention and control group, the analysis will focus on the comparison of the difference in outcomes measured at two points in time, before and after the

implementation of the SDM intervention. The analysis will be limited to about 10 to 15 frequently occurring and preference-sensitive conditions. These conditions will include but are not limited to cardiologic diseases, benign prostatic hyperplasia and other urologic diseases, benign uterine diseases and obstetrics, neurosurgery / back pain, and orthopaedic diseases such as knee or hip replacement.

**Complementary Formative Assessment**

Complementary assessment of the implementation processes will be based on the NPT theory. In specific, the NoMAD construct based on NPT will guide us in the design of respective formative qualitative assessment elements. (44-46)

**Implementation**

The intervention implementation strategy is based on the theoretical constructs of PBT and NPT as well as inspired by the Norwegian DA factory concept. It aims to produce a strong identification of the users with the final SDM products by engaging them early on in the development and application of interventions. A professional implementation team consisting of clinicians from UKSH, psychologists and health scientists will engage in activities to promote S2C in the clinic as wells as to support and monitor implementation progress (eg. scheduling and reminding clinicians of training appoinments, using Scorecards to document project progress, providing regular feedback to clinicians on DA development and use). The NPT construct is used to instruments assessing implementation progress throughout the project. The CFIR is used to consistently follow-up on and document implementation in a structured way (Table 1).

# ETHICS AND DISSEMINATION

The Medical Ethics Committee of the Medical Faculty of the Christian Albrecht University (CAU) Kiel has provided ethics approval to this study (reference number A111/18). This study will be conducted in accordance with German laws and regulations of the Medical Ethics Committee of the CAU, Kiel, Germany. Eligible patients or health care providers will be fully informed about the study and asked to

participate in each part of the study: conducting personal interviews with patients (needs assessment), or video sequences with clinicians/patients, or involving clinicians in training sessions. Patients/providers will receive a respective information letter and will be informed about the implications of participation. They will have sufficient opportunity to ask questions and to consider the implications of the study before deciding to participate. Before participation, all individuals will provide written informed consent, compliant with the local and ethical data regulations. Patients will be allowed to withdraw from the study without giving a reason, at any time. The results arising from this implementation study will be presented at scientific meetings, on project-hosted websites at UKSH and by S2C, and published in peer-reviewed journals. There is no intention to use professional writers and authorship will be based on the International Committee of Medical Journal Editors Guidelines.

Table 1. Consolidated Framework for Implementation Research (CFIR), S2C project-specific information

| Construct | | Evidence-based Decision Aids* | SDM Training for clinicians / Training program for "decision coaching/decision coaches"* |
|---|---|---|---|
| **I. INTERVENTION CHARACTERISTICS** | | | |
| A | Intervention Source | Online Evidence-based Patient Decision Aids (EbPDAs) are developed internally by the S2C project team. Topics for new EbPDAs are generated together with the clinicians at UKSH since the project is based on the principle that developers of EbPDAs (the S2C-team) work closely together with knowledge users, i.e., patients and clinicians. Patients are involved early on via needs assessments to inform EbPDA development. Evidence syntheses are conducted by well-known best-in class external consultant groups, namely EBSCO (producers of the DynaMed point in care services, well-known to UKSH clinicians) and Kleijnen Systematic Reviews (KSR). | The training program for clinicians was previously developed and validated by members of the S2C team (17, 18, 23).<br>The training program for „decision coaching" is developed internally and specifically for the project by the S2C trainer team based on existing decision coaching programs (24, 25) and experience from the clinician training.<br>With a group of trained and experienced psychologists/coaching specialists, the trainer team combines scientific and practical expertise to excellently prepare different types of health care providers in SDM communication skills and in coaching patients in how to use EbPDAs. |
| B | Evidence Strength & Quality | A current systematic review demonstrates that decision aids improve decision and indication quality (14). Our EbPDAs follow the International Patient Decision Aids Standards (IPDAS) (26, 27) and provide balanced and easy to understand information on the pros and cons of treatment alternatives to patients. With the Patients' Rights Law in place in Germany since 2013, the S2C project with its EbPDAs also puts the patients' right for balanced information into practice. | The training program for clinicians was developed and validated by Geiger and Kasper et al. (17, 18, 23). This program guided the development of a new training program as decision coaches for other health care staff. Further evidence supported the refinement and adaptation of the coaching program to meet the specific demands in difficult indications/target populations in a hospital setting (24, 25). |
| C | Relative Advantage | The format of online EbPDAs with components like easy to understand written/graphical information, videos with patient narratives, and videos with clinicians from the UKSH explaining disease or treatment concept are likely attractive to patients and clinicians. While clinicians are involved in development and invest time into it, EbPDAs will facilitate better informed dialogue with patients. By providing more structure to the dialogue between patient and clinician, EbPDAs are expected to make communication more efficient (28). | The online SDM training is a relatively quick and easy-to-do training program teaching SDM basics to clinicians. The video-feed-back based training is highly individualized and based on concrete patient-clinician communication allowing a thorough SDM learning experience. The training of decision coaches focuses on providing support with EbPDA use to patients. This may be helpful if patients are emotionally or physically not able to effectively use EbPDAs without support, e.g. elderly or if patients are emotionally or phsycologically impaired. |

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| D | Adaptability | The format of the EbPDAs follows a standard structure. However, this structure is flexible enough to allow for topic- or clinic-specific adaptations. Each decision aid will contain a printable summary sheet on all relevant aspects of alternatives (Questions & Answers-Sheet). This paper-based version can be used in communication with patients not willing or able to use the online EbPDAs. | Training units are flexible and adaptable to specific demands. The online training can be easily integrated into a busy clinician schedule. If clinicians do not want to do personal training in a group setting, it can be done with clinicians individually. If health care providers are not willing to video-tape interactions with their patients, trainers may offer participating observation instead and rate "live" patient-physician interactions. |
| E | Trialability | In each clinic, few EbPDAs will be initially developed. If a clinic is then willing and interested to support further topics, additional EbPDAs may be developed upon demand. If a clinic is rather unwilling to support the project, no pressure will be exerted but the clinic will be invited to rejoin EbPDA development at a later point in time. Also, since the clinics are approached in a stepwise approach, learnings from one clinic might be transferred to upcoming clinics. | It is not an imperative for UKSH staff to undergo SDM training sessions, but clinic directors are asked to motivate their staff to take part in these. Also, clinic directors are asked to make sure that training sessions can be done within working hours.<br>As for the EbPDAs: if a clinic is unwilling to support the project at a specific point in time or to provide the time to their clinicians to undergo training, no further pressure will be exerted. In selected instances, SDM training might remain limited to online sessions. |
| F | Complexity | Patients will have to invest at least 30-40 minutes to go through one EbPDA. This might be tiring to some patients. The patient-friendly and flexible format of EbPDAs addresses this issue in parts. The "Infotainment"-system at UKSH and the availability of portable notebooks will make access to EbPDAs easy for patients in the hospital.<br>Clinicians will have to invest time for EbPDAs. They might not in the first place realize that EbPDAs can support them and help save time in patient communication. Also, the clinics/clinicians will have to integrate the EbPDAs into patient pathways. This might not always be easy in a busy hospital setting and make pathway adaptations necessary. | Training sessions for clinicians and decision coaches are time-consuming, between 1-2 full days for clinicians and for those who undergo training as decision coaches.<br>This time needs to provided by clinic directors but it might still be difficult to integrate training sessions into a busy clinic schedule. Health care staff might refuse videotaping themselves in patient interaction for various reasons (e.g., worries about an external rating of their performance).<br>Even for well trained clinicians or decision coaches, it might sometimes be difficult to integrate SDM and decision coaching into patient pathways and adaptations of treatment pathways might be needed. |
| G | Design Quality & Packaging | The EbPDA is developed by a highly professional S2C team of medical writers working according to the standards of evidence-based patient information and a professional film team with wide experience in patient filming. Evidence syntheses are done by best-in class external consultants together with the S2C evidence team. All EbPDAs strictly adhere to the IPDAS criteria (26, 27). | All training sessions were developed and are conducted by a group of trained and experienced psychologists/ coaches.<br>The online-training was developed and realized by the S2C trainer team in cooperation with the S2C film time and didactic support from external consultants. All training evaluations strictly adhere to the rating criteria of the Mapping-SDM questionnaire (18, 23) |

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| H | Cost | Costs of the intervention and costs associated with implementation are covered by a grant of the German Innovation Fonds (IF). The IF is hosted by the German Federal Joint Committee. Opportunity costs will occur since patients and clinicians have to invest time in decision aid production and/or use. Research indicates that adding EbPDAs to patient-physician-interaction can make communication and decisions more effective and more efficient (14, 28) | As for the EbPDAs all costs related to the development of training sessions are covered by the IF. Furthermore, clinicians have to invest time into the different training sessions. Ideally, these can be done within their working hours. Clinicians will be rewarded by continued medical education credits by the German Medical Associations.<br>Health care staff undergoing training as decision coaches will need to invest 2 full days. |
| **II. OUTER SETTING** | | | |
| A | Patient Needs & Resources | As primary cooperation partner in the S2C project, the administration of the UKSH acknowledges the need for better patient participation at UKSH and the resulting need for change. While the UKSH puts no formal pressure on its clinicians to cooperate in the project intervention, the directors of each clinic are asked to provide support (e.g., by having their staff undergo training sessions within working hours) and to motivate their clinicians support the S2C programj (e.g. participate in trainings or support EbPDA development) | |
| B | Cosmo-politanism | UKSH and the S2C project team work in close cooperation with other National and International players in the field of evidence-based Medicine and SDM. Cooperation is initiated with, e.g., the patient information group of the German Institute for Quality and Efficiency in Health Care (gesundheitsinformation.de) and the evidence-based guideline developers within the German Association of the Scientific Medical Societies (AWMF), primarily trying to avoid the redundant production of patient content or evidence reviews. At the International level, UKSH and the project team get engaged for example in the International Shared Decision Making (ISDM) Society and maintain relationships with its partners. | |
| C | PeerPressure | This is the first full implementation of SDM at a University Hospital in Germany (and likely worldwide). | |
| D | External Policy & Incentives | The objective of IF funded projects in Germany testing new forms of health care provision is to finally transfer these into statutory health insurance funding (in case of successful implementation). Therefore, the S2C project can be considered a “lighthouse” project, gaining a lot of attention in the media already. In the context of the Patients’ Rights Law and with SDM being a generally approved concept in German politics, this project aims to serve as a role model for other hospitals and settings. Cooperation with other National players (e.g. AWMF, IQWiG) aims to support this development towards more SDM-based patient care. | |
| **III. INNER SETTING** | | | |
| A | Structural Charac-teristics | The UKSH is a tertiary care hospital with 27 primary clinics. Each of these clinics and all clinicians will be involved. Since the UKSH is very hierarchically structured, our approach is to get clinics involved in the project in a top-down approach. Clinic directors get involved first, followed by the clinicians at the next-lower levels in the hierarchy. One physician in each clinic will be chosen together with the director to be the designated “SDM responsible” who oversees activities in the respective clinic (e.g. training activities, EbPDA development, patient activation activities). Other clinicians will be responsible for individual EbPDA topics. | |
| B | Networks & Communicat ions | At the level of clinicians, the hierarchical structures need to be respected and taken into account. If the director supports SDM, it is more likely that the entire clinic supports SDM. At the patient level, the UKSH offers the Infotainment system which can be used to make EbPDAs available to patients at the bedside. | |

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| D | Implementation Climate | Our objective in this project is to initiate a paradigm shift towards more SDM-based health care in a hospital setting. While the UKSH is open for change at an administrative level, time and economic constraints might limit the clinicians' willingness and perceived liberty to support the project.<br>Implementation climate will be assessed using summative (Patient questionnaire; Mappin'SDM evaluation to assess SDM training success) and formative (based on NPT) evaluation components as described. |
| E | Readiness for change | While the UKSH is open for change at an administrative level, time and economic constraints might limit the clinicians' willingness and perceived liberty to support the project. |
| **IV. CHARACTERISTICS OF INDIVIDUALS** | | |
| A | Knowledge & Beliefs about the Intervention | Preliminary research indicates that many patients in the UKSH setting might not yet be regularly involved in decisions about their own health, but are open to more information and more involvement. Individuals' attitudes toward the SDM interventions and their role in it will be measured in the pre-post evaluation by:<br>- Using a range of patient-based instruments to assess patient-physician interaction and the perceived role of the patient before and after the interventions.<br>- Using the Mappin'SDM tool to get a reviewer perspective on whether interventions/trainings influence/improve patient-physician interaction.<br>Clinicians might often rather focus on the demands placed on them by the S2C project team and less the advantages in later patient communication. It is planned to use an NPT-based online survey tool to assess key stakeholder/clinician perceptions of the intervention throughout implementation . |
| **V. PROCESS** | | |
| A | Planning | The individual components of the S2C program have been tested/validated previously in other contexts and will be implemented by a team of implementation experts. |
| B | Engaging | The S2C team will engage in intervention realization at different levels (i.e. recruiting patients for needs assessments, discussing new topics with clinicians, providing support in case of problems etc.). Besides, these teams will realize patient activation and other marketing/exchange initiatives to foster engagement and identification with the S2C concept among patients and health care staff. |
| 1 | Opinion Leaders | The directors of each clinic are important to actively support the S2C intervention and engage their clinicians to follow them. Also, the "SDM clinician" at each clinic plays a crucial role in this context. |
| 2 | Formally App.Internal Implementation Leaders | One physician in each clinic will be the designated "SDM clinician" who oversees activities in the respective clinic. For each topic, one clinician or a group of clinicians will be nominated to carry primary responsibility from a clinical point of few. |
| 3 | Champions | The "personal flagship" of the project, Dr. Eckhart von Hirschhausen, is a very prominent TV-physician, comedian and moderator. He will play a very active role in project marketing. He will be present in videos and on posters and demonstrate his support of the S2C program at all levels and in all its components. Dr. von Hirschhausen is also an official cooperation partner in the project. |
| C | Executing | The program is sponsored by the IF. This national sponsor requires regular milestone reports on project success every six months. |
| D | Reflecting & Evaluating | The individual teams (trainers, implementation team, evidence team, decision aid team) in the project will continuously report on the progress of implementing S2C in their respective domain and document issues, problems or highlights throughout the course of project time. |

*The intervention component “patient activation program” is not separately described in the CFIR table but in the publication text only, given that this program is limited to a marketing and information strategy within each clinic using postcards, posters and stand-up-boards.

**Legend of Figures:**

Figure 1. Project components and involved S2C teams

Figure 2. Sequential quarterly enrollment of new clinics over 4 year project time

Figure 3. Project stages and data collection schedule for SDM assessment

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## Authors' contributions

FG, FS, KW and JR developed the study concept and methods, designed the intervention program and are responsible for its implementation. LS and AM developed the evaluation concept and are responsible for its realization. TS provided substantial scientific and methodological contribution. AR provided methodological input and critically revised the manuscript. MD drafted the manuscript and provided scientific and methodological input to the study concept.

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## Competing Interests

None declared

## Ethics Approval

This study was approved by the Medical Ethics Committee of the Medical Faculty of the Christian Albrecht University (CAU) Kiel, reference number A111/18

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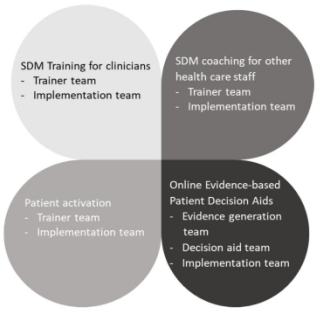


Figure 1. Project components and involved S2C teams

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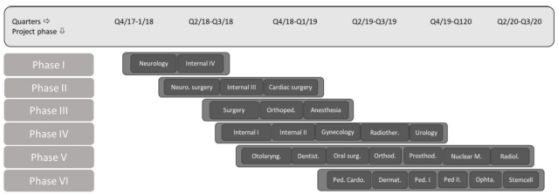


Figure 2. Sequential quarterly enrollment of new clinics

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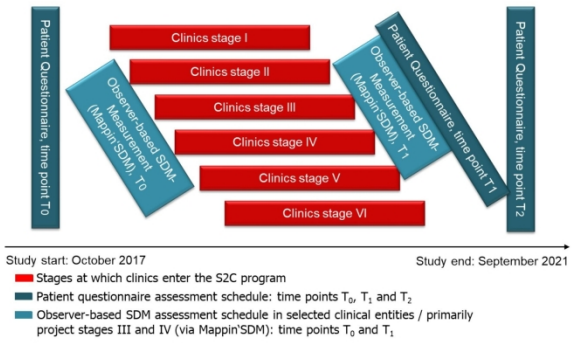


Figure 3. Project stages and data collection schedule for SDM evaluation

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# Making Shared Decision Making (SDM) a Reality: protocol of a large-scale long-term SDM implementation program at a Northern German University Hospital

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# TITLE PAGE

**Making Shared Decision Making (SDM) a Reality: protocol of a large-scale long-term SDM implementation program at a Northern German University Hospital**

**Running title**: Protocol of a large-scale long-term SDM implementation program

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# ABSTRACT

**Introduction:** Shared Decision Making (SDM) is not yet widely used when making decisions in German hospitals. Making SDM a reality is a complex task. It involves training health care professionals in SDM communication and enabling patients to actively participate in communication, in addition to providing sound, easy to understand information on treatment alternatives in the form of evidence-based patient decision aids (EbPDAs). This project funded by the German Innovation Fund aims at designing, implementing, and evaluating a multicomponent, large-scale and integrative SDM program - called SHARE TO CARE (S2C) - at all clinical departments of a University Hospital Campus in Northern Germany within a four-year time period.

**Methods and Analysis:** S2C tackles the aforementioned components of SDM: (1) training physicians in SDM communication (2) activating and empowering patients (3) developing EbPDAs in the most common/relevant diseases, and (4) training other health care professionals in SDM coaching. S2C is designed together with patients and providers. The physicians' training program entails an online and an in situ training module. The decision coach training is based on a similar but less comprehensive approach. The development of online EbPDAs follows the International Patient Decision Aid Standards (IPDAS) and includes written, graphical and video-based information. Validated outcomes of SDM implementation are measured in a pre-post-intervention evaluation design. Process evaluation accompanies program implementation. Health economic impact of the intervention is investigated using a propensity-score matched approach based on potentially preference-sensitive hospital decisions.

**Ethics and Dissemination:** Ethics committee review approval has been obtained from Medical Ethics Committee of the Medical Faculty of the Christian-Albrechts-University (CAU) Kiel. Project information and results will be disseminated at conferences, on project-hosted websites at UKSH and by S2C as well as in peer-reviewed and professional journals.

**KEYWORDS (max. 6):** Shared Decision Making (SDM), SDM training, Evidence-based Patient Decision Aid (EbPDA), patient activation, decision coaching

## STRENGTHS AND LIMITATIONS

- This study is the first large-scale long-term implementation of SDM in an entire University Hospital involving all stakeholders in patient care in a multi-component intervention.
- Due to the size of our target intervention unit a comparative study randomizing comparable hospitals was neither feasible nor affordable.
- This study aims to detect important SDM implementation barriers and supporting factors in a busy and profit-oriented hospital setting.
- One limitation might be that there are no strong incentives for health care professionals' and patients' to contribute to the implementation of SDM.
- Another limitation is that no patients were involved in the design of this study.

# INTRODUCTION

Shared Decision Making (SDM) between health care professionals like physicians or nurses and patients is currently not a standard in German hospitals. (1, 2) SDM has rather been implemented sporadically in individual indications and health care settings. (3, 4) This lack of SDM in routine settings might be due to a range of provider, patient, organizational, economic, and contextual factors. (1, 2, 5) On the other hand, German legislation with the Patients' Rights Act gave SDM a more prominent role in German health care in 2013. (6) The act implies that health care professionals and patients follow SDM communication rules. For example, physicians have to comprehensively inform their patients about relevant treatment alternatives (§630e). (6) In this context, the law points out that written material like patient decision aids may support professionals in meeting these legal requirements. While legislation in Germany hence seems to be ready for SDM and supporting instruments such as evidence-based Patient Decision Aids (EbPDAs), stakeholders in daily practice are not yet routinely implementing it.

For SDM to be effective, the patients' and the health care providers' ability and willingness to participate in SDM are crucial. (2, 7) To make SDM a reality in any health care setting is an ambitious endeavor and a complex multi-level task. (5) It involves training physicians and other health care professionals in SDM communication skills as well as encourage patients to actively participate in communication, in addition to providing evidence-based, easy to understand information on treatment alternatives to patients and their physicians. (8) To be effective in daily practice, SDM should be co-designed with involved stakeholders to gain acceptance and recognition. (3) In addition, it needs an inner (i.e., within the institution that wants to do SDM) and an outer (concerning the external conditions in which the institution works) setting, in which program implementation is possible, as defined e.g. by the Consolidated Framework for Implementation Research (CFIR) (see Table 1 for this project). (9) The Norwegian "Decision Aid (DA) Factory" approach of the University Hospital North Norway, in which researchers and developers of SDM components – so-called "knowledge producers" – work in close cooperation with the physicians and patients – so-called "knowledge users" – inspired implementation processes in this project. (10)

Individual components of SDM such as SDM training for health care professionals, patient activation/empowerment programs or decision aids have all been previously tested in specific indications, populations and using different study designs. (11-15) Their effectiveness and impact on decision processes have been assessed. For example, according to a recent systematic review of 115 Randomized Controlled Trials (RCTs) with about 35.000 patients altogether, the use of only EbPDAs to inform patients in specific indications led to improved health education/literacy, more active participation and value congruent choices, more accurate expectations regarding course of disease and risk perceptions, more treatment satisfaction and better adherence to treatment. (14) This finding has been reinforced by reviews in other specific populations. (16) However, most of the EbPDAs previously tested in RCTs while having proven effectiveness are not subsequently used in the settings they were developed in. (3) A recent study by Stacey et al. 2019 concluded that "To improve subsequent use, researchers should codesign EbPDAs with end users to ensure fit with clinical practice and develop an implementation plan". (3) That study surveyed EbPDA developers who reported that the lack of physicians supporting and agreeing with the EbPDAs often hindered successful implementation. Training physicians in SDM in theory and practice has equally demonstrated to be effective, but the certainty of this evidence is low and limited to specific treatment settings. (15, 17-19) While there may still be a lack of evidence regarding the effectiveness of SDM on patient-relevant clinical endpoints, there is growing agreement and consensus that SDM is a necessity, a patients' and a citizen's right, and an ethical imperative. (7)

It has also become clear that effectiveness to a large extent will depend on effective implementation strategies and consistent stakeholder involvement. (3, 5) Hence, given a growing body of evidence supporting the effectiveness of individual SDM interventions, the next step on the "continuum of increasing evidence" according to Campbell et al. (20, 21) would be to roll out the combined implementation of SDM interventions on a larger-scale in a long-term implementation study. Few programs until now have addressed the simultaneous implementation of a range of SDM components at the same time (see e.g. Sondergaard 2019, Dahl Steffensen 2018 (22, 23)), some are currently ongoing

(see e.g. Scholl 2018 (24)), but none have yet introduced a multi-component SDM program at all departments of a hospital at a time. Therefore, in this publicly funded project the objective was to design, implement and evaluate a multicomponent, large-scale and integrative SDM program - called SHARE TO CARE (S2C) - at the University Hospital Medical Center Schleswig Holstein (UKSH), Campus Kiel, within a 4 year time period - from October 2017 until September 30, 2021. The project is designed and implemented in cooperation between the UKSH, Kiel, Germany, and the University Hospital of Northern Norway, Tromsø, Norway.

# METHODS AND ANALYSIS

## Study design

This study implies the large-scale implementation of SDM at the University Hospital Campus Kiel within a four-year time period based on the S2C intervention program. It includes comprehensive outcome evaluation with measurement of (1) SDM level in patient-physician-interactions based on patients' and external observers' perceptions before and after S2C implementation and (2) measuring the impact of the S2C intervention on health care use and costs in comparison to a propensity-score matched comparison population not exposed to S2C. The program will be accompanied by a process evaluation based on the recommendations of the Medical Research Council Guidance and using the Consolidated Framework for Implementation Research (CFIR) to guide development and implementation activities. (9, 25)

The term "multicomponent" in the S2C program refers to four different interventions (components) designed and implemented simultaneously in several clinical departments. This includes (1) SDM training for physicians (17-19, 26), (2) SDM qualification as "decision coach" for other health care professionals like nurses or physiotherapists (18, 27), (3) the Ask Three Questions program that aims at patient activation and empowerment, and (28, 29) (4) development of online EbPDAs (14). These components and the respective responsible S2C project teams are depicted in Figure 1.

*Insert here:* Figure 1

The term "large-scale" means that the program will sequentially be implemented at the University Hospital Campus Kiel involving 27 clinical departments with more than 650 physicians. The aim is to develop 83 EbPDAs enrolling new clinical departments into the program every six months and identifying EbPDA topics at each clinic (Figure 2). At the same time, each physician in the respective clinic undergoes SDM training. The Ask Three Questions patient activation is implemented simultaneously. In addition, in selected departments a total of 150 other health care professionals will be trained as decision coaches to facilitate EbPDA use in specific patient target groups.

*Insert here:* Figure 2

The term "integrative" in S2C means that patients and health care professionals will be actively involved from the very beginning and throughout implementation, most actively in EbPDA development but also e.g. in training evaluation and in the patient activation program (10). The integrative approach begins with identifying new topics together with physicians and conducting needs assessments with patients. It ends with having physicians distribute EbPDAs to patients in their clinical departments. Sample patients will also user-test the EbPDAs before these will be administered to patients in daily practice.

**Patient and Public Involvement**

No patient was involved in the development or design of this study.

**Theoretical Framework**

At the micro-level (level of health care professionals or patients), the S2C program is designed and implemented on the grounds of the Theory of Planned Behavior suggesting behavior is a result of motivation (intention) and ability (perceived behavior control) (30, 31). Accordingly, the S2C program aims to induce attitude and perception-changes by training physicians and other health care professionals in SDM and by informing patients to enable simultaneous behavior change at the level of patients and health care providers. The interactive process of EbPDA-development also aims at changing attitudes at the individual physician level. The implementation of the S2C program is at the microlevel guided by the

concept of Normalization Process Theory (NPT). The four components of the NPT are coherence (does the program make sense to those who are involved?), participation (how do relevant stakeholders participate in implementation?), collective action (what to do to make implementation successful?) and reflexive monitoring (how do the involved individuals judge implementation processes?). (32) As part of a process evaluation, these questions/constructs will be addressed with key stakeholders at specific points in time throughout the four-year project time to continuously monitor implementation processes at the level of all involved stakeholders at the University hospital campus Kiel.

The complexity of this project taking into account context and processes of project implementation is depicted in Table 1 following the CFIR (https://cfirguide.org/). This framework comprises five domains (intervention characteristics, outer setting, inner setting, characteristics of individuals, and process) and 39 related constructs. (9, 33, 34). The constructs of the CFIR were used to describe the status quo of relevant project characteristics, project settings, and potential interactions between these at project initiation. CFIR will also guide our implementation processes as described later.

*Insert somewhere here:* Table 1.

**Setting and Study population**

Campus Kiel as part of the UKSH Medical Center is a tertiary care hospital with more than 200.000 cases treated each year. 27 clinical departments with more than 650 physicians and more than 150 other health care professionals and their patients will be part of either training modules or development and use of decision aids or both. New clinical department and their patients will be sequentially enrolled in the study (Figure 2).

**S2C Intervention components**

*Intervention "SDM training for physicians"*

This module aims at providing structured SDM training in three steps to a minimum of 80 % of physicians working at the UKSH (i.e., at least 520 physicians should receive training). The module is based on the pretested and validated training approach that has demonstrated to be effective and lead to an increased patient, physician and observer perception of involvement in decision making. (17, 18) Preceding training, each physician has to take a baseline video of him or herself with a patient in a real decision making interaction. The physician then undergoes an online video tutorial which contains general information on SDM and its application in clinical practice. It also contains fictional interactions between physician and patient actors teaching physicians to differentiate "good" from SDM communication "in need of improvement". For the subsequent video-based small group training sessions, the baseline video recording of a patient-physician interaction and a second recording (following online training) are rated by the S2C trainer team (see Table 2 for additional information). In the subsequent group training, each physician receives video-based trainer and group feedback. The aim is to provide an interactive and common SDM learning experience to physician. To increase their motivation, training participation is rewarded by continued medical education credits by the German Medical Associations.

*Intervention "Activation of patients"*

The "Ask Three Questions" program has originally been developed in Australia and tested in European countries (28, 29). Patients are instructed and motivated to actively participate in communication by asking their doctors questions regarding their specific (treatment) situation. Our patient activation concept communicates the message "Ask Three questions - decide together" in a unique design at all departments using various distribution channels: paper postcards, posters/stand-up displays, and screen-based messages inside UKSH. It will be embedded in several other interventions, like a patient homepage within the UKSH-homepage, the bedside infotainment system, information screens and special SDM-days in the central lobby.

*Intervention "(Online) Evidence-Based Patient Decision Aids (EbPDAs)"*

Eigthy-three online EbPDAs will be developed, at least one in each department. The number is arbitrary, as there is no recommended number per department. We calculated the maximum possible number given the resources and the time frame of our grant. Consistent with the DA factory approach implementation starts with the identification of EbPDA topics together with physicians. Topics should be important for physicians, involve at least two preference-sensitive treatment alternatives, and occur frequently. Topic specification with respect to target patient population, relevant treatment options, and patient-relevant outcomes/issues of treatment is done based on a literature/guideline review and in exchange with physicians and patients. Needs assessments are conducted with about 4-8 patients per topic to guide and structure EbPDAs as closely to patient needs as possible. Development of EbPDAs involves a systematic search and assessment of best available evidence for all relevant interventions, focusing on systematic reviews and evidence-based guidelines. Methods are based on the German standards of evidence-based patient information and the methods of evidence generation in patient information. (35, 36) Text information on disease and treatment will be accompanied by video sequences with UKSH physicians and patients. In these sequences physicians explain treatments and patients share their experience in decision making. The latter is to motivate users of the online DAs to actively participate in decision-making. To avoid bias by testimonials, patients do not rate the different interventions in their video sequences but limit themselves to talking about their experience with the disease and their individual decision process. The process of DA development follows the International Patient Decision Aids Standards (IPDAS) criteria (www.ipdas.ohri.ca (37, 38)). Each EbPDA undergoes external review.

*Intervention "SDM Training for other health care professionals to be Decision Coach"*

This qualification module provides SDM training to about 150 nurses or other health care professionals in specific indications, where patients most likely will need support in using EbPDAs. Training principles are based on the physician training and decision coaching application in specific settings. (12, 13, 27, 39) The goal is to train health care staff like nurses or physiotherapists to act as "decision coaches" for their patients when using EbPDAs, i.e., to simultaneously provide emotional, psychological and technical

support. The qualification consists of two workshop days communicating the principles of SDM and EbPDAs and including two individual decision coaching sessions for each participant. In addition, each decision coach will be asked to videotape coaching communications with a patient twice and receive individual SDM trainer feedback. Coaching communication with the patient centers around a relevant EbPDA.

**Study Outcome and outcome measures**

The primary intervention outcome is whether and to what degree SDM-based interaction is provided to patients at UKSH. To cover different perspectives, we focus on two types of outcome measures, one providing the patient perspective and one providing an observer-based perspective (Table 2). The primary outcome is based on a validated SDM measurement instrument, the Perceived Involvement in Care Scales (PICS). (40, 41) It is a patient-reported outcome instrument translated and validated in Germany, and consists of three subscales with 4-5 items each. The subscales are (1) patient activation by doctors (5 items), (2) active information seeking behavior (4 items) and (3) perceived patient participation in decision making (5 items). Each item is measured on a scale from 1 = „do not agree at all“ to 4 = „totally agree”. The second primary outcome consists in an observer rating of patient-physician interaction before and after intervention using the MAPPIN'SDM-O-dyad instrument. (17, 18, 26) MAPPIN'SDM-O-dyad measures the degree of SDM performance realized by the doctor-patient dyad (i.e., by the unit made up of patient and physician) as rated by independent observers. The instrument consists of 9 items assessing the process and quality of SDM. Each item is scored from "0" ("the indicator is not present") to "4" ("the indicator is present at an excellent standard"). The observer ratings are provided by independent but trained raters who rate video recordings of patient-physician-interactions before and after the intervention (see "data collection and analyses"). All observers are blinded to the measurement objects and time points of video recordings.

Additional secondary outcomes included in the patient questionnaire are two validated and widely-used questionnaires, the Preparation for Decision Making Scale (PrepDM: 10 items; 5-point scale) (42) and collaboRATE (43) (3 items; 5-point scale). All outcome measures are detailed in Table 2.

*Insert somewhere here:* Table 2.

**Data collection**

Primary outcome data collection is conducted via patient questionnaire (including the PICS instrument) before (T0) and twice after the intervention (T1, T2). The data collection and evaluation schedule is depicted in Figure 3.

*Insert here:* Figure 3

The first patient questionnaire/PICS measurement ($T_0$) is scheduled at study initiation. The second ($T_1$) is taken after completion of the S2C intervention at each department to assess immediate intervention effect. The intervention is considered complete at the department level when at least 80% of physicians have undergone training, EbPDAs are developed and in use, and the patient activation program is in place. The last measurement ($T_2$) is scheduled six months before study completion. It aims to appraise the sustainability of the S2C intervention. At T0 and T2, the patient questionnaire is mailed to a consecutive sample of patients that were hospitalized at the UKSH Kiel campus within the preceding weeks with a return envelope included in each mailing. At T1, the questionnaire is sent to a respective sample of patients from a clinical department that completed the intervention. Patients who do not return the questionnaire within a 2- or 4-week time frame, respectively, will get a reminder either once or twice. Based on the Total Design Method approach by Dillmann et al. (44). Final response rates of at least 60-70% are expected.

The observer-based outcome measurement via MAPPIN'SDM-O-dyad is performed twice throughout the 4-year study period, at T0 and T1. To minimize workload for physicians, who must videotape encounters with patients to facilitate the MAPPIN'SDM-O-dyad evaluation, these assessments focus on central

domains of hospital medicine (internal medicine, oncology, gynecology, surgery, orthopedics) being covered by specific clinical departments (departments of general surgery, internal medicine, radiotherapy, oncology & hematology,gynecology, trauma surgery & orthopedics, urology, gynecology).

**Sample size calculation and data analyses**

Sample size calculation for the patient-based primary outcome is based on published PICS data (41, 45). An assumed difference of 0.4 in the PICS outcome at $T_1$ versus $T_0$ and a standard deviation of 0.7 yields a sample size of about 40 for each clinical department at each measurement, using an independent sample t-test and assuming a power of 80% and a level of significance of 5% (one-sided, assuming a positive effect of the SDM-intervention). This yields a campus-wide sample of 1080 patients (27 clinics, 40 patients per clinic). A difference in PICS scores of 0.4 comparing before and after measurement is considered relevant (Hedges $g > 0.5$, which corresponds to a medium size effect). If the distribution does not allow the assumption of normality, appropriate non-parametric tests will be applied in data analyses.

A presumed response rate of 60-70% to the patient questionnaire mailings leads us to target about 1600 patients at measurement point T0 and T2 the campus level to finally achieve at least about 1000 patient questionnaires returned, yielding on average between 30-60 returned questionnaires per clinical department. These numbers will allow to measure significant differences in the primary endpoint not only at the campus but also at the individual department level (at least in the larger ones). At T1, a minimum of 65-70 patients has to be contacted to have at least 40 questionnaires returned.

Sample size for the second primary outcome assessment (MAPPIN'SDM observer assessment) is given by the number of physicians at the involved clinical departments. 7 of the 27 UKSH departments will be part of the MAPPIN'SDM assessment. Physicians in these departments sum up to 200 to 220 in total. Each physician will deliver a patient-physician-interaction video for outcome measurement at each measurement point. This analysis includes general surgery (n=30-40 physicians), internal medicine (n=62), radiotherapy (n=16), oncology/hematology (n=21), orthopedics (n=27), gynecology (N=34), and

urology (N=10-20). Based on a previous study including training of physicians only (18), we aim at an effect size of d=0.5 (Hedges g). To yield a power of 80% (alpha=5%), minimal sample size should be N=51. Assuming a response rate above 60% (N≥120), the sampling strategy leads to a sufficient sample size. It is hypothesized that in 80% of patient-physician-interactions patients will receive satisfactory SDM-based treatment at the second department-wide measurement ($T_1$) compared to less than 80% before the intervention (T0). To answer the latter study hypothesis, a MAPPIN-SDM-O-dyad mean value of greater or equal to 1.5 was defined as satisfactory basic patient involvement in decision making based on previous validation research. (18)

**Health Economic Evaluation**

In addition to the pre-post SDM evaluation, an economic evaluation will be conducted. This analysis will be based on insurance claims data provided by the largest German Health Insurance provider (Techniker Krankenkasse; TK). In Germany, approximately 88 % of the population (72,8 million) is covered under the comprehensive statutory health insurance system. The TK provides health insurance for approximately 9.8 million people (13% of the statutory contributors) and routinely collects data for reimbursement purposes on hospital stays, physician visits, medical procedures, medication, and medical diagnoses. In the economic evaluation, incremental costs and use of specific services of patients admitted to the UKSH with preference-sensitive conditions in specific clinical departments (intervention group) will be compared to a matched population (control group) drawn from the administrative dataset from the TK. The control group includes patients with a hospital admission to another German University or Educational hospital (tertiary medical center). From this sample population, patients will be matched to the intervention group using exact matching, propensity score matching or a combination of exact and propensity score matching. (46, 47) Matching criteria will include patient characteristics like age and sex, the main diagnosis of the hospital admission as well as measures of morbidity within 12 months preceding hospital admission. In line with previous research (48), variables that are compared across groups include preference-sensitive surgery rates, imaging rates, inpatient costs, total medical costs and

hospital and emergency department admissions within 12 months after the admission to the hospital. To account for systematic differences between intervention and control group, the analysis will focus on the comparison of the difference in outcomes measured at two points in time, before and after the implementation of the SDM intervention. The analysis will be limited to about 10 to 15 frequently occurring and preference-sensitive conditions. These conditions will include but are not limited to cardiologic diseases, benign prostatic hyperplasia and other urologic diseases, benign uterine diseases and obstetrics, neurosurgery / back pain, and orthopaedic diseases such as knee or hip replacement.

**Process evaluation**

Starting point for our evaluation are the CFIR constructs as depicted in Table 1. They summarize each study component, involved stakeholders, context (inner/outer setting), and processes at study initiation. Each construct is followed up throughout the course of the study aiming to (1) identify areas where adaptations to initially planned implementation might be needed and (2) better understand which clinical departments might be more/less accessible to the SDM interventions and why. Process evaluation is done by using (a) documentation (e.g. documentation of decision aid use by simply counting click/user numbers and times or documentation of number of physician trainings performed per clinical department) (b) interview or structured questionnaire data. Interviews and structured questionnaires with stakeholders regarding implementation processes will be developed based on the described four concepts of the NPT theory (49-51). In addition, field notes are used by the respective project teams (Figure 1) to adapt implementation strategies and processes to the specific demands of individual department's circumstances during the intervention phase.

# ETHICS AND DISSEMINATION

The Medical Ethics Committee of the Medical Faculty of the Christian-Albrechts-University (CAU) Kiel has provided ethics approval to this study (reference number A111/18). This study will be conducted in accordance with German laws and regulations of the Medical Ethics Committee of the CAU, Kiel,

Germany. Eligible patients or health care providers will be fully informed about the study and asked to participate in each part of the study: conducting personal interviews with patients (needs assessment), or video sequences with physicians/patients, or involving physicians in training sessions. Patients/providers will receive a respective information letter and will be informed about the implications of participation. They will have sufficient opportunity to ask questions and to consider the implications of the study before deciding to participate. Before participation, all individuals will provide written informed consent, compliant with the local and ethical data regulations. Patients and clinical staff will be allowed to withdraw from the study without giving a reason, at any time. The results arising from this implementation study will be presented at scientific meetings, on project-hosted websites at UKSH and by S2C as well as published in peer-reviewed journals. There is no intention to use professional writers and authorship will be based on the International Committee of Medical Journal Editors Guidelines.

Table 1. Consolidated Framework for Implementation Research (CFIR), S2C project-specific information for Evidence-based Decision Aids and SDM Training for physicians / Training program for decision coaching for other health care professionals*

| Construct | Evidence-based Patient Decision Aids (EbPDAs) | SDM Training for physicians / Training program for "decision coaching" |
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| **I. INTERVENTION CHARACTERISTICS** | | |
| Intervention Source | EbPDAs are developed internally by the S2C team. Topics for new EbPDAs are generated together with the physicians based on the DA factory approach. Patients are involved early on via needs assessments to inform EbPDA development. Evidence syntheses are conducted by well-known best-in class external consultant groups (EBSCO, USA (producers of the DynaMed point in care services, well-known to UKSH physicians, and Kleijnen Systematic Reviews (KSR), UK). | The training for physicians was developed and validated by members of the S2C team (17, 18, 26). The decision coaching training is developed by the S2C team in line with the physician training and based on existing decision coaching programs (27, 52). With a group of psychologists/coaching specialists, the trainer team combines scientific and practical expertise to train different types of health care providers in SDM communication / decision coaching skills. |
| Evidence Strength & Quality | A current systematic review demonstrates that decision aids improve decision and indication quality (14). Our EbPDAs follow the International Patient Decision Aids Standards (IPDAS) (37, 38) and provide balanced and easy to understand information on the pros and cons of treatment alternatives to patients. With the Patients' Rights Law in place in Germany since 2013, the S2C project with its EbPDAs also puts the patients' rights into practice. | The training program for physicians was developed / validated by Geiger et al. (17, 18, 26). This program guided the development of decision coach training for other health care professionals. Further evidence supported the refinement and adaptation of the coaching program to meet the specific demands in difficult indications/target populations in a hospital setting (27, 52). |
| Relative Advantage | The format of online EbPDAs with easy to understand written/graphical information, videos with patient narratives, and videos with physicians from the UKSH explaining disease or treatment concepts are likely attractive to patients and physicians. | The online SDM training is a relatively quick and easy-to-do training program teaching SDM basics to physicians. The video-feed-back based training is highly individualized and based on real patient-physician communication allowing a thorough SDM |

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| | While physicians are involved in development and invest time into it, EbPDAs will facilitate better informed dialogue with patients. By providing more structure to the dialogue, EbPDAs are expected to make communication more efficient (48). | learning experience. The training for decision coaching focuses on providing support with EbPDA use to patient, especially if patients are emotionally or physically not able to effectively use EbPDAs without support. |
| Adaptability | The format of the EbPDAs follows a standard structure. However, this structure is flexible. It allows for topic- or clinic-specific adaptations. Online decision aids will be administered to patients via printed access codes that patients receive in an envelope. Each EbPDA will contain a printable summary sheet on all relevant aspects of alternatives (Questions & Answers-Sheet). This paper-based version can be used in communication with patients not willing or able to use the online EbPDAs. | Training units are flexible and adaptable to specific demands. The online training can be easily integrated into a busy physician schedule. If physicians do not want to do personal training in a group setting, it can be done with physicians individually. If health care providers are not willing to video-tape interactions with their patients, trainers may offer participating observation instead and rate "live" patient-physician interactions. Other adaptations might be needed throughout. |
| Trialability | Each clinic starts with 1 or 2 EbPDAs. If a clinic is interested to support further topics, additional EbPDAs may be developed. If a clinic is rather unwilling to support the project, no pressure will be exerted but the clinic may rejoin EbPDA development at a later point in time. Also, since the clinical departments are approached in a stepwise approach, learnings from one clinic might be transferred. Features of the EbPDAs may be adapted according to specific clinic or patient needs (length of texts, number of films, graphics, description of clinical studies, strength of evidence, ect.) | It is not an imperative for UKSH staff to undergo SDM training sessions, but clinic directors are asked to motivate their staff to take part in these. Also, clinic directors are asked to make sure that training sessions can be done within working hours.<br>If a clinic is unwilling to support the project at a specific point in time or to provide the time to their physicians to undergo training, no further pressure will be exerted. In selected instances (e.g., if physicians of a department are under extreme time pressure), SDM training might remain limited to online sessions. |
| Complexity | Patients will have to invest at least 30-60 minutes to go through one EbPDA. This might be tiring to some patients. The patient-friendly and flexible format of EbPDAs addresses this issue in | Training sessions for physicians and decision coaches are time-consuming, between 1-2 full days for physicians and for those who undergo training as decision coaches. This time needs to be |

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| | parts. Availability via the bedside - "Infotainment"-system at UKSH and via portable tablets will make access to EbPDAs easy for patients. Physicians have to invest time for EbPDAs. They might not initially appreciate that EbPDAs can help save time in patient communication. Also, the departments/ physicians will have to integrate the EbPDAs into patient pathways. This might not always be easy in a busy hospital setting and make pathway adaptations necessary. | provided by clinic directors but it might still be difficult to integrate training sessions into a busy clinic schedule. Health care staff might refuse videotaping themselves in patient interaction for various reasons (e.g., worries about an external rating of their performance). Even for well-trained physicians or decision coaches, it might sometimes be difficult to integrate SDM and decision coaching into interactions/treatment pathways. Adaptations of treatment pathways might be needed. |
| Design Quality & Packaging | The EbPDA is developed by a highly professional S2C team of medical writers working according to the standards of evidence-based patient information and a professional film team with wide experience in patient filming. Evidence syntheses are done by best-in class external consultants together with the S2C evidence team. All EbPDAs strictly adhere to the IPDAS criteria (37, 38). | All training sessions were developed and are conducted by a group of trained and experienced psychologists/coaches. The online-training was developed and realized by the S2C trainer team in cooperation with the S2C film team. All training evaluations strictly adhere to the rating criteria of the MAPPIN'SDM instrument (18, 26) |
| Cost | Costs of the intervention and costs associated with implementation are covered by a grant of the German Innovation Fonds (IF). The IF is hosted at the Federal Joint Committee. Opportunity costs will occur since patients and physicians have to invest time in decision aid production and/or use. Research indicates that using EbPDAs in patient-physician-interaction can make communication and decisions more effective and more efficient (14, 48) | As for the EbPDAs all costs related to the development of training sessions are covered by the IF. Furthermore, physicians have to invest time into the different training sessions. Ideally, these can be done within their working hours. Physicians are rewarded by continued medical education credits by the German Medical Associations. Health care staff undergoing training as decision coaches will need to invest 2 full days. |
| **II. OUTER SETTING** | | |
| Patient Needs & Resources | As primary cooperation partner in the S2C project, the administration of UKSH acknowledges the need for better patient participation and the resulting need for change. While it puts no formal pressure on its physicians to cooperate in the project, the directors of each | |

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| | department are encouraged to provide support by signing specific SDM goal attainment contracts. In these, they agree to have their staff undergo training sessions within working hours and to motivate their physicians/other staff to support the S2C program. |
| Cosmo-politanism | UKSH and the S2C project team work in close cooperation with other (Inter)National players in the field of Evidence-based Medicine and SDM. Cooperation is initiated or ongoing with, e.g., the German Institute for Quality and Efficiency in Health Care (IQWiG, gesundheitsinformation.de) and the evidence-based guideline developers within the German Association of the Scientific Medical Societies (AWMF), primarily trying to avoid the redundant production of patient content or evidence reviews. At the International level, UKSH and the project team get engaged e.g. in the International Shared Decision Making (ISDM) Society. |
| Peer Pressure | This is the first full implementation of SDM at a University Hospital in Germany. Nevertheless SDM is becoming increasingly demanded, i.e., it is on the German political agenda. For example, the AWMF established a committee to add EbPDAs to its evidence-based clinical guidelines. The German branch of Choosing Wisely claims to carry forward SDM. The National Cancer Plan and the National Plan for Health Literacy demand for SDM. Also, patient organizations and the German Independent Patient Council (UPB) stipulate SDM in health care. |
| External Policy & Incentives | The objective of IF funded projects in Germany is to test new forms of health care provision, to scale them up and to finally transfer these into general statutory health insurance funding (in case of successful implementation). Therefore, the S2C project can be considered a "lighthouse" project, gaining a lot of attention in the media already. In the context of the Patients' Rights Law and with SDM being a generally approved concept in German politics, this project aims to serve as a role model for other hospitals and settings. Cooperation with other National players (e.g. AWMF, IQWiG, German Society of Evidence Based Medicine, German Society for Health Literacy) aims to support this development towards more SDM-based patient care. |
| **III. INNER SETTING** | |
| Structural Charac-teristics | The UKSH is a tertiary care hospital with 27 clinical departments. Each of these departments and all physicians will be involved. Since the UKSH is very hierarchically structured, our approach is to get departments involved in the project in a top-down approach. Clinic directors get involved first, followed by the physicians at the next-lower levels in the hierarchy. One physician in each clinic will be chosen together with the director to be the designated "SDM responsible" who oversees activities in the respective clinic (e.g. training activities, EbPDA development, patient activation activities). Other physicians will be responsible for individual EbPDA |

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| | topics and it is assumed that early involvement of physicians in EbPDA development will increase their acceptance and support. At the same time the UKSH Employee Committee and individual multipliers ("clinical champions") will be involved early in the project. |
| Networks & Communi-cations | At the level of physicians, the hierarchical structures need to be respected and taken into account. If the director supports SDM, it is assumed to be more likely that the entire clinic supports SDM. At the patient level, the UKSH offers the Infotainment system which can be used to make EbPDAs available to patients at the bedside. |
| Implementa-tion Climate | Our objective in this project is nothing less than to initiate a paradigm shift towards more SDM-based health care in an entire hospital setting. While the UKSH is open for change at an administrative level, time and economic constraints might limit the physicians' willingness and perceived liberty to support the project. Implementation climate will be assessed using summative (Patient questionnaire; MAPPIN'SDM evaluation) and process evaluation components (based on the CFIR constructs and NPT) as described. |
| Readiness for change | While the UKSH is open for change at an administrative level, time and economic constraints might limit the physicians' willingness and perceived liberty to support the project. |
| **IV. CHARACTERISTICS OF INDIVIDUALS** | |
| Knowledge & Beliefs about the Intervention | Preliminary research indicates that many patients in the UKSH setting might not yet be regularly involved in decisions, but are open to more information and more involvement. Individuals' attitudes toward the SDM interventions and their role in it will be measured in the pre-post evaluation by (1) using a range of patient-based instruments to assess patient-physician interaction and the perceived role of the patient before and after the interventions. (2) using the MAPPIN'SDM instrument to get a reviewer perspective on whether interventions/trainings influence/improve patient-physician interaction. Physicians might often rather focus on the demands placed on them by the S2C project team and less on the potential advantages/time savings in patient communication. NPT-based questionnaires/interviews to assess key stakeholder/physician perceptions of the intervention throughout implementation will be used. |
| **V. PROCESS** | |
| Planning | The individual components of the S2C program have been tested/validated previously in other contexts and will be implemented by a team of implementation experts. |
| Engaging | The S2C team consists of four teams: the evidence team, the decision aid team (working closely together on decision aids), the trainer team (physician training, training for "decision coaching"), and the implementation team (engaging at all levels in implementation- |

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| | related activities in the hospital, e.g. recruiting patients for needs assessments, reminding physicians or other health care professionals to undergo trainings etc.). Besides, the latter will realize patient activation and other marketing/exchange initiatives to foster engagement and identification with the S2C concept among patients and health care staff. |
| Opinion Leaders | The directors of each clinic and other "SDM champions" are important to actively support the S2C intervention and engage their physicians to follow them. Also, the "SDM physician" at each clinic plays a crucial role in this context. |
| Internal Implementation Leaders | One physician in each clinic will be the designated "SDM physician" who oversees activities in the respective clinic. For each EbPDA topic, one physician or a group of physicians will be nominated to carry primary responsibility from a clinical point of few. These physicians are expected to support the S2C team and drive project activities forward in the respective department. |
| Champions | The "personal flagship" of the project, Dr. Eckhart von Hirschhausen, is a very prominent TV-physician, comedian and moderator. He will play a very active role in project marketing. He will be present in videos and on posters and demonstrate his support of the S2C program at all levels and in all its components. Dr. von Hirschhausen is also an official cooperation partner in the project. |
| Executing | The German Innovation Fund as national sponsor requires regular milestone reports on project success every six months. |
| Reflecting & Evaluating | All S2C teams will continuously report on the progress of implementing S2C in their respective domain and document issues, problems or highlights throughout the course of project time (field notes/documentation) |

*The intervention component "patient activation program" is not separately described in the CFIR table but in the publication text only, given that this program is limited to accompanying marketing and information strategies within each clinic using postcards, posters and stand-up-boards.

Table 2. Details on outcome measurement

| Outcome, Instrument | Outcome definition | Target population | Measurement scale | Reasons for Choice of Instrument | Assessment schedule / mode (Time points, T0, T1, T2) | Planned number of interviewed individuals |
|---|---|---|---|---|---|---|
| **Outcomes elicited from patient perspective via Patient Questionnaire** | | | | | | |
| Primary Outcome Measure (1): Perceived Involvement in Care Scales (PICS) (3rd subscale used as primary outcome measure) (41,45) | Perceived Involvement in patient-physician interaction from patient perspective | Sample of UKSH patients receiving patient questionnaires (all clinical departments or specific departments) | 3 subscales:<br>1. doctor facilitation of patient involvement<br>2. level of patient's active information seeking<br>3. perceived patient involvement<br>Individual scores range from 1 (no agreement) to 4 (total agreement) | Measures patient perception of involvement in decision making with physician in general, not restricted to or focused on one specific decision situation; Takes the perspective of a patient and is not limited to assessing the patient perceived degree of physician's endeavor | T0: before program starts (baseline)<br>T1: after completion of program in each department; immediate effect<br>T2: 6 months before the end of the project: sustainability of "effect" | 1.600 at T0 and T2, respectively; a minimum of 40 per clinic at T1; Different samples are taken at each measurement |
| Secondary Outcome Measure: Preparation for Decision Making Scale (PREP-DM-Scale) (42) | Perceived level of individual preparation for decision situation | same as for PICS | 10 items<br>Individual scores in patient questionnaire range from 1 (no agreement) to 5 (total agreement) | Measures patient perception of involvement in decision making going beyond patient-physician communication, e.g. brochures, decision aids, information provided via other health care professionals. | T0, T1, T2 | same as for PICS |

| Outcome, Instrument | Outcome definition | Target population | Measurement scale | Reasons for Choice of Instrument | Assessment schedule / mode (Time points, T0, T1, T2) | Planned number of interviewed individuals |
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| Secondary Outcome Measure: Collabo-RATE (43) | Perceived level of attempts being made by physicians to actively involve patients in decision making | Same as for PICS | 3 items<br>Individual scores in patient questionnaire range from 1 (received no attention) to 5 (received much attention) | Allows comparison with other studies, since this questionnaire is widely used internationally. | T0, T1, T2 | same as for PICS |
| **Outcomes elicited from observer perspective** | | | | | | |
| Primary Outcome Measure (2): MAPPIN' SDM-O-dyad (17,18,19) | Observer-based assessment of how well the physician-patient-interaction is performed with respect to the MAPPIN'SDM criteria<br>Conducted by trained raters based on videos of specific interactions. | Patients and physicians in a personal decision-related interaction | Based on a MAPPIN'SDM rater manual.<br>6 items reflecting the 6 steps in shared decision making<br>Item 1: problem definition<br>Item 2: key SDM message<br>Item 3a: options (structure)<br>Item 3b: options (content)<br>Item 3c: options (quality of information)<br>Item 4: Patient expectations and worries<br>Item 5: Decision making<br>Item 6: Further steps | Provides an "objective" assessment of the patient-physician interaction by an independent rater, with respect to both interaction participants, the patient and the physician ("dyad") | T0, T1<br>Individual patient physician encounters at clinical departments*<br><br>Rater is blinded to the timing of the video taken. | 200-220 patient-physician interactions (all physicians at 7 involved clinical departments will submit one video at each measurement time point)*<br>Physicians are mostly the same at each measurement but patients in interaction are different. |

* Evaluated clinical departments at the University Hospital Campus Kiel are: general surgery, internal medicine I (gastroenterology, hepatology, pneumology, internal intensive care medicine, endocrinology, infectiology, rheumatology, nutritional and ageing medicine), radiotherapy, internal medicine II (hematology, oncology), trauma surgery & orthopedics, gynecology and urology

**Legend of Figures:**

Figure 1. Project components and respective S2C project teams

Figure 2. Sequential quarterly enrollment of new clinical departments

Figure 3. Project stages and data collection schedule for SDM evaluation

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**Authors' contributions**

FG, FS, KW and JR developed the study concept and methods, designed the intervention program and are responsible for its implementation. LS and AN developed the evaluation concept and are responsible for its realization. TS and CK provided substantial scientific and methodological contribution. AR and MDE provided methodological input and critically revised the manuscript. MD drafted the manuscript and provided scientific and methodological input to the study concept.

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**Competing Interests**

FG, FS, JUR and KW incorporated the SHARE TO CARE GmbH (https://share-to-care.de/), to perpetuate the resulting interventions/experiences of this project. This is the decided will of the funding body and has been communicated transparently.

**Ethics Approval**

This study was approved by the Medical Ethics Committee of the Medical Faculty of the Christian Albrecht University (CAU) Kiel, reference number A111/18

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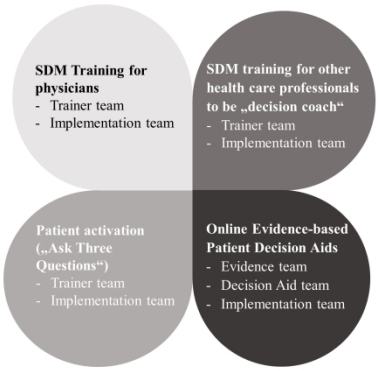


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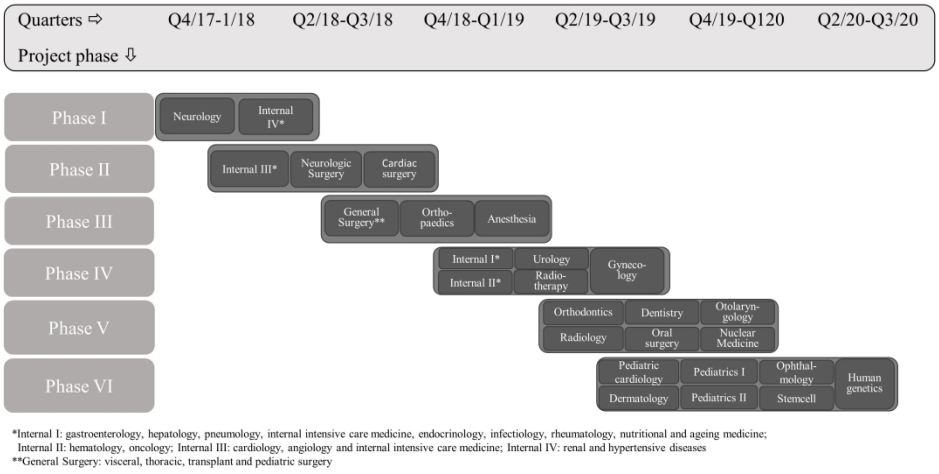


*Internal I: gastroenterology, hepatology, pneumology, internal intensive care medicine, endocrinology, infectiology, rheumatology, nutritional and ageing medicine; Internal II: hematology, oncology; Internal III: cardiology, angiology and internal intensive care medicine; Internal IV: renal and hypertensive diseases
**General Surgery: visceral, thoracic, transplant and pediatric surgery

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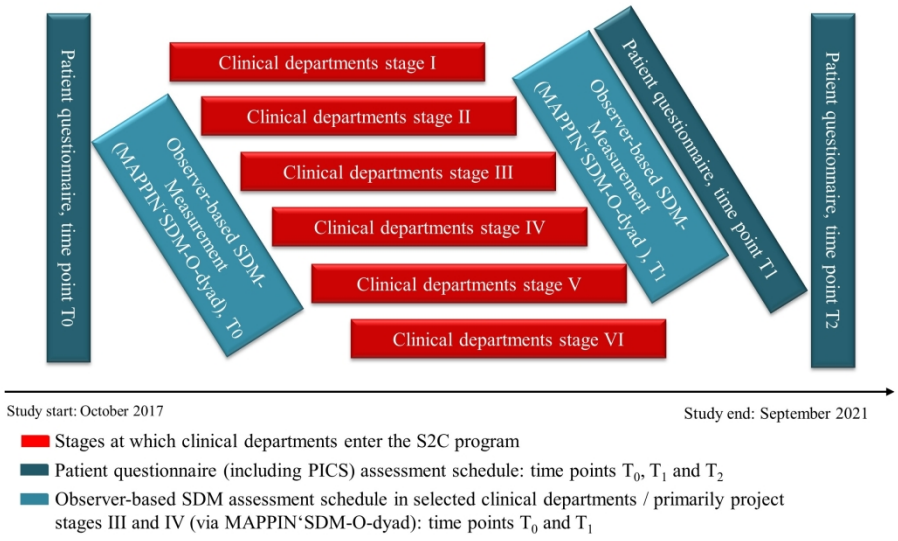


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