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Clinicians and patients perspectives on follow-up care and eHealth support after allogeneic hematopoietic stem cell transplantation: A mixed-methods contextual analysis as part of the SMILe study

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ABSTRACT

Purpose: We report on our contextual analysis's methodology, as a first step of an implementation science project aiming to develop, implement, and test the effectiveness of an integrated model of care in SteM-cell transplantatIon faciLitated by eHealth (SMILe).

Methods: We applied an explanatory sequential mixed-methods design including clinicians and patients of the University Hospital Freiburg, Germany. Data were collected from 3/2017 to 1/2018 via surveys in 5 clinicians and 60 adult allogeneic stem-cell transplantation patients. Subsequently, we conducted 3 clinician focus groups and 10 patient interviews. Data analysis followed a 3-step process: (1) creating narrative descriptions, tables, and maps; (2) mapping key observational findings per dimension of the eHealth-enhanced Chronic-Care Model; (3) reflecting on how findings affect our choice of implementation strategies.

Results: Current clinical practice is mostly acute care driven, with no interdisciplinarity and weak chronic illness management. Gaps were apparent in the dimensions of self-management support and delivery-system design. Health behaviors that would profit from support include medication adherence, physical activity and infection prevention. The theme "being alone and becoming an expert" underpinned patients need to increase support in hospital-to-home transitions. Patients reported insecurity about recognizing, judging and acting upon symptoms. The theme "eHealth as connection not replacement" underscores the importance of eHealth augmenting, not supplanting human contact. Synthesis of our key observational findings informed eight implementation strategies.

Conclusion: Stakeholders are willing towards a chronic care-focused approach and open for eHealth support. The contextual information provides a basis for the SMILe model's development and implementation.

1. Introduction

Advances in transplantation expertise have led to increasing numbers of allogeneic stem cell transplant (alloSCT) survivors (Passweg et al., 2019). Given that 70–90% of alloSCT recipients experience long-term complications, necessitating life-long follow-up, they can be considered as chronically ill (Majhail, 2017). However, their needs are not only biomedical but also psychosocial and behavioral. Besides transplant-related complications such as chronic graft-versus-host-disease (GvHD; 30–70%), endocrine (9–99%), cardiovascular (5–22%), or neurocognitive diseases (20–42%), many also suffer from fatigue (9–70%), depression (8–20%), emotional distress (22–43%), or low

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social support (Beattie et al., 2013; Bevans et al., 2017; Hilgendorf et al., 2015). They also report health behavior challenges including medication non-adherence and physical inactivity, which increase their risk of poor long-term outcomes (Gresch et al., 2017; Harashima et al., 2018; Kirsch et al., 2014). Finally, newly arising co-morbidities both reduce their quality of life and, compared to the general population, increase their risk of mortality within 15–20 years of transplantation by 20% (Battiwalla et al., 2017).

Internationally, transplant centers' resources are strained in view both of the growing number of alloSCT survivors and of their complex long-term needs, particularly concerning self-management support, care coordination and care continuity. As the prevailing care models focus predominantly on detecting and managing acute problems, they mostly lack an integrated care approach (Khera et al., 2017; Majhail and Rizzo, 2013), i.e., one that addresses the entire care continuum-including the noted behavioral and psychosocial dimensions) (Bevans et al., 2017; Dyer et al., 2016).

Integrated models of care are based on the principles of chronic illness management (CIM), of which the Chronic Care Model is the best known (Wagner et al., 1996). The Chronic Care Model (CCM) combines four building blocks: patient self-management support, decision support, clinical information systems and delivery system design. Driven by effective and productive interactions between prepared, proactive practice teams and informed, activated patients, the Chronic Care Model addresses complex care needs with a strong emphasis on patient outcomes. Evidence from other chronically ill populations, e.g., those with diabetes, heart failure or asthma, has demonstrated that care organized following CIM principles decreases mortality, improves health behaviors, social role functionality and treatment satisfaction, and improves economic outcomes (i.e., lower costs, fewer hospital admissions) (Coleman et al., 2009; Davy et al., 2015; Nolte and Pitchforth, 2014). In general, concerning chronically ill populations, the more CCM building blocks of chronic care are implemented, the better the outcomes (Bodenheimer et al., 2002).

In the last years, the CCM has been increasingly powered by eHealth. In 2015, Gee and colleagues conceptualized the eHealth-enhanced Chronic Care Model (eCCM) (Gee et al., 2015). eHealth, i.e., the use of information and communication technology for health, can potentially facilitate the implementation of integrated care models (World Health Organization, 2016). Recent evidence in cancer and solid organ transplant populations highlights the benefits of eHealth-powered care models regarding survival, re-hospitalization rates (Basch et al., 2016, 2017), knowledge (Slev et al., 2016), physical activity (Haberlin et al., 2018) symptom burden (Warrington et al., 2019), medication adherence (Schmid et al., 2017) and overall health care utilization (Kaier et al., 2017). Moreover, in cancer patients using electronic symptom monitoring combined with unstructured nurse support, Basch et al., 2016 showed significantly improved quality of life, fewer re-admissions and improved survival. Still, while a similar care model tailored to the comprehensive care needs of alloSCT-patients would very likely improve their outcomes, none have yet been developed this patient population.

The complexity of an intervention is commonly echoed – or amplified – in its implementation. As a result, the sustainability of eHealth is often suboptimal: studies have reported drop-out rates between 44% and 67% (Jeffs et al., 2016; Simblett et al., 2018; Thies et al., 2017). In fact, only 0.01% of available eHealth applications are sustainably used (IQVIA Institute, 2017). However, combining a user-centered design approach with implementation science methodology has a strong potential to overcome the observed issues with eHealth regarding both uptake and sustainability (Dabbs et al., 2009; Dopp et al., 2019; Peters et al., 2013).

Implementation science "is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care" (Eccles and Mittman, 2006). Specifically, the strength of implementation science lies in its integration of numerous methodological considerations, including stakeholder involvement, contextual analysis or theory driven intervention development (Glasgow et al., 2014).

Successful implementation of and intervention as complex as an eHealth-powered chronic care model begins with a thorough contextual analysis. Informed by multiple sources, including patients, caregivers and clinicians, the implementation team needs a solid theoretical framework upon which to assess and map relevant dimensions and factors that will later shape the project (Davidoff, 2019; Nilsen, 2015). Unfortunately, however, methodological guidance on how to conduct and use contextual analyses is scarce.

One of the theoretical framework to offer meaningful guidance for contextual analysis is the Context and Implementation of Complex Interventions (CICI) framework (Pfadenhauer et al., 2017). This model's principal weakness is that it requires support from another model for such problems as where to position the contextual analysis, and says little about performing systematic, detailed assessments of prospective settings. For this task, the eCCM can guide the assessment of a setting, while helping to operationalize all necessary CIM dimensions (Gee et al., 2015). Therefore, we embedded the eCCM dimensions (self-management support, delivery system design, decision support, clinical information systems and eHealth education) within the CICI framework (Fig. 2). To allow the richest yield of information to map a specific setting in terms of structural characteristics, practice patterns concerning CIM, and openness to technology, we used a mixed methods approach combining quantitative and qualitative methodology for data collection.

This study is the first step of a two-phase, multi-site implementation science project to develop (Phase A), implement, and test the effectiveness (Phase B) of an integrated model of care in allogeneic <u>S</u>te<u>M</u>-cell-transplantat<u>I</u>on faci<u>L</u>itated by <u>e</u>Health (SMILe; see Fig. 1(Leppla et al., 2018)). Reflecting these objectives, this report serves several aims: First, through its detailed description of the methodology underpinning of a contextual analysis, it provides a guideline to map any prospective context for the development of an intervention. Second, by summarizing the findings of the contextual analysis at our first participating center, it fulfills three minor aims: (1) to identify the target organization's structural characteristics and practice patterns in view of chronic illness management; (2) to assess how self-management and behavioral support is currently being supported; and (3) to assess the technology openness of clinicians and alloSCT patients regarding eHealth use along the eCCM dimensions.

2. Methods

2.1. Design and setting

We applied a single-center explanatory sequential mixed-methods design using quantitative (QUAN) and qualitative (QUAL) methods guided by the dimensions of the eCCM. From one sample of clinicians and one of patients, we gathered quantitative and qualitative data. The study was conducted at the 1600-bed University Hospital Freiburg, Germany, one of the largest hospitals in southwest Germany. It was approved by the Ethical Committee of the University of Freiburg (EK 67/17). All participants provided written informed consent before contributing data.

2.2. Clinician sample

The transplant director and a random sample of five clinicians were surveyed, followed by focus-group interviews with 11 clinicians (including those who completed the survey) (Fig. 3). Three criteria determined eligibility for both the survey and the focus group interview: 1) > 6 months' employment in the transplant center; 2) ≥ 50% in direct clinical practice; and 3) familiarity with post-transplant care.

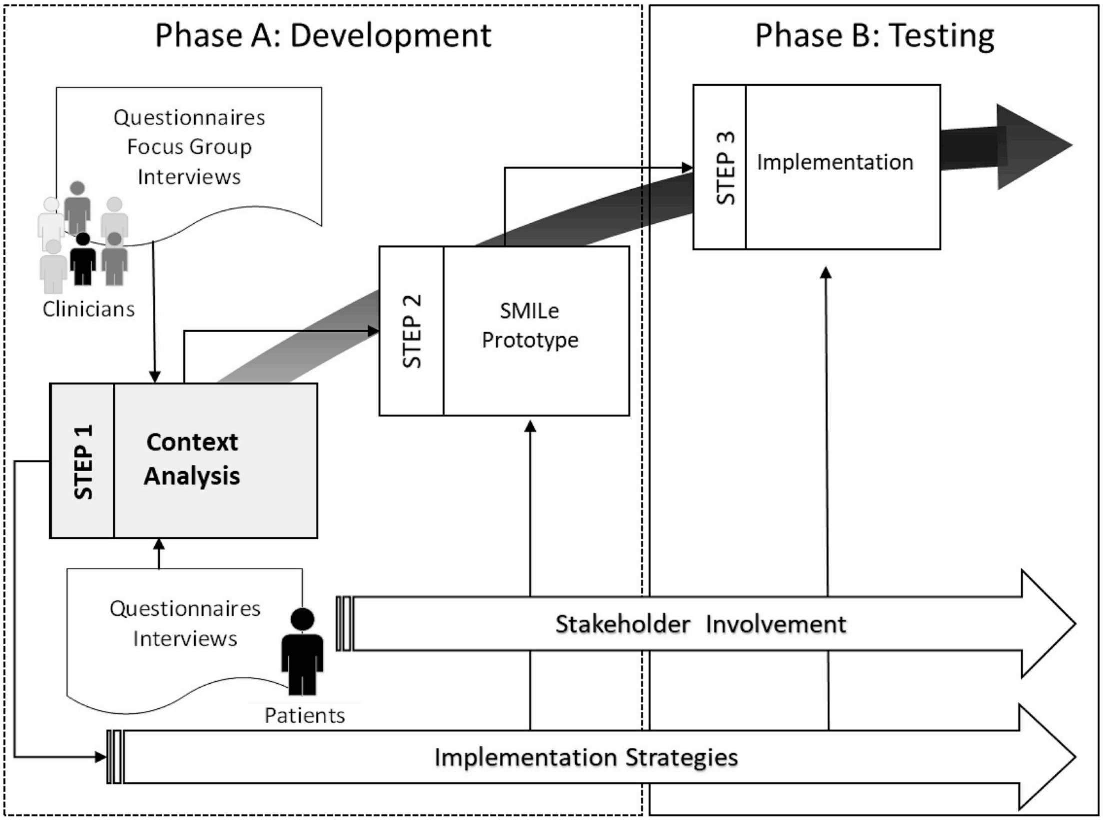


Fig. 1. Overview SMILe project phases and steps.

2.3. Patient sample

We surveyed a convenience sample of 60 alloSCT patients during their regular outpatient clinic follow-up visits. Then, for the individual interviews, using purposive sampling based on age, gender and time after alloSCT, we added 10 who did not participate in the survey. For both samples, inclusion criteria were 1) transplantation and follow-up at the University Hospital Freiburg; 2) ≥18 years; 3) six weeks to three years post-SCT; and 4) ability to communicate in German. Based upon the treating physician's judgment, patients with any cognitive or physical condition that would impair adequate communication were excluded.

2.4. Quantitative variables and measurement

We assessed clinicians' and patients' demographic characteristics via a specially-developed self-report questionnaire. Building on our research group's previous work, we assessed the alloSCT center's structural characteristics, practice patterns regarding CIM, overall CIM level, technology openness (defined as mastery, i.e., patients' technology experience), acceptance (i.e., willingness and confidence to use eHealth), and perceived importance of eHealth for healthcare applications (Berben et al., 2015; Vanhoof et al., 2018). Supplementary Table 1 provides the list of variables, the operational definitions, scoring, aggregation method and psychometric characteristics of the collected variables.

2.4.1. Structural/organizational characteristics of the SCT center

Structural characteristics (the SCT center's organization and size) were assessed by the transplant director using six items from the alloSCT-adapted BRIGHT Transplant Director Questionnaire (Berben et al., 2015; Denhaerynck et al., 2018).

2.4.2. Practice patterns and overall CIM level

Practice patterns were assessed at three levels – transplant director, clinician and patient – using 10 items from the BRIGHT questionnaires (Supplementary Table 1). The level of CIM was assessed from clinicians' and patients' perspectives. Clinicians completed the adapted 55-item CIMI-BRIGHT questionnaire (Berben et al., 2014) which is conceptually embedded in the WHO's Innovative Care for Chronic Conditions framework and operationalized based on the principles of CIM (Nuño et al., 2012). The total score is calculated as the mean of all item scores (range: 1–4), with higher scores indicating higher CIM levels (Berben et al., 2015; Denhaerynck et al., 2018). Patients also completed the 11-item PACIC (patient assessment of chronic illness care). For that, individual item scores are summed (range: 11–55), with higher values indicating higher patient-perceived CIM levels (Denhaerynck et al., 2018).

2.4.3. Current self-management and behavioral support

Additionally, using the 60 BRIGHT study self-report items (see Supplementary Table 1 for its content, scoring and interpretation), patients rated their self-management and health behaviors, as well as the degree of support they received from their team in following their therapeutic regimen.

2.4.4. Technology openness

Patients' technology openness towards the use of eHealth across the various eCCM dimensions was assessed using an adapted 26-item self-report instrument developed by the PICASSO-Tx team (Vanhoof et al., 2017). Two items were added to evaluate patients’ acceptance of symptom monitoring and data sharing with clinicians through eHealth applications (see Supplementary Table 1 for scoring and interpretation).

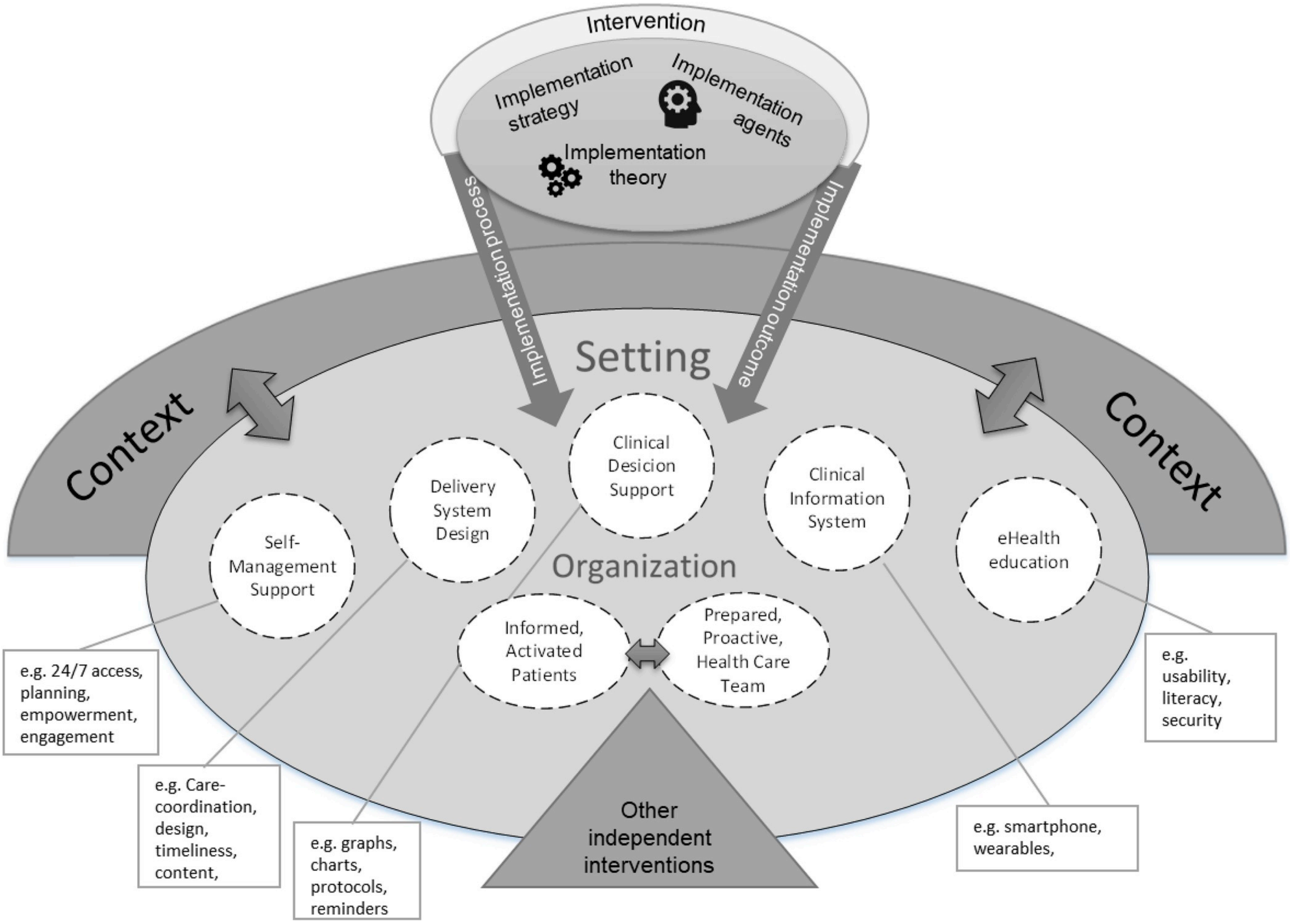


Fig. 2. eCCM embedded within the CICI framework
Mapping the setting of an organization as part of the context where the setting is embedded, by using the eHealth enhanced Chronic-Care Model nested in the Context and Implementation of Complex interventions (CICI) framework. Implementation consists of implementation theory, implementation strategies, implementation agents, implementation process and implementation outcomes which facilitate the implementation into a specific setting.

2.5. Qualitative methods

Guided by the eCCM, we used qualitative methods (i.e., clinician focus group, individual patient interviews) to map out the setting regarding relevant aspects of CIM and technological support. Both individual and focus-group interviews used open-ended questions based on an interview guide following the eCCM dimensions (Gee et al., 2015). AlloSCT follow-up care questions explored self-management-support (e.g., *How do you provide/perceive self-management* support?), delivery system design (e.g., *How do you experience care coordination?*), decision support (e.g., *How certain are your patients/you in making decisions when complications occur?*), clinical information systems (e.g., *What does eHealth mean to you?*), and eHealth (e.g., *What are your experiences with eHealth in* supporting *health or health behavior, what would be helpful?* To facilitate understanding of the “eHealth” concept, a definition and examples of eHealth applications within healthcare were provided. Focus groups and interviews were audio recorded and transcribed.

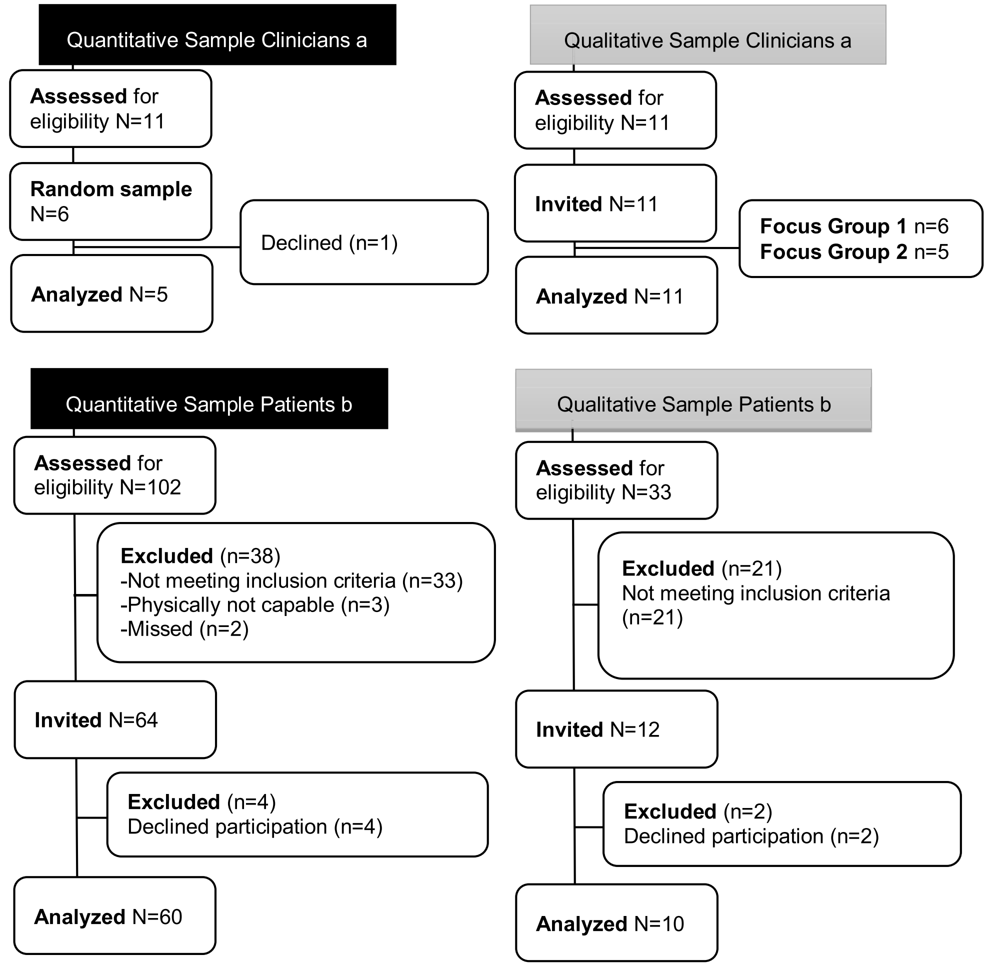
2.6. Study procedures

The clinicians' survey was conducted between end of March and end of April 2017, followed by the focus-group interviews between May and June 2017. The focus groups were led by a research associate (MK) and the first author (LL). From the end of June to the end of July 2017 the electronic health records were reviewed daily by the first author (LL) to identify patients eligible for the patient survey. All those fulfilling the inclusion criteria were asked to participate. From August 2017 to end of January 2018, the electronic scheduler was reviewed once weekly to identify eligible patients for the qualitative interviews. Individual interviews were conducted by one researcher (MK), in a separate clinic room, immediately after the subject's outpatient visit.

2.7. Data analysis

As this study was intended to be the basis for an implementation science study through an eCCM-guided contextual analysis, we will report our findings with the goal of making the invisible visible. Our data analysis process followed a three-step process. First, we developed descriptive tables for the QUAN data, using narrative descriptions and a meta-map for the QUAL eHealth support data (Supplementary Tables 2, 3, 4, Fig. 1). For this purpose, quantitative data were analyzed descriptively, using appropriate descriptive statistics as appropriate for data measurement levels and distributions (means, SDs, medians, IQRs, frequencies). After calculation of the total CIMI-BRIGHT and PACIC scores, Likert Scales were dichotomized (often and almost always = yes) and proportions for each variable displayed based on total N per question, sorted by eCCM dimension. Analysis was done using SPSS 24.

Qualitative data were analyzed using two methods. For the clinician focus groups, mind-mapping was used (Burgess-Allen and Owen-Smith, 2010). This method allows an ongoing discussion on the evolving map,



Note: ^{a}= same sample; ^{b}=different sample

Fig. 3. Sampling procedure of clinicians and patients.

to which emerging themes can be added. Once data collection was completed, mind maps of each focus group were merged into a single meta-map. The individual interviews with patients were transcribed verbatim and imported into MAXQDA (VERBI Software) by a research associate (MK). Data were iteratively analyzed and discussed according to Braun and Clarke's six thematic analysis steps: familiarization with the data, generation of initial codes, searching for themes, reviewing themes, defining and naming themes, and writing the report (Clarke and Braun, 2014). The deductive analysis followed the eCCM dimensions and was accompanied by meaningful quotes from the patient interviews.

Second, we mapped all key contextual findings – both QUAN and QUAL – according to the corresponding eCCM dimensions, side by side within a joint display. This led to a synthesis and implications regarding the first SMILe prototype. The third and final step included reflection on how the synthesized findings could inform the choice of implementation strategies most appropriate for the target context.

3. Results

We conducted 3 clinician focus-groups (N = 11; mean duration 56 min (SD 11 min)) and ten individual patient interviews (N = 10; mean duration 71 min (SD 22 min)). Table 1 provides detailed information on the clinicians' and participants' demographic characteristics; Table 2 shows the identified key contextual QUAN and QUAL findings regarding the organization's structural characteristics, practice patterns and technology openness – mapped according to their corresponding eCCM dimensions and relevance for intervention development, presented within a joint display.

3.1. *Structural characteristics of the allo-SCT center*

The University Hospital Freiburg, located in southern Germany, has 18 beds allocated to alloSCT. Germany's compulsory universal health insurance covers most alloSCT costs. The hospital started its transplant program in 1989 and now performs around 100 adult alloSCTs annually. The outpatient clinic follows up 800–1000 alloSCT patients – accounting for about 3000 visits – per year.

3.2. *Practice patterns and CIM level*

At transplantation, patients are hospitalized a mean of 35 days (5 weeks). After the stem cells have engrafted, and peripheral blood values and general physical condition are stable, patients are discharged. After leaving the transplant center, most attend a 3-week inpatient rehabilitation program. Patients return for follow-up 1–2 times per week for the first 3 months, then monthly until 6 months post-SCT. Provided their condition remains stable, follow-up intervals gradually increase to once yearly after five years. Facilitating continuity of care, each patient is usually assigned the same attending physician, each of whom has a fixed consultation day. In the event of complications, patients are instructed to call the outpatient clinic or emergency room directly. As the current follow-up model focuses primarily on medical aspects of alloSCT, with no structured self-management or behavioral support and

Table 1
Clinicians and Patients demographics of quantitative (QUAN) and qualitative (QUAL) samples.

Clinicians		QUAN	(N = 5)	QUAL	(N = 11)
Sex; n (%)	Male	2	(40%)	5	(45%)
Age; Mean (SD) /range		45.6 31–58	(10)	47.8 30–61	(17)
Physician		3		6	(55%)
Registered Nurse		2		5	(45%)
Working experience (median years/ range/IQR)		21 20.5	4–34	17.5 11.5	2–25
Patients		**QUAN**	**(N = 60)**	**QUAL**	**(N = 10)**
Sex; n (%)	Male	36	(60)	6	(60)
Age; Mean (SD) /range		52 21–76	(15)	50.2 21–75	(16)
Time after alloSCT; Mean (SD)/ range	(months)	15.8 3–36	(9.7)	16.5 2–36	(13)
Marital status; n (%)	Single	12	(20.0)	2	(20)
	Married/living with partner	41	(68.3)	8	(80)
	Divorced/ separated	5	(8.3)		
	Widowed	1	(1.7)		
	Missing	1	(1.7)		
Highest educational degree; n (%)	Primary school	8	(13.1)	1	(10)
	Secondary school	10	(16,3)	3	(30)
	Apprenticeship	25	(42.5)	5	(50)
	University degree	15	(25.0)	1	(10)
	Missing	2	(3.1)		
Employment; n (%)	None	37	(61.7)	9	(90)
	Part time	5	(8.7)	1	(10)
	Full time	13	(21.7)		
	Missing	5	(7.9)		
Reason for no employment; n (%)	Student	2	(3.4)	1	(10)
	Unable to work (temporarily)	19	(31.6)	5	(60)
	Retired	18	(30.0)	3	(20)
	Missing/ double/not applicable	21	(35.0)	1	(10)

Note: alloSCT = allogeneic hematopoietic stem cell transplantation.

no nurse interventions, clinicians describe it as mainly physician-centered. Clinicians spend a mean of 19 min (SD 8.5 min) with each patient per visit. No routine formal psychiatric, psychological, social or financial evaluation is performed before or after alloSCT.

As clinicians frequently gave conflicting answers, their CIM ratings showed high variability (overall mean CIMI-BRIGHT score: 2.74, possible range: 0–4, SD 0.41). Fifteen critical items showed CIM deficits, i.e., < 50% positive responses. These related to four of the five CIM dimensions: self-management support (8 items), followed by delivery system design (3 items), clinical decision support (3 items) and use of clinical information systems (1 item) (see Supplementary Table 2 for details).

Patients (N = 60) reported spending a mean of 22 min (SD = 11.7) with their transplant team at each follow-up appointment. The mean overall patient-perceived CIM rating was 32.6 (range: 11–55, SD: 10.8) (see Supplementary Table 3 for details).

3.3. Current self-management and behavioral support in view of CIM and technology openness, by eCCM dimension - QUAN and QUAL results

3.3.1. Dimension of self-management support: clinicians

According to our QUAN results, 75% of clinicians report not having enough time to support patients with their self-management, with 67% of clinicians feeling unable to discuss with patients how they manage their treatment plan or specific self-management behaviors (see Supplementary Table 2 for details). In the focus groups, clinicians noted that adequate physical activity, application of infection prevention measures, and excellent adherence to immunosuppressive medication is crucial for long-term outcomes; however, they frequently see patients who struggle to perform these behaviors. Patients' insecurity regarding recognizing, judging and acting upon new symptoms was deemed the most crucial problem. Clinicians explained that, as fear of re-hospitalization frequently causes patients to report new symptoms too late for timely treatment adaptions, they see eHealth as a valuable tool to support patients in assessing, interpreting and acting upon their symptoms. For example, using eHealth to monitor symptoms, complications such as GvHD could be detected earlier and better controlled. Further, they acknowledged a role for eHealth in supporting health behaviors such as medication adherence or physical activity. Concerns included the lower reliability of patient-reported symptoms and the possibility that some patients would find eHealth use burdensome (Supplementary Fig. 1).

3.3.2. Dimension of self-management support: patients

The questionnaire responses revealed that 78% of patients struggled in performing adequate physical activity and had problems adhering to their immunosuppressive regimes (e.g., 21.6% at least occasionally forget to take them). Having nobody to help them read health-related information was reported by 45.8%; and 18.6% did not understand the written information provided. Overall, 73.4% reported not being asked how alloSCT affects their daily life; and only 12.7% received treatment plans tailored to their daily life. Just over 69% would be open to try new technologies; and 56.2% would like to receive electronic feedback supporting positive health behaviors (Supplementary Table 3).

"*Being alone – and becoming an expert*" was a major theme within the eCCM dimension of *self-management* support. Patients described the transition from full support to weekly visits as the most distressing treatment phase: *"The attendance by medics and staff is excellent. But then – pow! – it ends and you're left all alone"* (male, 60–70 years, 6 months post-SCT). In their first 6 months post-alloSCT, all patients experienced several physical limitations, often including tiredness or exhaustion. Even simple activities (e.g., showering, cooking, brushing teeth) were perceived as burdensome and demanding. They further expressed a need for additional information and more emotional, physical and social support to master the demands of post-SCT life. Most also commented that they were unable to adapt the information provided during their inpatient stay to life at home. This led to wishes for increased self-management support regarding infection prevention measures, medication intake, assessment of and appropriate reactions to changes in symptoms, long-term outcomes, possible courses of therapy and follow-up. To overcome these knowledge deficits, patients bought books, asked their peers or sought information on the internet, but for some, it was difficult to identify trustworthy and valid information via internet searches.

Unfortunately, the copious information available online often *"doesn't help at all and that would make you mad. Too much information" (male, 60–70,* 36 months *post-SCT)*. However, patients mentioned not daring to ask for support or information, assuming that the attending physicians' schedules would be too busy: *"No. No, that's difficult with … the senior physician. … Well, he's got a tightly synchronized day even without me. And I think that he'd barely be available for patients outside of consultation hours" (male, 50–60 years,* 24 months *post-SCT*).

Patients felt especially insecure in recognizing and evaluating new symptoms: *"No idea what's relevant and what's not" (male, 40–50 years,* 3 months *post-SCT)*. When concerned, some patients immediately contacted a physician; some waited for their next scheduled appointment; and some, fearing re-hospitalization, never reported their concerns. Overall, then, the prospect of 24–7 at-home technological support to assess and judge the severity of symptoms was considered useful. *"Yes*

Table 2

Joint display of the key contextual observations from clinicians and patient's perspective: structural characteristics and practice patterns in view of CIM including level of CIM at organizational level and within the eCCM dimensions (self-report on self-management/health behavior and perceived support; technology openness).

		Transplant Director & Clinicians		Patients		Synthesis & Implications for Intervention
		QUAN	QUAL	QUAN	QUAL	
Organizational level		− 3800 follow-up visits per year - no interdisciplinarity - inconsistency how clinicians evaluate care processes - CIMI BRIGHT score of 2.74 - existing electronic records - no system available to monitor pts. at home	- one attending physician per working day - nutritional counseling before discharge - clinicians state that guidelines are available and used in clinical practice	PACIC score of 32.6	perceive that physicians are tightly scheduled	- gaps in CIM as no interdisciplinarity - low to mid level of CIM The intervention should facilitate interdisciplinarity following the principles of CIM
Self-Management support (SM-S)	***Practice Pattern***	**33% of clinicians** - check if pts. are dealing effectively with treatment plan - asks pts. on their SM efforts - review pts. SM performance - follow-up after new SM goal - assess individual concerns or goals **25% of clinicians** - have time for SM-Support - refer to community services helping to self-manage care at home - works directly with these agencies	- physical activity, infection prevention, adherence to immunosuppressive medication are most important health behaviors - clinicians observe that pts. struggle with being physically active, adhering to infection prevention measures and prescribed medication - structured SM support is limited to inpatient time - some physicians already use simple, unstructured behavioral interventions (e.g. reminder system for medication intake) - clinicians are satisfied with own availability for pts. - clinicians observe insecurity of pts. in recognizing judging and acting upon symptoms	- **78% of pts.** are not adequately physically active - reported various problems of taking immunosuppressive medication as prescribed (e.g. 21% forget to take them) - **45.8% of pts.** have nobody helping to read health related materials - **18.6% of pts.** have problems to understand health-related information - **pts.** Health literacy of **3.41** - **38.9% of pts.** were given choices about treatment - **35.1% of pts.** were asked how alloSCT affects their life - **26.6% of pts.** were asked about health behaviors - **16.3% of pts.** received help to plan ahead - **15% of pts.** were encouraged going to self-help group - **12.7% of pts.** received a treatment plan fitting to their daily life	***"being alone- and becoming an expert"*** - expressed a need for more informational, emotional and physical support - felt physically exhausted - follow-up reduces anxiety as pts. know that everything is alright - would like SM-S regarding infection prevention, medication intake, symptom assessment and management - became experts over time in managing symptoms	Congruency between clinicians and patients about gaps in SM-Support The intervention should include structured behavioral, psycho-social and self-management support elements, building on principles of CIM. i.e regarding: Medication adherence, Infection prevention, physical activity, symptom recognition. Congruence between clinicians and patients about benefits of technology to promote health behavior or symptom monitoring and management.
	Technology Openness		- see potential support medication adherence and physical activity by technology - technology could empower pts.	−**69.1% of pts.** Try out new technologies −**63.7% of pts.** easily get used to new technologies **56.2% of pts.** would like to get electronic feedback to promote favorable health behavior or on symptom development	-would benefit from a monitoring element supervising medical, behavioral and symptom related signs combined with information platform to support symptom recognition	
Delivery System Design	***Practice Pattern***	**25% of clinicians** - are given incentives for effective clinical processes and improved outcomes **20% of clinicians** - state that the SCT follow-up team is based on interdisciplinary team care **0% of clinicians**	- clinicians are satisfied with own continuity of care - clinicians state that there are long waiting times	- pts. spend in mean **22 min** with transplant team at follow-up - **93%of pts.** are satisfied how care is organized	***"having someone accompanying me"*** - pts. describe transition phase as most distressing, felt left alone - felt challenged by managing household and coordinating appointments - depict the need for a more easy reachable and accompanying person	Dis-congruency as clinicians are satisfied and pts. perceive gaps in chronic care delivery. Pts. state a need for an easy reachable person. Continuity of care could be realized by eHealth powered integrated care model with care-coordination. Technology can be used to power an

(*continued on next page*)

Table 2 (*continued*)

		Transplant Director & Clinicians		Patients		Synthesis & Implications for Intervention
		QUAN	QUAL	QUAN	QUAL	
		- state that there is a specific long-term care-coordinator				integrated care model and connects pts. Virtually to the SCT-center.
	Technology Openness		- electronic guideline reminders (e.g. vaccination, bone marrow biopsies) would be helpful - electronic monitoring of pts. to identify complications early	− **70.4% of pts.** would use a health application from the hospital, − **61.7%** on own smartphone - With a **mean of 8.05, pts.** state that it is important to develop new technologies supporting health behaviors	- technology would need to be connected to a person within the transplant center to increase acceptance	Technology part needs to be provided by the hospital.
Clinical Decision Support		***Practice Pattern***	**25% of clinicians** − state that the information system is used to give feedback to individual clinicians − state that the information system gives feedback about quality of care/ areas of improvement **0% of clinicians** − state that the information system flags pts. when overdue for follow-up	− Clinicians observe problems in adherence with recommendations		− describe insecurity in recognizing and judging upon new symptoms when discharged − would benefit from decision support when to contact the transplant center
Technology Openness	Congruency in the perception of insecurity in recognizing, judging and acting upon new symptoms. Congruency that technology could support recognizing, judging and acting upon new symptoms. SMILe should include feedback loops allowing to empower patients and visualization over time for treatment decisions by clinicians		- state that pts. would benefit from technology support in interpreting their symptoms - electronic symptom monitoring would help identify complications in the home setting - concerns that pts. could feel overwhelmed by entering data or dealing with technology		- Technology could support symptom assessment and decision making how to act upon	
Clinical Information System	***Practice Pattern***	**0% of clinicians** - state that the information system is used to monitor pts. at home	- work with electronic medical records	− **55% of pts.** are confident in filling in medical documents		Congruency that technology needs to be connected to a person in the Tx center, overviewing incoming data and judging when a physician needs to be involved.
	Technology Openness		- express a need for interoperability the new technology with existing systems in the hospital - they would need a person looking at incoming values and decide when a physician needs to be included. They cannot invest more time	− **47% of pts.** would send data upon request −**63% of pts.** would be willing to share their data with clinicians and -**57.2% of pts.** would feel more secured − **47% of pts.** would use step	***“eHealth as connection not replacement”*** − technology should be connected to a person within the hospital and located in the clinic information system − should also display lab values	Interoperability as important factor for acceptance of technology. Technology should connect end- users and be integrated in existing systems.

(*continued on next page*)

Table 2 (*continued*)

		Transplant Director & Clinicians		Patients		Synthesis & Implications for Intervention
		QUAN	QUAL	QUAN	QUAL	
			- see benefit of timeliness data availability	counters − **40% of pts.** would use electronic symptom monitoring		
eHealth education	***Practice Pattern***		- Not familiar with technology monitoring patients- - technology should not replace human contacts		- technology as additional element in follow-up care, - it should not replace human contacts	Congruency that technology should not replace human contacts A technology-delivered model of care needs to include both, human aspects and technology. Congruency that a User-Centered Design is crucial.
	Technology Openness		state that good usability of a new technology is important	− **86% of pts.** Have WLAN **-78.3% of pts.** Own a smartphone − **97.9%** will also use it in future	- patient were open towards eHealth - good usability of the technology is needed	

Note: CIM = chronic illness management; SM-M = self-management support; pts. = patients, SMILe = integrated model of care for allogeneic SteM cell transplantatIon faciLitated by eHealth.

that would help me decide whether or not to come immediately" (female, 20–30 years, 3 months *post-SCT)*. Most said they would find a monitoring element helpful to track medical, behavioral or symptom-related signs, combined with an information platform to support symptom recognition or health behaviors, e.g., listing *"immune response[s] or other reactions such as a rash … and how to respond to … [them]" (female, 40–50 years,* 5 months *post-SCT)*.

Patients were also challenged in managing their households, coordinating their appointments and following the instructions concerning medication taking or regular physical activity "*I had many appointments, when I was back home … family practitioner, physiotherapist, outpatient clinic … and my children. I was so completely done and weak that it turned out to be a huge challenge. You see your day planner and you feel that you are too weak to manage … you need to be careful with your energy" (female, 30–40 years,* 5 months *post-SCT)*.

The longer patients had to manage their post-SCT symptoms and self-management tasks, the more they felt their expertise growing. And as their experience and knowledge increased, they gained confidence assessing and managing their symptoms: *"You kind of get a feeling of whether you should give them a call or not, because I always had so many adverse effects" (female, 20–30 years,* 9 month*'s post-SCT)*. Additionally, by one year post-transplantation, increased physical stamina and decreased self-management demands resulted in reduced support needs.

3.3.3. Dimension of delivery system design: clinicians

Of the five clinicians who completed questionnaires, four noted that no interdisciplinary team approach had been implemented and that no long-term care coordinator was available (Supplementary Table 2). The focus group interviews revealed that, to facilitate continuity, participating clinicians (N = 11) always try to ensure that patients are followed up by the same physicians. They would see an eHealth support system that enabled clinicians to monitor their patients from a distance *"as a long leash to the transplant center"*, but that at the same time would allow for risk-adjusted individual follow-up (Supplementary Fig. 1).

3.3.4. Dimension of delivery system design: patients

Regarding delivery system design, the questionnaire data showed that 93% of patients are satisfied with care organization and 70.4% would be open to use an eHealth application provided by the hospital (Supplementary Table 3). In the qualitative interviews, the theme of *"having someone accompanying me"* emerged in this eCCM dimension. Patients perceived follow-up as important and described it as a source of reassurance in terms of infection and disease control. Extending intervals between follow-up visits intensified anxiety and concerns: *"This time, during the three weeks, my head was rather preoccupied with whether everything was okay" (female 60–70 years,* 6 months *post-SCT)*. Although they felt well cared-for during outpatient visits, they voiced a need for an easily reachable, trustworthy professional familiar with their individual situation able to support them via technology: *"Just someone who accompanies you a bit on that path" (male, 50–60 years,* 4 months *post-SCT)*. Several patients expressed a wish to have their relatives more involved in their follow-up care, as many had difficulty understanding their conditions and challenges, leading to emotional conflicts that burdened their partnerships: *"I was just done when I got home from the stem-cell transplantation. And my wife couldn't understand. … Only after she'd talked to a medic did I realize: now something's changed "(male, 40–50 years,* 3 months *post-SCT)*. Yet, patients also realized that their relatives also had to handle additional worries and burdens.

3.3.5. Dimension of clinical decision support: clinicians

The QUAN results showed that, although the team was already working with electronic health records (100%), the system did not flag patients who were overdue for their appointments; nor did it provide feedback about the quality of care provided (75%, Supplementary Table 2). In the focus groups, clinicians agreed that, by facilitating faster and better-targeted follow-up, remote electronic patient monitoring would support both diagnostic and treatment decisions (Supplementary Fig. 1).

3.3.6. Dimension of clinical decision support: patients

No quantitative questions in the used questionnaires addressed the dimension of clinical decision support. Regarding the qualitative results, those concerning symptom recognition, judgment and decision support overlap those of the self-management support dimension.

3.3.7. Dimension of clinical information system: clinicians

All clinicians confirmed the absence of any system to monitor patients at home. In the focus groups, they appreciated the potential benefits of such a system, particularly to provide remote health data (see also the dimension of self-management support), but highlighted the importance of interoperability with existing electronic systems. Clinicians emphasized that they cannot invest additional time learning a new system. They agreed that, in addition to fulfilling the need for a trustworthy professional to monitor and screen incoming data, a nurse-counselor would also be able to identify potential threats and provide triage (Supplementary: Table 2, Fig. 1).

3.3.8. Dimension of clinical information system: patients

About 63% of patients surveyed would be willing to share their health data with the transplant team. Of these, most (57.2%) believed this would increase their feeling of security. In total, 70.4% would use a health application provided by the hospital. However, in the qualitative interviews, the theme of *"eHealth as connection not replacement"* underpinned the role of eHealth as a supplementary tool, not something to replace human care. The principle that human contact remains crucial in follow-up care is very strong, especially among the more recently transplanted patients: *"You still have an unpleasant feeling about that [symptom] and want to see the doctor in order to know that everything's alright" (female, 20–30 years,* 3 months *post-SCT).*

In general, patients were open towards the idea of eHealth support: in the interviews nine out of ten rated eHealth support in alloSCT follow-up care as positive: *"… I'd be positive if something like that [technological* support*] existed" (male, 50–60 years,* 24 months *post-SCT).* They also expressed a wish for functionalities such as a lab value diary, their current medication plan and a calendar to display upcoming outpatient appointments, diagnostics or vaccinations. Fewer than half would use stand-alone step counters (47%) or electronic symptom diaries (40%); however, if connected to the hospital and able to share data with clinicians, on a scale from 0 to 10, their mean rated value of such new technologies was 8 (Supplementary Table 3).

3.3.9. Dimension of eHealth education: clinicians and patients

For clinicians, not only would the technology have to be highly useable/intuitive, but above all it should never be seen as a replacement for human contact (Supplementary Fig. 1). As all patients (N = 58) owned at least one computer-enabled electronic device – a smartphone being the most common (78.3%) – the prevalence of technology experience was 100% (Supplementary Table 4). In order to support uptake and use of an eHealth technology, patients believed any new eHealth application would also require a user-friendly design: *"Well yes. You don't want to break off your fingers. Well, in this phase the eyes are dry, your motor function is limited. So, it needs to be simple to use "(male, 50–60 years,* 24 months *post-SCT).* Conversely, usability issues such as a non-intuitive interface, the use of medical terminology and a lack of data protection standards were all noted as barriers to technology use.

3.4. Contextually informed implementation strategies

Based on our synthesis of the key contextual findings, we choose eight of the Powell et al.'s 73 recommended implementation strategies (Powell et al., 2015) to facilitate the first implementation of our proposed eHealth-powered model of integrated care in a transplant center. For instance, combined with its lack of interdisciplinarity, this context's low level of CIM may call for the creation of new clinical roles (e.g., integration of advanced practice nursing roles) or revision of existing roles to provide the needed self-management and behavioral support, which in turn will demand further strategies, e.g., to access the necessary funding (see Table 3 for all chosen strategies). By evaluating the outcomes and processes of usual care and collecting stakeholder opinions within this contextual analysis, we have already applied one important implementation strategy – that of conducting a local needs assessment. The findings of the contextual analysis clearly indicate a need both to devise further implementation strategies and to tailor those strategies to the target context (Table 3).

4. Discussion

Although eHealth-delivered integrated care models are emerging in chronically ill populations, none yet exist, to our knowledge, in the alloSCT setting. This mixed-method study focused on the methodology of a contextual analysis prior to implementing of an eCCM-based integrated care model within our setting. This report demonstrates how that analysis can inform not only our content and development processes but also our choices regarding implementation strategies.

Most studies reporting on contextual analysis focus exclusively on facilitators and barriers of implementation. Few are embedded in theoretical models and even fewer use mixed-methods techniques or combine theoretical underpinnings (Best et al., 2019; Li et al., 2018; Urquhart et al., 2014). To our knowledge, the presented method – combining implementation science theory with a clinically relevant model (the eCCM) to illustrate each step of our setting-specific contextual analysis – has not been described before. Reflecting both our insights concerning this composite methodology and on our results, the report offers valuable guidance on how to approach an implementation science driven intervention development.

As an in-depth contextual analysis represents a considerable investment of resources, especially time, interventions are commonly implemented with no formal assessment of how they will fit the target context (Lyon and Bruns, 2019). This impacts sustainable implementation (Slater et al., 2017) leading to limited adoption or early de-implementation (Thies et al., 2017). To be clear, it cannot be assumed that any complex intervention – and certainly not one as complex as a care model – can easily be implemented into daily clinical practice (Glasgow et al., 2014). Successful implementation methodology supports translation from the controlled context of a trial to a comparatively chaotic, resource-competitive clinical setting (Chambers et al., 2013). So while poor adoption of potentially beneficial eHealth interventions into chronic illness contexts reflects a lack of perceived benefit, it also reflects developers' failure to tailor their solutions specifically to their target populations (Slater et al., 2017). Successful implementation of interventions in complex settings, e.g., a healthcare system, demands a comprehensive knowledge of the target context. However, especially regarding self-management and eHealth support expectations, different chronic illness populations' needs and abilities vary widely (Huygens et al., 2016). In response to that variation, the marriage of implementation science methods to user-centered design processes is a dynamic match: implementation science calls for and guides contextual analyses; following user-centered design principles, developers can tailor the potential solution to the stakeholders' needs and preferences.

4.1. Clinicians and patients perspective on practice pattern in view of CIM

High congruence between our clinicians' and patients' perspectives on CIM practice patterns resulted frequently in similar statements. Both groups saw the widest gaps in the most important dimensions – self-management support and delivery system design. However, concerning the latter, while clinicians were satisfied with care organization and

Table 3
How the synthesis of the key contextual observations (Table 2) informs possible implementation strategies.

	Synthesis	Implementation strategies
SM-S	Congruency about gaps in Self-Management Support and benefits of eHealth support.	• **Obtain and use patients/consumers and family feedback** Use data of contextual analysis to re-engineer the current model of care.
DSD	Dis-congruency between clinicians and pts. in terms of current care model. Low levels of CIM, indications that there are gaps in chronic care delivery. Pts. state a need for an easy reachable person. Continuity of care could be realized by eHealth powered integrated care model with care-coordination connecting pts. to the SCT-center. Technology part needs to be provided by the hospital.	• **Conduct educational meetings** Inform and educate clinicians and other relevant stakeholder about pts. feedback. • Conduct local consensus discussions Discuss how dis-congruence can be overcome, give feedback on CIM levels • Create new clinical teams As physicians are tightly scheduled with > 3000 visits per year, the current follow-up care team can be expanded by new roles (e.g. APNs) to allow more interdisciplinarity. • Revise professional roles Assess if available nurses can be further developed to advanced roles and included in the follow-up of alloSCT pts. Providing structured behavioral and SMS interventions are a core competency of nurses. • Develop educational materials Advanced Nurses involved in follow-up care need protocols which interventions need to be delivered and when. • Access new funding Access new funding to allow role revisions and development of new clinical teams. • Obtain and use patients/consumers and family feedback Use data of contextual analysis to re-engineer the current model of care. And design content of technology.
CDS	Congruency in the perception of insecurity in recognizing, judging and acting upon new symptoms. Congruency that technology could help to overcome these deficits.	• **Conduct local consensus discussions** Clinicians need to be involved and find a consensus when designing a technology supporting symptom assessment; rating and decision support what to do. • Develop educational materials A protocol guiding the decision upon symptoms, needs to be developed based on the consensus decision from clinicians to guide the technology development.
CIS	Congruency that technology is connected to a person in the Tx center Interoperability as important factor for acceptance of technology.	• **Create new clinical teams** As physicians are tightly scheduled, the current follow-up care team can be expanded by new roles (e.g. APNs) to allow eHealth driven care-coordination • Inform local opinion leaders Constantly inform and include different stakeholders at higher levels (e.g. transplant director, director of clinical data center, nursing director) to facilitate acceptance and option of interoperability.
eHed	Congruency that a User-Centered Design is crucial. An eHealth-delivered integrated model of care needs to include both, human aspects and technology.	• **Obtain and use patients/consumers and family feedback** Use data of contextual analysis to design technology and apply a user-centered design process with ongoing usability tests to obtain continuous feedback. • Create new clinical teams As physicians are tightly scheduled, the current follow-up care team can be expanded by new roles (e.g. APNs) to allow eHealth driven care-coordination

Note: SM-M = self-management support; DSD = Delivery System Design; CDS = Clinical Decision Support; CIS = Clinical Information System, eHed = eHealth education.

provision, patients experienced gaps in care delivery, leading to unmet needs. This disagreement might have resulted from different perspectives regarding daily life support needs. Our mean PACIC and CIMI BRIGHT scores (respectively 2.74 and 32.6) were low compared to those from solid organ transplant centers (Denhaerynck et al., 2018) indicating that investment is needed to improve CIM to a clinically meaningful level. As evidence also shows that the more CCM dimensions are addressed, the better the outcomes (Bodenheimer et al., 2002; Nuño et al., 2012) it may also be necessary to focus more on those.

Our results also confirm previous findings that alloSCT-patients' support needs are highest in the first months post-transplantation, while they adjust to the transition from in-to outpatient care (van der Lans et al., 2017). Despite frequent outpatient appointments, both clinicians and patients described CIM gaps regarding self-management or behavioral support: both noted patients' problems recognizing, judging and acting upon new symptoms, inadequate physical activity, medication non-adherence and problems with infection prevention measures in the early months post-discharge, i.e., following discharge, this population needs more support to gain confidence and expertise, particularly regarding symptom management.

4.2. Clinicians' and patients' perspectives on eHealth support

Clinicians mainly described potential benefits of using technology to support health behaviors and to monitor early signs of complications. They also reported concerns regarding both human replacement and the lack of additional resources to monitor electronically collected data.

While most patients were already quite familiar with technology, a slight majority of 52% stated that, while technologies such as activity trackers were associated with the hospital, which increased their perceived importance, they would be unwilling to use them as stand-alone devices. Patients also expressed the fear that technology would replace human contacts. As noted above, and as was observed in a previous study in cancer patients (McCann et al., 2009), uptake and use of an eHealth-powered care model will demand easy, direct access to a trustworthy professional within the transplant center. Electronic symptom monitoring was perceived as helpful in managing symptoms and patients felt more secure knowing a person would be watching over them, i.e., the human component remained a vital element. In support of this principle, Mooney et al. (2017) reported better outcomes when combining electronic symptom monitoring with nurse practitioner interventions. They concluded that a technology's efficacy and success depends largely on its link to timely and personal health care provider responses. Without that link, it is unlikely that a stand-alone technology that covers only one dimension of eCCM – as this does – could adequately support highly burdened cancer or alloSCT patients.

4.3. Implications for the first SMILe prototype and potential implementation strategies

Our contextual analysis provided information essential to the intervention elements of the first eHealth-delivered integrated care model for alloSCT patients (Table 2). As the current system's CIM level require improvement, structured behavioral, psychosocial and self-management elements building on the principles of CIM should be included (Bodenheimer et al., 2002). Our results show that interventions are needed for medication adherence, infection prevention, physical activity and symptom recognition.

While eHealth can meet these needs, while improving continuity of care and allowing remote patient monitoring between clinic visits, it cannot replace human interaction. Physicians' tight scheduling prevents them either from delivering structural self-management and behavioral support interventions or from monitoring eHealth systems. However, as these types of interventions typically involve nursing competencies, advanced practice nurses would be ideal to deliver most or all needed support within an integrated interdisciplinary care approach.

This study has several limitations. First, while our samples provided us with relevant information, they were rather small. Second, resource limitations precluded home visits, which might have provided a broader understanding of patients' post-alloSCT situations. As Vanhoof et al. (2018a) gained rich insights into patients' needs by conducting contextual in-home interviews, future studies should consider using this method. Further, the lack of a gold standard methodology for contextual analyses including QUAN and QUAL methods indicates a clear need for future research. Therefore, based on previous work by Stange and Glasgow (2013) we are currently developing the Basel Approach for Contextual Analysis (BANANA). Building on to perform a contextual analysis consisting of following steps (1) choice of a theoretical framework underpinning analysis of context and a setting specific theory for increased granularity; (2) use of available empirical evidence on relevant contextual information; (3) involvement of multilevel stakeholders; (4) collection and analysis of data by applying mixed methods; (5) determine contextual and setting factors' relevance for implementation strategies, outcomes and intervention co-design; (6) publication of findings of contextual analysis by using appropriate guidelines (Mielke et al., 2019).

This study's greatest strength is its comprehensive method-driven approach to mapping out the target setting before beginning development of a care model. This allows development of a setting-specific prototype and strategies to support sustainable implementation in clinical practice. Although we used a monocentric population, our methodology can easily be applied to other settings in which evidence-based interventions will be implemented.

5. Conclusions

This study provides important information for re-designing alloSCT care from the current acute-care perspective towards an eHealth-facilitated integrated chronic care approach. As alloSCT patients are at a high risk for chronic long-term complications, they require comprehensive, proactive follow-up care that integrates behavioral and psychosocial support to improve long-term outcomes. However, we question whether any current care model covers those needs. And while we are certain that, across countries, diseases and settings, the future of health care will include eHealth, we cannot successfully implement any care model into a clinical setting without knowing the context and end-users' needs and preferences.

This report describes the methodological approach and findings of a mixed-methods examination and mapping-out of our target context as it applies to a single organizational setting. Our findings concern structural characteristics, CIM-related practice patterns and technology openness from the perspectives of clinicians and patients. They have also allowed us to synthesize further findings with implications either for the intervention itself or for our choice of strategies regarding the new care model's implementation. Overall, these results will directly inform the development of the SMILe eHealth-delivered integrated model of alloSCT care.

CRediT authorship contribution statement

Lynn Leppla: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing - original draft. **Juliane Mielke:** Formal analysis, Data curation, Methodology, Writing - review & editing. **Maria Kunze:** Data curation, Formal analysis, Investigation, Writing - review & editing. **Oliver Mauthner:** Conceptualization, Formal analysis, Writing - review & editing. **Alexandra Teynor:** Conceptualization, Methodology, Supervision, Writing - review & editing. **Sabine Valenta:** Conceptualization, Methodology, Writing - review & editing. **Jasper Vanhoof:** Methodology, Writing - review & editing. **Fabienne Dobbels:** Conceptualization, Methodology, Supervision, Writing - review & editing. **Lut Berben:** Methodology, Writing - review & editing. **Robert Zeiser:** Conceptualization, Supervision, Writing - review & editing. **Monika Engelhardt:** Conceptualization, Supervision, Writing - review & editing. **Sabina De Geest:** Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing - review & editing.

Declaration of competing interest

No conflict of interest apply to this study. This preparatory part of the SMILe project did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Appendix A. Supplementary data

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