Health Literacy and Shared Decision-Making in the Context of Predictive Medicine - a Mixed Methods Study on the Perspectives of Patients and Healthcare Professionals

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Zusammenfassung

Die vorliegende Dissertationsschrift beschäftigt sich mit Ansatzmöglichkeiten zur Förderung der individuellen Gesundheitskompetenz und partizipativen Entscheidungsfindung im Kontext prädiktiver Medizin.

Der medizinisch-technische Fortschritt ermöglicht die Vorhersage und Früherkennung von Krankheitsrisiken und Anfangsstadien einer Krankheit zu einem immer früheren Zeitpunkt. Personen, die mit einem erhöhten Krankheitsrisiko konfrontiert sind, aber auch Gesundheitsprofessionelle, die Ratsuchende hinsichtlich individueller Krankheitsrisiken beraten, stehen der Herausforderung gegenüber, zunehmend komplexe Gesundheits- und Risikoinformationen zu kommunizieren und auf deren Basis prädiktive und/oder präventive Entscheidungen zu treffen. Dabei erlauben bisherige Studien keine Schlussfolgerung darüber, welche Voraussetzungen für einen subjektiv gesundheitskompetenten Umgang mit Krankheitsrisiken und das Gelingen partizipativer Entscheidungen im Kontext prädiktiver Verfahren aus Sicht Betroffener und Beteiligter gegeben sein müssen.

Mit Hilfe eines Mixed Methods Studiendesigns exploriert die vorliegende Arbeit Risikoperzeptionen und Bedürfnisse von Personen, die an medizinischen Früherkennungsverfahren teilnehmen, sowie Erfahrungen und Einschätzungen von Gesundheitsprofessionellen, die Ratsuchende in prädiktiven Verfahren beraten und behandeln.

Im Ergebnis bietet diese Dissertation eine empirisch begründete, konzeptionelle Erweiterung der Modelle ‚Gesundheitskompetenz' und ‚Partizipative Entscheidungsfindung' in der prädiktiven Medizin: Die beiden Konzepte bedingen einander, Kommunikation mit sich selbst und mit anderen wird als zentrales Medium verstanden, um Gesundheitsrisiken auszuhandeln und prädiktive und/oder präventive Entscheidungen zu treffen. Ein Drei-Säulen-Modell bietet Ansatzpunkte zur Förderung einer subjektiven Gesundheitskompetenz und der partizipativen Entscheidungsfindung im prädiktiven Setting.

Die Ergebnisse und abgeleitete Implikationen für die prädiktive Praxis werden vor dem Hintergrund vorangegangener Forschung und relevanter theoretischer Konzepte diskutiert. Im Zentrum stehen dabei Rollenverständnisse und -anforderungen in Bezug auf ‚Risikopersonen' und Gesundheitsprofessionelle, der Stellenwert von Subjektivität und das normative Potenzial prädiktiver Verfahren als maßgebende Parameter im Verstehen von und Umgehen mit Gesundheit, Krankheit und Risiko sowie die Gegenüberstellung objektivierbarer und subjektiver Ansätze in der Vermittlung und Aushandlung von Krankheitsrisiken.

Die Erkenntnisse werden im Hinblick auf praktische Implikationen für die medizinischen Aus-, Fort- und Weiterbildung operationalisiert und es werden konzeptionelle Vorschläge zu deren Umsetzung in der prädiktiven Beratung und der organisationalen Ausgestaltung prädiktiver Angebote ausgesprochen.

Summary

This dissertation investigates how health literacy and shared decision-making can be promoted in the context of predictive medicine.

The ongoing medical-technical progress allows for the prediction of individual disease risks and the detection of early disease stadia at an ever earlier stage. People confronted with an increased disease risk as well as healthcare professionals who consult patients in predictive procedures are challenged to communicate and negotiate increasingly complex disease risk information and to make preventive decisions upon disease probabilities. However, relevant aspects with respect to a subjectively health literate decision-making in the context of predictive medicine from the perspective of people involved and affected have not yet been investigated.

Using an inductive, qualitative study design, the present work explores risk perceptions and needs of people who participated in predictive procedures to determine their personal risk for developing a certain disease; it also examines experiences and concerns of healthcare professionals who consult and treat advice seekers in predictive procedures with respect to preventive options.

The results of this dissertation offer an empirically founded, conceptual broadening of health literacy and shared decision-making in predictive medicine: the two concepts are interwoven, communication with oneself and with others is central for the negotiation of predictive and/or preventive measures. A three-pillared approach derived from this work's findings is to serve the promotion of subjective health literacy and shared decision-making in predictive medicine.

This thesis discusses its results and implications for predictive practice in the light of previous research and relevant theoretical concepts. Central aspects addressed are role understandings and requirements of 'persons at risk' as well as healthcare professionals, the meaning of subjectivity and normative potentials of predictive procedures for the understanding of and dealing with health, disease, and risk, and objectifiable versus subjective approaches of communicating and negotiating disease risk.

For their operationalization, practical implications are constituted in the setting of (med.) education and training and include tools for the predictive practice as well as conceptual suggestions for healthcare organizations that provide predictive procedures.

Content

List of Abbreviations

Abbreviation	**Definition**
AD	Alzheimer’s Disease
AR	Ayda Rostamzadeh
BMBF	Bundesministerium für Bildung und Forschung
CECAD	Excellence Cluster on Cellular Stress Responses in Aging-Associated Diseases
CERES	Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health
CHD	Coronary heart disease
CW	Christiane Woopen
DZNE	German Center for Neurodegenerative Diseases
EI	Expert Interview
FBOC	Familial breast and ovarian cancer
FJ	Frank Jessen
HCPs	Healthcare professionals
HL	Health literacy
HSBI	Hochschule Bielefeld
HS Gesundheit Bochum	Hochschule für Gesundheit
IPHS	Interdisciplinary Program Health Sciences
LH	Laura Harzheim
MCI	Mild cognitive impairment
ML	Mariya Lorke
PhD	Philosophiae doctor
PSY	Psychosis
SCD	Subjective cognitive decline
SDM	Shared decision-making
SJ	Saskia Jünger
Q	Question

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Introduction

This thesis empirically investigates and theoretically reflects the concepts of health literacy (HL) and shared decision-making (SDM) in the context of predictive medicine. With an inductive, qualitative research design, it analyzes the perceptions, experiences, and needs of patients and healthcare professionals (HCPs) with respect to disease risk prediction.

First, the context and aims of this thesis will be introduced before clarifying the terms and concepts referred to. After defining the setting and outlining the respective state of research, the research questions addressed as well as the methodological approach of this thesis will be presented.

Context and Aims

In a society where efficiency and optimization are central approaches to life, healthcare continuously widens its focus from the treatment of diseases towards the prevention of health-related ‘abnormalities’ and the detection of risks or early stages of a disease (Hahn, 2010). Ongoing medical-technical progress allows the prediction and early detection of diseases and risk factors at an ever earlier stage, and possibilities of preventive measures are becoming increasingly diverse (Newsholme, 2015). This does not only entail changes on a normative level (Hahn, 2010); people dealing with disease risk, patients and relatives, but also HCPs, are challenged to navigate progressively complex information on estimated health developments, risk probabilities, and preventive options. With the potential of disease risk prediction to prevent the outbreak or positively influence the onset of a disease (Fusar-Poli et al., 2013), predictive medicine also comprises the precariousness of shifting the health status of a supposedly assumed to be healthy person to being ‘at risk’ and thereby potentially influences this person’s health-related self-perception as (about to) being ill (Meier et al., 2017). When being classified as a ‘person at risk’, the negotiation of one’s own health status implies the decision-making in favor of or against preventive measures. With medical interventions being a physical intrusion by nature (Meyer, 2011), *preventive* medical interventions entail the complexity of ‘harming’ a (yet) healthy body or at least having a psychological effect on an individual. It is therefore crucial to consider the way disease risk information is framed, understood and interpreted, and how risk-related decision-making evolves on this basis - not only by the individuals concerned, but also in terms of the awareness and professional ethics of HCPs.

In this context, two concepts play a key role for the course and outcome of predictive and preventive procedures: HL[1] and SDM[2]. Both concepts will form the theoretical framework of this thesis, since HL plays a central role in the context of risk-adjusted decision-making (Schmidt-Kaehler, 2016; Sørensen et al., 2012) – the understanding and critical evaluation of disease risk information enables people to make informed choices about preventive interventions or towards a health-promoting lifestyle (Oliveira et al., 2018) – SDM, relating to the demand-based negotiation of health (and disease risk) information and treatment options (Kaldjian, 2017), is equally important in preventive procedures, since it also determines the course and outcome of these procedures (Altin & Stock, 2016; Hauser et al., 2015; Joseph-Williams et al., 2014; Smith et al., 2009).

Reflecting upon the (prospective) relevance of predictive medicine, various aspects substantiate a focus in health science research on related matters. These comprise: (a) ethical challenges, when considering potential benefits and risks of disease risk prediction for individuals:

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[1] The term will be differentiated when defining the terminology and concepts for this thesis (Chapters 1.2.1).
[2] The concept will also be further elaborated in the terminology and concepts section (Chapter 1.2.2).

how is risk being perceived and dealt with, what effect does it have on people?; (b) interactional and communicational aspects, addressing possible challenges of communicating about and deciding upon risk prognoses: what difficulties do participants of predictive procedures face, how can they be supported?; and (c) factors related to the understanding and application of risk information: how can health literate decision-making in the negotiation of risk be ensured?

Against this background, the aim of this thesis is to empirically investigate and theoretically reflect upon the concepts of HL and SDM in the context of predictive medicine, in order to (a) identify HL- and SDM-relevant aspects for persons involved in disease risk prediction and to operationalize the findings for medical practice, making recommendations on how to support HL in dealing with disease risks and facilitating SDM about preventive measures; and to (b) empirically contribute to the theoretical concepts of HL and SDM.

Subordinate objectives to address the overall aims of this thesis are presented in detail in the respective publications. The following table provides an overview of this study's aims and subordinated aims as well as the empirical works/included articles contributing to these aims.[3]

Table 1

Aims addressed by this thesis

Aims and subordinated aims	**Empirical work/articles**
Empirical investigation of HL and SDM in predictive medicine, derivation of practical implications	
• Learning about patients' risk perceptions	Harzheim et al., 2020; Harzheim et al. 2023a
• Identifying HL-relevant aspect from the perspective of people confronted with disease risk	Harzheim et al., 2020; Harzheim et al. 2023a
• Identifying starting points for promoting HL and SDM in predictive consultations from the perspective of HCPs	Harzheim et al. 2023b
• Speaking out recommendations for the development of tools and teaching concepts for HL and SDM promotion in predictive practice	Harzheim et al. 2023b

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[3] The table of thematic and conceptual convergences of included articles in the findings section will illustrate the coherences of the respective research aims and empirical works more detailed.

Theoretical reflection of the concepts of HL and SDM	
• Theoretically contributing to the concept of HL and SDM with a qualitative, inductive study design, letting individuals involved define relevant criteria	Harzheim et al., 2020; Harzheim et al. 2023a; Harzheim et al. 2023b

Terminology and Concepts

With HL and SDM being investigated in various contexts, a brief clarification of the terms is needed to situate this thesis' alignment within the field of research. The interaction between patients and HCPs as protagonists in the setting of predictive medicine and early diagnostic procedures will be considered as key for both HL and SDM; this thesis' understanding of the terms 'patient' and 'HCP' as well as of the setting addressed will also be defined in the following.

Health Literacy

The core of the HL concept describes a person's ability to find, understand, assess, and apply health information (Sørensen et al., 2012). Due to its importance for understanding (and predicting) health behavior of individuals and social groups, there has been increasing research on the concept (Mackert et al., 2015). This involved an extension of the term, differentiating between functional, interactive, and critical HL[4] (Nutbeam & Lloyd, 2021) on the individual level, but also emphasizing the concept's reach to the organizational and system-related level[5] (Schaeffer et al., 2018; Sørensen et al., 2012).

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[4] Functional HL: Basic, education-related skills to obtain and understand health information; Interactive HL: Ability to abstract health information, to translate them in their meaning for one's personal life, and to exchange and interact with others about it; Critical HL: Most advanced form of negotiating the meaning of health information for oneself, appraising the complex interplay of health-relevant determinants like social, environmental, and economic aspects (Nutbeam & Lloyd, 2021).

[5] Organizational HL: Efforts of an organization to provide an environment that enables patients to better understand and use health information and health services (Farmanova et al., 2018); System level HL: Social, political and economic determinants that frame services and work ethics of a healthcare system (Baumeister et al., 2021).

This thesis focuses on individual HL, with the extended understanding of it being a form of multidimensional knowledge, negotiated and evolved in social interaction and communication (Harzheim et al. 2020; Samerski, 2019). With incorporating HCPs in this study, professional HL[6] is also a relevant nuance of the concept which will be addressed and discussed along with its organizational impact in the following.

Shared Decision-Making

The concept of SDM describes a development from a paternalistic decision-making process in medical encounters, where HCPs chose the 'best' option for patients from a rational-medical standpoint, towards a mutual negotiation of and an agreement on diagnosis and treatment options between patients and HCPs (Elwyn et al., 2012). This thesis understands SDM as a process in which patients and HCPs mediate health-related decisions, reflecting and discussing values, personal circumstances, and preferences of patients with respect to their (future) health (Hauser et al., 2015). The concept will also be reflected from the perspective of social and professional roles in medical encounters, addressing aspects like autonomy and informational preferences in the patient-HCP-dyad (Kasper et al., 2010).

Participants

The setting of predictive medicine (which will be contoured further below) opens up a definitional space of the terms 'patient' and 'healthcare professional', since the context of risk prediction and the detection of early disease stages shifts the entry point to healthcare services and widens the spectrum of diagnostic and therapeutical range as well as of professions involved in

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[6] Professional HL: The competence of professionals interacting with patients to discover difficulties of patients with dealing with health information and to communicate/find a solution in a patient-centered manner (Mullan et al., 2017).

the predictive process. While inclusion and exclusion criteria of the respective study parts will be defined in detail in the articles included (Harzheim et al., 2020; Harzheim et al. 2023a; Harzheim et al. 2023b), the following section is to clarify the terminology used to describe this thesis' participations.

Patients

While a patient can be understood as a person in need of medical care, being injured or having a disease (Neuberger, 1999), a yet healthy person undergoing medical procedures to determine a disease risk may drop out of this ‚classical' definition of a patient.[7] Predictive medicine is also to identify causes of a disease before symptoms occur and is therefore not only a matter of diagnosing a disease, but detecting disease predispositions. With this in mind, 'patients' can be seen as persons who have their disease probabilities medically determined on the basis of (genetic) predispositions (Irrgang & Heidel, 2015), which coincides with the definition of 'patient' as a person who makes use of health services provided by health professionals (Neuberger, 1999).

The term 'person at risk', as an equivalent to a patient within the field of predictive medicine, implies the definite presence of a medically diagnosed risk; since participants of this study were not exclusively diagnosed as such (Harzheim et al. 2020; Harzheim et al. 2023a), their description as people *facing* a disease risk is preferred in this thesis.[8]

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[7] There is an extensive theoretical discourse on the changing definition and meaning of the term 'patient', of which the elaboration would go beyond this thesis' scope.

[8] The identity-relevant dimension of being defined as 'at risk' will be elaborated more closely throughout the findings and the discussion of this thesis.

With ‘patients’ or ‘persons facing a disease risk’ this thesis therefore refers to people who underwent predictive procedures to determine their personal disease risk profile, as equivalent to ‘advice seekers’.

Healthcare Professionals

Nurses, psychiatrists, physiotherapists and physicians or professionals of other medically related areas can be understood as healthcare professionals (Neuberger, 1999); depending on the respective indication or the structure of a predictive procedure, biologists or geneticists may also be pooled under this term in the context of this study. With this research work focusing on the medical encounter between patients and professionals in predictive procedures, this thesis’ understanding of HCPs primarily addresses physicians and professionals of other related areas who directly consult advice seeking patients and who are involved in the decision-making process with respect to predictive and preventive measures within the course of a predictive diagnostic procedure (Harzheim et al. 2023a).

Going beyond their particular medical specialty, HCPs with differing professional backgrounds will be jointly considered under the light of professional role-perceptions and -expectations in the discussion of this thesis’ findings.

Setting

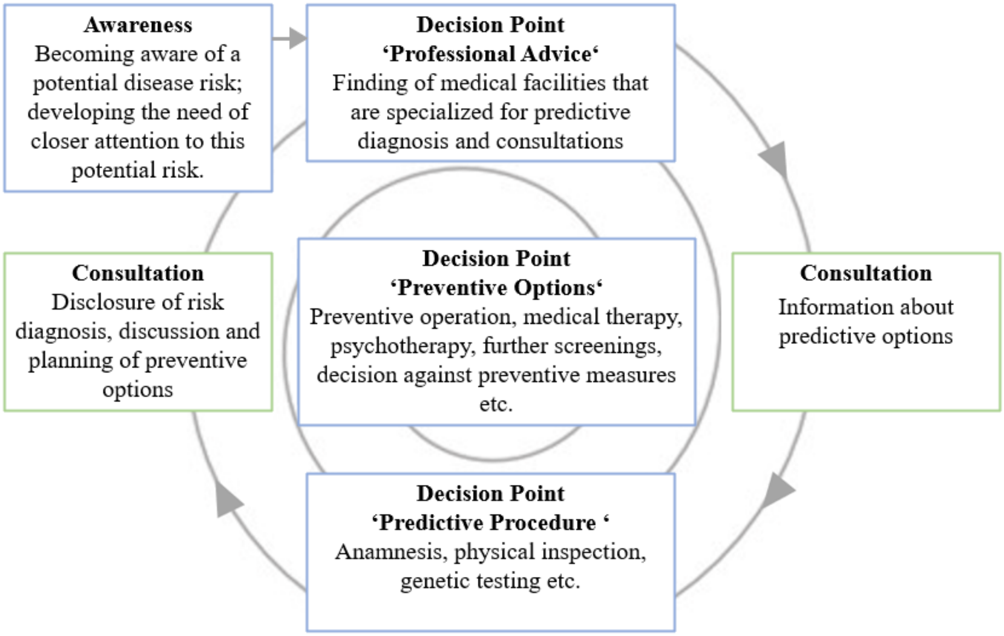
Predictive Medicine

Predictive (and preventive) medicine comprises research and medical practice to determine disease risk probabilities in order to prevent the outbreak of a disease or to milden its onset (Jen et al., 2022). The concept of predictive medicine originally stems from diagnostic procedures to identify genetic predispositions that favor the development of a disease (Dausset, 1997); nowadays it also comprises risk assessments on the basis of behavior- and lifestyle-related determinants. In contrast to many other preventive interventions, predictive medicine is performed on an individual basis (Dausset, 1997; Jen et al., 2022).

It may be assumed that people who consider undergoing medical assessment of a certain disease risk, face different decision points throughout the process of ‘entering predictive medicine’. To define the predictive settings referred to in this thesis, a simplified, exemplary, and indication-unspecific illustration shall frame the entering point and potentially decisive moments within the process of moving through the field of predictive medicine from the perspective of a patient.

Figure 1

Decision Points in Entering Predictive Medicine



Although this figure does not intent to cover the complexity of decisioning within the field of predictive medicine, it introduces central encounters between patients and HCPs in predictive procedures that shall be investigated in the course of this study.

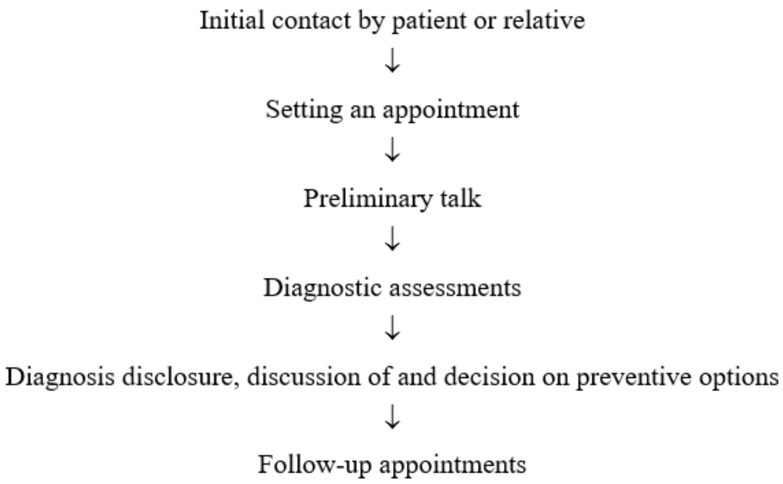
Predictive Procedures

In this research work, predictive procedures are being understood as the process of consulting, diagnosing, and advising patients with respect to their personal disease risk profile at specialized centers for early detection and diagnostics. Wishing to investigate communicational and interactional aspects with relevance for HL and SDM promotion in the predictive setting, this context is assumed to be central with regard to the negotiation of disease risk and related decision-making between patients and HCPs.

Referring to a predictive procedure as described by one of the cooperating clinics of this study (Harzheim et al., 2020) and considering the above mentioned decision points within the field of predictive medicine, an exemplary predictive procedure as depicted may help defining the scope of the research setting.

Figure 2

Exemplary Predictive Procedure



(Own illustration based on the presentation of Prof. Josef Kambeitz during the 2. Kölner Fachsymposium „Studieren mit psychischen Erkrankungen und Belastungen“ (2nd Cologne Symposium „Studying with mental diseases and strains“) on February 17, 2020.)

Exemplary Clinical Fields

In order to concretize the empirical setting and to provide findings that are applicable to predictive practice, this study focuses on the diagnosis of and consultation about individual risk factors for developing diseases in four exemplary fields of indication: Familial breast and ovarian cancer (FBOC), Alzheimer's Disease (AD), psychosis (PSY) and coronary heart disease (CHD) (Harzheim et al., 2020). These fields are considered important for research on preference-sensitive risk information and health literate decision-making because of their epidemiological relevance (Moreno-Küstner et al., 2018; Niu et al., 2017; Petrucelli et al., 2010; Vilahur et al., 2014), covering areas of oncology, neurology, cardiology, and psychiatry and thereby allowing to analyze risk perceptions and decision-making on risk in the context of physically and mentally manifested conditions. By focusing on these fields, different types of risk profiles based on a variety of parameters can be considered, including family history, biomarkers, imaging techniques, behavioural factors, and symptom assessment (Harzheim et al., 2020). The broad spectrum of preventive options or therapeutic approaches (e.g., preventive surgery (FBOC), medical therapy (AD, CHD, FBOC, PSY), educative or psychotherapeutic measures (CHD, PSY), or behavioral approaches (AD, PSY) (Harzheim et al., 2020; Harzheim et al. 2023a) also reasons the choice of exemplary indications in this study.

State of Research

After having outlined the research field this thesis intends to explore, the respective state of research will be examined before defining research questions with an added value to the domain. At this point, the research state with respect to this thesis' overall scope will be briefly delineated focusing on (a) HL and SDM in the context of predictive medicine, (b) patients' and HCPs' perspectives on the concepts, and (c) recommendations and tools on how to promote HL and SDM within predictive practice. A detailed elaboration of the respective state of research regarding the particular empirical phases of this study will be given in the related publication.

Since the shift from the traditional medical consultation model towards the model of SDM (Clayman et al., 2017; Stiggelbout et al., 2015) there is a demand for encouraging patient involvement in the decision-making on health information and for promoting HL in medical encounters (Jorm, 2015); the complexity of decision-making in the context of risk is, however, underrepresented in health research (Godolphin, 2003). One factor contributing to this complexity is the controversial impact of providing information: on the one hand, in SDM it can be considered as a HCP's duty to provide all available information to a patient in order to equip them for informed choices (Godolphin, 2003), implying that being informed imparts a beneficial outcome for the patients (Altin et al., 2014; Hauser et al., 2015). On the other hand, risk disclosure can be associated with potential harm for the psychological wellbeing of a patient (Andorno, 2004; Chiolero, 2014; Cook & Bellis, 2001; Davies & Savulescu, 2021; Godolphin, 2003). SDM in the context of risk consultations thereby begins with balancing out what information *can* be provided and what information *shall* be provided. With this perspective, HL and SDM entail the recognition, understanding, and respecting of patients' (own) needs and capacities with respect to risk information. The idea of a rational, fact-based understanding of and dealing with numerical risk estimations is thereby rescinded (Godolphin, 2003; Molewijk et al., 2008). Slovic and colleagues (2004) already pronounced the interplay of analytical and emotional aspects in negotiating risk, emphasizing the relevance of biographically formed and individually mediated risk perceptions. This centers the subjectivity of HL and SDM in general and in risk prediction in particular. Yet, literature research did not lead to any studies on HL and SDM relevant factors in the context of risk-adjusted decisions from the perspective of patients and HCPs as actors involved in the decision-making process. Although there are elaborations addressing the importance of SDM in risk prediction in general (Edwards et al., 2005; Godolphin, 2003; Laight, 2022), there is a lack of evidence-based research on the subject, exploring perceptions of HCPs and patients.

The innovative value of this thesis also lies in the methodological approach of empirically contributing to the concepts of HL and SDM in predictive medicine from an inductive, bottom-up perspective. While most studies on HL and SDM use pre-set, standardizable criteria, intending to find a unifying way of framing the concepts (Mazor et al., 2012; Schaeffer et al., 2017; Wolfs et al., 2012), this thesis intends to explore patient- and HCP-driven definitions of what is relevant for HL and SDM in predictive medicine. This is based on the assumption that HL research will gain from a participatory research process, collaborating with the addressees of the research work (Harzheim et al., 2022). Participatory approaches in health sciences most often target the development of interventions to improve health outcomes for social groups with respect to a particular indication (Bruland et al., 2019; Shalowitz et al., 2009; von Unger, 2012). The participatory approach of this thesis aims at distilling theoretical implications as well as practical recommendations for a healthcare domain (predictive medicine), with a desired benefit across indications and social diversities within that setting.

Research on tools or recommendations on how to promote HL or SDM in medical encounters mainly focuses on the evaluation of instruments (like question prompt lists in patient-physician-communication) that are to assist patients in managing health information or to help them participate in conversations with HCPs in a more balanced manner (e.g., Blake et al., 2010; Galliher et al., 2010; M. Tracy et al., 2022; M. C. Tracy et al., 2020; Tsai et al., 2022). There is less research on how *professionals'* HL and skills for SDM could be supported, neglecting the relevance of professional and organizational HL (Palumbo & Annarumma, 2018). There is, however, a systematic review on HL interventions that identified barriers for successfully implementing HL-promoting measures on an organizational level: Farmanova and colleagues (2018) named aspects like lack of resources (e.g. time), role ambiguities of staff, insufficient training, and low prioritization of HL in clinical practice as hindrances to organizational HL. They thereby highlight most relevant aspects when wishing to implement tools for HL and SDM promotion in medical practice: work ethics and the professional environment or culture.

Hence, previous research to date did not explicitly (1) assess tools for HL/SDM promotion from the perspective of patients *and* professionals, (2) identify approaches to respond to named barriers to successfully implement such tools, and (3) develop recommendations for HL and SDM promotion in predictive consultations that consider role dynamics in medical encounters and the evolving requirements towards HCPs.

Research Questions

Against the background of the state of research outlined above, and the arising research gaps, the following research questions were identified and addressed in the scientific publications included in this thesis.

The first article, *Health Literacy as Communicative Action – A Qualitative Study among Persons at Risk in the Context of Predictive and Preventive Medicine*, addressed the following questions:

(1) In what way does HL and being confronted with disease risk interrelate?, (2) What are HL-relevant factors from the perspective of patients partaking predictive procedures?, and (3) How can HL of individuals be promoted in order to enable them to integrate the meaning of ‘being at risk’ into their lifeworlds? (Harzheim et al., 2020).

The second article, *The Promotion of Health Literacy: An Ethical Task in the Prediction of Alzheimer's Dementia Risk*, in-depth analyzing the patient perspective in one of the exemplary indicational fields, explored:

(1) How do people facing an increased risk of developing Alzheimer's dementia perceive disease risk?, (2) What aspects with respect to HL are important to them, especially in the context of a disease (prospectively) affecting cognitive capacities?, and (3) How can HL of individuals facing an increased Alzheimer's dementia risk be promoted in predictive consultation? (Harzheim et al. 2023a).

The article covering the perspective of HCPs, *Health literacy and shared decision-making in predictive medicine – professionals' perceptions and communication strategies*, dealt with the questions:

(1) How can HL of individuals facing disease risk be promoted from the perspective of HCPs?, (2) What aspect do HCPs consider relevant with respect to SDM in the context of predictive consultations?, and (3) Wich communication strategies help HCPs in communicating to patients in the course of predictive procedures? (Harzheim et al. 2023b).

Methodological Approach

In order to answer to the research questions of this thesis and to fulfill its overall aim, the conducted research work comprises two empirical phases: (1) the exploration of risk perceptions and HL-relevant aspects from the perspective of persons confronted with disease risk (patients), investigated in the course of the research project RisKomp[9]; and (2) the subsequent examination

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[9] RisKomp (Health Literacy of Persons at Risk – From Information to Action) was a research project conducted from 01/2016 to 12/2020 at the Cologne Center of Ethics, Rights, Economics, and Social Sciences of Health (ceres) of the University of Cologne; funded by the Robert Bosch Stiftung (Funding number: 11.5.A402.0002.0)

of HCPs' experiences and impressions especially with respect to patient information, risk communication, and SDM in the context of predictive consultations. Both projects were granted ethics approval by the ethics committee of the Medical Faculty of the University of Cologne[10] and align with the Helsinki Declaration of 1964, as revised in 2013, respective human and animal rights (World Medical Association Declaration of Helsinki, 2013). Data collection and analysis was carried out from 2018 to 2020; the results were presented in form of workshops, lectures, congress presentations, and articles, of which a selection contributes to this thesis' structure. Although there will be a detailed presentation of the methodological approach in the respective publications, the following graph shall give an overview of how the research field was approached in the course of this study.

Figure 3

Data Corpus of Empirical Phases

Empirical Phase I Patient Perspective (01/18-03/19)			**Empirical Phase II HCPs‘ Perspective (12/20-04/21)**		
Participants	Data material	Analysis	Participants	Data material	Analysis
33 persons facing disease risk in 4 exemplary indicational fields	Narrative Interviews Socio-demographic questionnaires Body-maps Memos	Reflexive Grounded Theory Methodology Descriptive statistic	32 HCPs conducting predictive consultations with persons 'at risk'	Expert interviews (n=7) Survey Memos	Reflexive Grounded Theory Methodology Descriptive statistic

Collation of results and distillation of key findings

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[10] Ethics approval of the first empirical phase (RisKomp): March 2018 (registration number: 18-014); ethics approval of the second empirical phase: December 2020 (registration number: 20-1290_1)

For the distillation of this thesis' key findings, thematic coherences were abstracted and modelled into contextual core statements that are to theoretically reflect on the concepts of HL and SDM in predictive medicine and to help operationalizing the findings for predictive practice based on the empirical findings. Theoretical and practical implications derived from this distillation will be discussed with respect to the empirical and theoretical state of research.

Findings

The presentation of findings is based on three articles that emerged from the empirical phases introduced above. These articles, their thematic and conceptual convergence with respect to the aim of this research, and the authors' contributions will be presented, before introducing and discussing this thesis' key findings.

Included Articles

The included articles (Table 2) depict (1) the conceptual expansion of HL and SDM in the predictive context from the perspective of 'persons at risk'; (2) an indication-specific example illustrates risk perceptions of people confronted with disease risk and HL- and SDM-relevant aspects with respect to a specific predictive setting; (3) experiences and recommendations of HCPs with regards to predictive consultations allow to derive implications for HL- and SDM-promotion in predictive practice.

Table 2

Included Articles

Article 1	Harzheim, L.* & Lorke, M.*; Woopen, C.; Jünger, S. (2020): **Health Literacy as Communicative Action—A Qualitative Study among Persons at Risk in the Context of Predictive and Preventive Medicine.** *International Journal of Environmental Research and Public Health*. 17. 1718. 10.3390/ijerph17051718.
Article 2	Harzheim, L.*; Lorke, M.; Rostamzadeh, A.; Jessen, F.; Woopen, C.; Jünger, S. (2023a): **The Promotion of Health Literacy: An Ethical Task in the Prediction of Alzheimer's Dementia Risk.** In: *GeroPsych*, Artikel 1662-9647/a000310. DOI: 10.1024/1662-9647/a000310.

Article 3	Harzheim, L.*; Lorke, M.; Schulz, S.; Jünger, S. (2023b): **Health literacy and shared decision-making in predictive medicine – professionals' perceptions and communication strategies.** *Journal of Public Health.* DOI: 10.1007/s10389-023-02110-0. (Accepted: 21/09/2023)

Thematic and Conceptual Convergences

The data collection and analysis of the included articles contributed to the conceptualization and the thematic alignment of this thesis. Table 3, "Thematic and Conceptual Convergences of Included Articles", provides an overview of these convergences, showing the theoretical, conceptual, and knowledge gain-related evolution of this thesis' research work. Details of the articles' contribution to the thesis will be given in the summary of the respective article.

Table 3

Thematic and Conceptual Convergences of Included Articles

Publications	**Health Literacy as Communicative Action—A Qualitative Study among Persons at Risk in the Context of Predictive and Preventive Medicine**	**The Promotion of Health Literacy: An Ethical Task in the Prediction of Alzheimer's Dementia Risk.**	**Health literacy and shared decision-making in predictive medicine – professionals' perceptions and communication strategies**
Theoretical contribution with respect to the research aim Subjects addressed Focus of analysis	Identification of HL-relevant factors, risk perceptions, and health and disease theories of persons at risk of developing a disease. Specification of the concept of HL by emphasising communication as a central aspect of the formation of HL. Identification of the patient's perspective on HL- and SDM-relevant aspects in the risk context. Identification of resources and challenges for HL promotion in predictive medicine.	Identification of the patient's perspective on HL- and SDM-relevant aspects in the risk context. Identification of resources and challenges for HL promotion in predictive medicine. Extension of the concept of HL by empirically identifying 'self-literacy' as a HL-relevant component. Centralizing subjective HL in early risk prediction in the field of neurodegenerative diseases.	Identification of relevant factors for HL and SDM with respect to an increased disease risk from the perspective of HCP. Identification of resources and challenges for HL and SDM promotion in predictive medicine. Designation of effective communication strategies from HCP in preclinical consultation. Identification of medical education and training as starting point to promote person-sensitive and demand-oriented consultation in predictive medicine.

Conceptual contribution to the research project Methodological reflexivity Transfer of findings to following project phases	Reflection of a qualitative approach (explorative, inductive) with respect to the research aim and integration of methods into the conceptualization of the following research phases (HCP perspective). Identification of communication and interaction during preclinical consultations with HCP as an essential prerequisite for health literate negotiation of risk information. Translation of results into the conceptual design of the HCP study.	Identification of communication and interaction during preclinical consultations with HCP as an essential prerequisite for health literate negotiation of risk information. Translation of results into the conceptual design of the HCP sub study.	Theoretical connection of the findings of both studies (patient's perceptions and HCP perspectives). Translation of findings into the development of practical recommendations.
Knowledge gain for HL- and SDM-research, implications for medical practice	Contribution to the methodological discourse in HL-research by using qualitative methods. Empirical reflection of the HL concept in the context of predictive medicine and risk-adjusted decision-making. Distillation of critical HL and strategic communication as a starting point for future research.	Empirically based recommendations on how to promote individual HL of persons at risk in the context of early diagnostic procedures. Empirical base for the development of strategies, instruments and tools for person-centered risk information and communication in the context of risk.	Empirically based recommendations on how to promote individual HL of persons at risk in the context of early diagnostic procedures. Development of recommendations with respect to patient information, risk communication, and SDM in the context of early diagnostic procedures and preventive medical interventions. Empirical base for the development of strategies, tools and teaching concepts and material for medical education and training, addressing the promotion of HL and SDM in the context of risk prediction.

Authors' Contribution

Before presenting the included articles, the authors' contributions for each article will be disclosed (Table 4) as well as the particular contribution of the PhD candidate to the respective article (Table 5).

Table 4

Authors' Contribution to Included Articles (alphabetic order)

	Article 1	Article 2	Article 3
Conceptualization	**L.H.**, M.L. and S.J.	**L.H.**	**L.H.**
Methodology	**L.H.**, M.L. and S.J.	**L.H.**, M.L. and S.J.	**L.H.**
Investigation	**L.H.**, M.L. and S.J.	**L.H.**, M.L. and S.J.	**L.H.**, S.S.
Formal analysis	**L.H.**, M.L. and S.J.	**L.H.**	**L.H.**, S.S.
Validation	**L.H.**, M.L. and S.J.	**L.H.,** M.L., S.J.	**L.H.**, M.L., S.J., S.S.
Visualization	**L.H.** and M.L.	**L.H.**	**L.H.**
Writing—original draft	**L.H.** and M.L.	**L.H.**	**L.H.**
Writing—review and editing	S.J and. C.W.	M.L., F.J., S.J, A.R. and. C.W.	M.L., S.J., and S.S.
Funding acquisition	C.W.	C.W.	No funding
Project administration	C.W.	C.W.	**L.H.**
Supervision	S.J.	S.J.	S.J.

Table 5

Contribution of the PhD Candidate to Included Articles

Article 1	Due to the wide scope of the project underlying this article (33 face-to-face interviews in four different clinical fields and in-depth qualitative data analysis), my colleague M.L. and I shared the responsibility for the conceptualization and methodological framework for data collection and analysis, the planning and conduct of recruitment, the data collection and analysis, and the presentation and writing of the findings. To equally split the workload, I focused on the data collection and analysis of two of the four clinical fields (Alzheimer's disease and coronary heart disease). M.L. and I conceptualised the structure of the manuscript along with the theoretical model developed on the basis of the findings. M.L. and I wrote the original draft of the manuscript, were responsible for its visualization, as well as for the submission and the communication with the journal. S.J. supervised and was involved in all phases of the research project. C.W. organised the funding, ensured the organizational framework of the study and edited the draft of the manuscript.
Article 2	Together with my colleagues M.L. and S.J., I methodologically planned, conceptualised and conducted the data collection. I analyzed the empirical data,

	discussed the findings, conceptualised the article, and wrote and visualised the original draft of the manuscript. M.L. and S.J. validated the data analysis and reviewed and edited the manuscript, together with C.W. who was also responsible for the funding and administration of the project. I am responsible for the communication and coordination with and the submission of the manuscript to the journal.
Article 3	I was responsible for conceptualising the study and its methodological approach, conducting the data collection and analysis, theoretically reflecting on and discussing the findings, as well as for writing and visualizing the original draft of the manuscript. My colleague S.S. technically supported me in setting up and analysing the questionnaires. M.L., S.S. and S.J. validated my work and critically reviewed and edited the manuscript. S.J. supervised my work throughout the whole research process. I am responsible for corresponding with the journal and for submitting the final version of the manuscript.

Further Publications

A selection of publications the PhD candidate contributed to, that are also of relevance for this thesis, cover a methodological reflexion of qualitative study designs in HL research, particularly addressing benefits of participatory approaches; and in-depth insights in risk perceptions of people facing risk of familial breast and ovarian cancer shed light on yet another indication-specific example of HL in the context of disease risk prediction.

Harzheim, L.*, Lorke, M.*, Jünger, S. (2022). **Potenziale unterschiedlicher qualitativer Forschungszugänge für den Erkenntnisgewinn in der Gesundheitskompetenzforschung.** In: Rathmann, K., Dadaczynski, K., Okan, O., Messer, M. (eds) Gesundheitskompetenz. Springer Reference Pflege – Therapie – Gesundheit. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-62800-3_66-1.

Lorke, M.*, Harzheim, L., Rhiem, K., Woopen, C., Jünger, S. (2021). **The ticking time-bomb. Health literacy in the context of genetic risk prediction in familial breast-ovarian cancer; A qualitative study.** In: *Qual Res Med Health* 5 (2). DOI: 10.4081/qrmh.2021.9647.

Main Findings

The main findings of the two empirical phases will be introduced with a summary of the respective publication.

A Conceptual Expansion of HL and SDM in Predictive Medicine

Harzheim, L.* & Lorke, M.*; Woopen, C.; Jünger, S. (2020): **Health Literacy as Communicative Action—A Qualitative Study among Persons at Risk in the Context of Predictive and Preventive Medicine.** *International Journal of Environmental Research and Public Health*. 17. 1718. 10.3390/ijerph17051718.

In this article, the risk-perceptions of persons undergoing predictive procedures in four exemplary clinical fields are being investigated. Benefiting from an inductive, qualitative study design, HL- and SDM- relevant factors within the context of predictive medicine were analyzed. The data corpus consists of narrative interviews, body-maps, sociodemographic data, and reflexive field notes that were collected and analyzed between 01/2018 and 03/2019.

The focus of analyzes was on the impact of being 'at risk' on persons' self-perceptions and everyday-life, the interplay of HL and SDM in the predictive context, and the communication about disease risk between patients and HCPs. With this, HL-relevant factors for people confronted with disease risk, subjective risk perceptions and theories, key situations in dealing with disease risk, as well as the processing and meaning-making of risk information and peoples' agency for their health-related future allowed to empirically undergird and theoretically reflect on the concepts of HL and SDM.

This article's findings expand the concepts of HL and SDM in predictive medicine by endorsing to look at these concepts from a bottom up-perspective, letting affected people themselves define the parameters for health literate decision-making on disease risk predictions. Agreeing with the understanding of HL as a multi-dimensional, situational, and social dynamic (Samerski, 2019), the data discussed in this article indicate the importance of communication in predictive consultations and its co-creational impact in medical realities. Adducing the theory on strategic versus communicative actions (Habermas, 2019), this contribution sensitizes for power-relations between patients and professionals and recognizes the medical encounters as a platform where biomedical, objective indications face biographically evolved, subjective perceptions and preferences. Emphasizing the analytical (facts) and emotional (intuition) systems to be equally relevant for risk assessments, the article indicates the communication with professionals as central in negotiating (understanding and finding consensus about) disease risk.

Contributing to this thesis' overarching aim, this article's results indicate incorporating the perspective of HCPs into further research, providing fruitful ground for the second empirical phase of this work. Acknowledging the role of professionals in the evolvement of HL and SDM in predictive procedures, their experiences and conceptions within that field needed to be explored. The results of this article informed the design and conceptualization of the subsequent research on HCPs' perspectives.

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Environmental Research
and Public Health

Article

Health Literacy as Communicative Action—A Qualitative Study among Persons at Risk in the Context of Predictive and Preventive Medicine

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Abstract: Predictive and preventive medicine play an increasingly important role in public debates on health, providing cutting-edge technologies with the potential to measure and predict individual risks of getting ill. This leads to an ever-expanding definitional space between being "healthy" and being "ill", challenging the individual's everyday life, attitudes and perceptions towards the self and the process of health-related decision-making. "How do the condition of 'being at risk' and individual health literacy interrelate?" is the leading question of the current contribution. Drawing on empirical qualitative data, collected by means of narrative interviews with persons at risk in four clinical fields, a bottom-up ethnographic and health sciences perspective on health literacy (with an emphasis on critical health literacy) is employed. The findings will be embedded within theoretical approaches dealing with power relations and communication in healthcare encounters, particularly Habermas' theory of communicative action. The core outcome of our study is a concept for an overarching model of health literacy in the context of health-related risk prediction across indications, based on empirical insights gained through interpretative analysis of the four clinical domains.

Keywords: health literacy; persons at risk; ethnographic approach; health sciences; qualitative research; perceptions of health and disease; critical health literacy; shared decision making; communicative action

1. Introduction

Being confronted with a health risk entails the solicitation to deal with risk-related information. When conducting research on the phenomenon of being at risk, it is therefore important to consider the evolving possibilities of predictive and preventive medicine, and their effects on individual needs with respect to information and support in decision-making processes. Communication between health care professionals and persons at risk is an essential element in this course. In the following, we wish to briefly introduce the meaning of the notion of 'being at risk', the role of health literacy, and the relevance of interpersonal communication in the setting of predictive medicine.

1.1. Being at Risk

Technical innovations in the field of predictive and preventive medicine allow for early detection of individual risk factors concerning a constantly increasing number of diseases. This presents health professionals, patients and their relatives with new manifold challenges. From a patient's perspective, to be confronted with a (suspected) increased risk of developing a certain illness does not only mean to correctly understand and appraise the medical 'objective' risk prognosis, but also to manage the emotional confrontation with the new, identity-relevant role of being a "person at risk". While the predicted event lies in the future and may not cause any current strain or suffering, individuals need to make choices and/or take action in the present, with immediate effect and sometimes serious intrusion upon their everyday life and quality of life. This condition and its medical, psychological and social consequences place special demands on individual health literacy (HL). Risk and health information need to be managed by the individual, transferred into the process of (shared) decision-making (SDM) in order to interact effectively with physicians, and integrated into one's subjective everyday life. The focus of this contribution is therefore at the interface between health risk, health literacy, and communication.

1.2. Health Literacy

Today's health-society [1] promotes an ideal image of self-effective, proactive patients who are able to make informed decisions successfully managing their own health and/or disease. The concept of health literacy (HL) has become a benchmark for doing health research for people and with people in the aspiration of a healthier society. According to the integrated definition developed by the European Health Literacy Consortium [2,3], "Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course" [2] (p. 3), [4] (p. 4). Based on this definition, risk related HL can be considered as the ability to access and understand information on risk factors for health, derive their meaning, interpret and evaluate this information and to make informed decisions with regards to risk factors for health [2].

Despite the ubiquitous presence of HL, there is a fundamental lack of consensus about the definition, the conceptualisation, and the scope of the term [5]. For the purpose of this contribution, we are drawing on a more comprehensive, resource-oriented approach [6]; following Samerski, we conceive of HL as a situational, multidimensional, and dynamic process, including a variety of sources and forms of knowledge, which is co-produced in social relations [7]. In this light, HL can be considered as being closely interwoven with processes of shared decision making (SDM) concerning medical interventions. For example, Smith et al. [8] found that people with higher health competence perceived decision-making as a joint negotiation process, which they could actively shape, while persons with lower levels of HL appeared to engage in the decision-making process less autonomously; rather than actively participating, they were more likely to accept the doctor's recommendation. At the same time, subjective HL and the involvement in SDM process have a positive impact on the satisfaction with medical care, the compliance and the success of medical interventions [9]. HL therefore plays an essential role in the extent to which people are involved in decisions about medical interventions and thus how satisfied they are with medical treatment. There is hence a widespread demand of promoting HL in terms of involving patients more actively in decision-making in the context of medical consultations [8–12].

1.3. The Value of Communication

As much as patients are facing challenges of navigating through complex information upon anticipated health conditions, risks and chances of predictive diagnosis and disease prevention, healthcare professionals are expected to provide them with full and comprehensive information about individual disease risks and preventive options, ensuring an environment where there is enough time, communication and empathy to mutually find individual-sensitive solutions. There is a shift in medical consultation models from the traditional, paternalistic patient-physician-relationship, where doctors make recommendations and patients give their consent, towards the model of SDM, meaning the exchange of information and preferences about diagnostic and therapeutic procedures between patient and physician [13]. There is also an ethical claim towards healthcare professionals with respect to risk-adjusted patient-information and preventive decisions: While every medical intervention is per se an act of bodily harm and only legal when informed consent is given by the patient, interventions in (still) healthy persons for the sake of pre-clinical measures and preventive treatment require special accuracy and comprehensibility of information provided by the physician [14]. Ishikawa & Kiuchi [15] almost ten years ago noted with respect to the role of HL in health communication that the concept of HL should be examined not only as an individual set of skills but also "in terms of the interactional processes between individuals and their health and social environment" [15] (p. 1). We believe that by now this approach remained highly underrepresented in the research on HL and are convinced that it may be crucial not only to better understand the interrelation between individual and organisational HL [16] (especially in context of risk), but also for the development of tools, instruments and interventions which can lead to an improved HL on an individual and a social level. In consequence, when striving for a bottom-up approach[1] to HL in "persons at risk", attention needs to be directed to the communicative character of the concept, situating it within the theoretical framework of SDM and health communication. Our approach is informed by a perspective on the interactional dynamics and the power relations that are shaping a communication process and its outcomes. In particular, Habermas' theory of communicative action is considered as fruitful for understanding how HL is co-constructed in healthcare settings, and as a framework for encouraging critical health literacy. This theory proposes claims of validity for judicious communication and mutual understanding, based on equal opportunities concerning the initiation of and participation in dialogue, and contributing to arguments and interpretations. Furthermore, it allows for insight into the individual's lifeworld without neglecting the organisational context, emphasising the interrelation between both. This concept, including its link to (critical) HL, will be elucidated in more detail in the discussion of our findings.

1.4. Aims and Research Questions

The overarching goal of this contribution is to approach HL in its interactional dimension. Employing a health sciences and an ethnographic research perspective, we aim at providing a new bottom-up definitional approach to the concept of HL in the context of health risk, with an emphasis on critical HL. The leading questions of the research project are: (1) How is a person's HL interrelated with the condition of 'being at risk'? (2) What kind of HL do people need in order to manage their health risks (from a bottom-up perspective)? (3) How can HL be promoted in order to support individuals in the process of SDM and of transferring medical risk information into their lifeworld? The aim is not only to enrich the body of research on the theoretical and conceptual underpinnings of HL [17–19] and to contribute to the understanding of HL in the context of risk, but also to provide an empirical foundation for the development of interventions for communication about risk in healthcare settings [15,20], hereby improving HL both on an individual and on an organisational level.

2. Materials and Methods

This qualitative study is part of the project Health Literacy of Persons at Risk – From Information to Action (RisKomp) which investigated the role of HL in persons with an increased risk of developing a disease in one of four exemplary clinical fields (Alzheimer's dementia (AD), familial breast and ovarian cancer (FBOC), coronary heart disease (CHD) and psychosis (PSY)). The choice of these exemplary clinical fields was based on the fact that they allowed a focus on disease patterns with epidemiological relevance in oncology, neurology, cardiology and psychiatry, and thus the exploration of risk perception and HL relevant factors in the field of mental as well as physical disease. By considering diseases with a diverse definition of risk factors and different methods of creating risk profiles (including symptom

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[1] When using the term bottom-up approach in this article, we refer to the attempt to take the perspective of those being studied (the so-called persons at risk) without imposing specialist-driven definitions of health, risk, and HL (top-down approach). Instead of empirically testing existing pre-defined scientific concepts, we put the emphasis on health, risk and HL as understood and enacted by our interviewees.

assessment as well as biomarker and genetic testing), it was possible to include diverse risk patterns in the analyses. A further gain of knowledge was made possible by the spectrum of prevention opportunities and therapeutic approaches, which can either prevent the onset or have a positive effect on the course of a disease. The intervention options concerning the four indication areas range from surgical or medicinal, psychotherapeutic and educational, to no effective medical prevention option so far in regard to Alzheimer's dementia. This allows taking into account strategical deliberations of persons at risk; depending on health-related future scenarios they were confronted with in the course of predictive procedures. The systematic reviews conducted in the first phase of the project provide an overview of the research landscape and current empirical evidence concerning the role of HL with respect to an increased risk in each of the four clinical fields; in addition, they revealed open questions and directions for future research [21–23][2].

The study was planned and conducted in close collaboration with partners in the cooperating specialist centres at the University Hospital Cologne (Appendix A)[3]. Ethics approval was obtained in March 2018 (registration number 18-014) by the Medical Faculty of the University of Cologne.[4]

2.1. Sampling and Recruiting Procedure

For the recruitment of interview candidates, indication specific inclusion and exclusion criteria (Appendix B) were defined in cooperation with the specialist centres for genetic testing or preclinical diagnosis of the University Hospital of Cologne. In a first step, for each clinical field, risk profiles were determined based on current medical evidence (e.g., a particular type of genetic risk or a combination of genetic, physiological, and behavioural risk factors). The aim of this purposive sampling strategy was to enclose a maximum variety of risk manifestations for each clinical field [24]. According to the in- and exclusion criteria, the clinical staff started recruiting the individual participants based on convenience sampling. There is no consensus about the ideal sample size [25]; while it is often necessary to specify a certain number of interviews for ethics approval and funding calculation, the inclusion of ten participants per clinical field was envisaged (40 in total). This number was based on the project aim, the research question, the chosen study design, as well as the available personal and institutional resources.

The collaborating clinics supported us in recruiting participants by pre-screening their patients' profiles with regard to the in- and exclusion criteria, by handing out brief information about the research project to the potential participants, by imparting their contacts to the project team, and by providing facilities for the interviews. In the field of coronary heart disease, in addition to cooperating with teaching practices of the University Hospital Cologne, online recruitment strategies, social media, public displays as well as the contacting of support-groups and relevant organisations were used as recruitment strategies. The clinical staff arranged the first contact with potential participants; all further steps like providing detailed study information, arranging the interview appointment, conducting the interview, and any further communication with the participants was at the authors' responsibility.

2.2. Data Collection

To answer the research questions, we chose a qualitative research design which incorporates three pools of data: (1) narrative interviews on risk and health, (2) body sketches visualising embodied

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[2] The systematic review in the field of familial breast and ovarian cancer is under revision and will be published in 2020.

[3] The collaborating partners were involved in the different phases of the project as follows: sampling and recruiting (clinical staff and the authors), data collection in terms of conducting interviews and taking field notes (LH, ML and SJ), data analysis for each clinical field (LH, ML and SJ), and interpretative analysis across the four clinical fields (LH, ML and SJ).

[4] Before the interview, all potential study participants were provided with information concerning the aims, methods (including details on the interview procedure, possible harms and benefits, and the continuing opportunity to withdraw from study participation), the exploitation of the research results, and data protection. At the outset of the interview, all participants signed a written consent form.

perceptions of risk and illness, and (3) ethnographic data based on notes and memos concerning reflexivity and the research relationship, created before, during and after the interview.

2.2.1. Narrative Interviews

The narrative interview, chosen to be a main source of data collection in this research project, is a methodology of qualitative social research to gain insights into the interviewees' personal experiences, feelings and subjective relevancies in a context of interest. The idea of the narrative interview is to let the interviewees tell their "stories" and herewith communicate their perspective on a subject without narrowing the course of information by giving a direction of conversation with a standardised interview guide [26]. Narrative interviews were deemed suitable for this project since they allow for a bottom-up approach to concepts such as risk and HL. Letting these be defined by the persons' individual perceptions, appraisals, and preferences, narratives can inform the development of theory which is grounded in empirical data. Being interested in HL relevant factors from the perspective of persons at risk, narrative interviews using a flexible topic-guide were the instrument of choice. This approach follows the principle of narrative interviews, starting the conversation with an open introductory question, but sharpening its focus by context-specific in-depth questions (incorporated in the topic guide), pre-defined by the researcher alongside the subject of interest [27]. The interviews started with a question about the first confrontation with being at risk of developing a certain disease[5] [28]. With reference to the interviewees' narratives, in-depth questions were asked on access, understanding, appraisal and application of risk-related health information. The interviews were concluded when no new themes or stories were raised, and upon the researcher's explicit invitation to think of any further potentially relevant issues that the interviewee may wish to describe.

The interviews were audio-recorded with the participants' given consent. The audio material was transcribed verbatim, and transcripts served the text-based analysis of the interviews using MAXQDA 2018 [29]. In addition, sociodemographic questionnaires were included into data analysis that had been handed out to and filled in by participants before the interviews.

2.2.2. Embodied Perceptions of Risk and Illness

At the end of each interview, participants were asked to perform a body-mapping exercise. A sheet of paper showing an empty body sketch was given to participants, who were subsequently asked to depict their feelings about being at risk of developing a disease. Interviewees had the opportunity to comment on their drawings if they felt the needed to do so. The method of body-mapping is an approach with which insights in the individual's embodied realities can be gained, and is used in health sciences [30,31]. Body-mapping allows the non-verbal and creative expression of perceptions, personal feelings and experiences and is therefore suitable for the inductive, bottom-up approach aimed at in this study.[6]

2.2.3. Ethnographic Data Concerning the Research-Relationship

During the interviews, the researchers took field notes concerning content, non-verbal communication, atmosphere and their own experiences and feelings during the interviews using a self-reflection tool developed for the purpose of this study (notes and memos). The documentation and reflection of one's own feelings and observations during and after interviews is a common practice to make the researchers' subjectivity comprehensible and transparent, which is a

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[5] More detailed information on strategies to minimise potential distress for participants, including a reflection on methodological and ethical issues in qualitative research on health risks, can be found in [28].

[6] An appropriate description of the body-maps would be beyond the scope of this article. To avoid an oversimplified presentation, we will therefore refrain from providing examples. The in-depth analysis of the body-maps and their role in the process of theory generation will be thematised in a separate article.

key quality criterion in qualitative social research [32,33]. The notes and memos were included in the data analysis and methodical reflection of the research process.

2.3. Data Analysis

The analysis process of this study is embedded in the overarching approach of the Reflexive Grounded-Theory-Methodology [34], and mirrors an iterative process of three analytical steps: (1) analysis of data (narratives, body-maps and ethnographic data) for each clinical field separately, using a field-specific coding system; (2) interpretative analysis of the findings in all four clinical fields, developing a new integrated coding system, and (3) interdisciplinary data validation and cross-check analysis.

2.3.1. Analysis of the Narratives, Body-Maps and Ethnographic Data for Each Clinical Field Using a Field-specific Coding System

In this first analytical step, data in each clinical field were analysed separately by different team members in an iterative process parallel to conducting subsequent interviews. The goal was to identify categories that are specific to the risk of disease in the respective clinical field, avoiding direct comparisons between data in the process of collection and first analysis. With the exception of CHD, thematic saturation[7] [35,36] was reached before completing analysis for all envisaged (n = 10) interviews in each clinical field; i.e., the main categories remained stable after having analysed approximately six to seven data sets in the respective clinical field, even when including further interviews in the analysis. During the process of open coding, we created a coding system embracing the different data types (narratives (verbal), body maps (visual), and field notes (reflexive)), which provided insights into different emic interpretations of risk, health and HL. Furthermore, through the integration of field notes into the analysis it was possible to address the question of researchers' subjectivity and make it as visible as possible in the analytical process. In the process of axial and selective coding, we searched for interconnections with the concept of HL, both describing it from the patients' perspective and relating it to existing definitions of the concept from the literature. Through this triangulation of methodology and theory [37], we aimed to emphasise the ethnographic, bottom-up character of the research.

2.3.2. Interpretative Analysis of the Findings of All Four Clinical Fields, By Developing a New Integrated Coding System

In the second stage of analysis, we conducted an interpretative analysis across coding systems, integrating the codes of all four clinical fields. Due to the restricted number of interviews in the field of CHD, interpretation was considered with reservation. Both indication-specific and cross-indication findings regarding HL-relevant factors in persons with an increased risk of disease, were compared and discussed within the research team, taking into consideration different perspectives from our disciplinary backgrounds (ethnology, psychology, and health sciences). In this way, we were able to identify categories and relations relevant for all four fields as well as those themes that are specific for each clinical field. For the purpose of this article, we created an overarching category system (Figure 1, Section 3.2) which emerged during the analysis across the clinical fields based on the research questions stated above, and the previously gained in-depth insights in the different fields. Through this approach, decision making processes of people with an increased disease risk regarding the use of early diagnostic procedures and preventive interventions can be reconstructed. This allows for reflecting on conducive models of risk communication in connection with health behaviour and contributes to the theoretical foundation of the concept of HL.

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[7] 'Saturation' can be defined from different perspectives and on diverse levels of research [35,36]; in line with our methodological approach, we refer to the model of 'inductive thematic saturation' [35] which relates to the emergence of new codes or themes during data analysis.

2.3.3. Interdisciplinary Data Validation and Cross-Check Analysis

In the final analytical phase, we aimed at researcher, methodological and theory triangulation, and interpreted and validated the interpretative analysis performed in the second analytical step. For this purpose, we organised interdisciplinary researcher discussions in order to relate the concepts which arose from the empirical data to existing theoretical frameworks in different academic fields, and to test the applicability of the developed theoretical considerations across the four clinical fields.

3. Results

In the following, we will shortly introduce the database of the research project, and present the central findings of our study along the structure of the main categories and sub-categories that we identified during the interpretative analysis.

3.1. Database

The interviews were conducted between April 2018 and August 2019. In total, 34 out of the envisaged 40 interviews were completed. During one interview in the AD group, it turned out that at the time of the study, the respondent already had dementia (exclusion criterion). Therefore, 33 interviews were included in the data analysis (a detailed presentation of the participants' characteristics is provided in Appendix C). In the area of CHD, despite various recruitment strategies during the period of data collection, no more than three persons could be recruited to participate in the research project (Table 1). (The recruiting strategy and possible reasons for the low response rate compared to the other clinical fields will be methodologically reflected in the further course of the evaluations).

Table 1. Interviews conducted and included in the data analysis.

	FBOC	**AD**	**CHD**	**PSY**	**In Total**
Planned	10	10	10	10	40
Conducted	10	11	3	10	34
Included	10	10	3	10	33

Audio material of approximately 34 h, 1036 pages of transcripts, 33 questionnaires and 31 body-maps, plus the researchers' memo material constituted the data sources used in the data analysis process (Appendix D).

3.2. Main Categories

Hereinafter, our findings concerning HL-relevant factors for people at risk of developing a disease, and HL-related aspects in order to manage these risks, will be presented. The results focus on the respondents' subjective risk and disease theories, as well as on their analytical-reflexive and emotional-intuitive interpretation systems. We identified three central categories which refer to key situations of risk perception, the processing and understanding of disease risk, and risk-related agency of "persons at risk" (Figure 1).

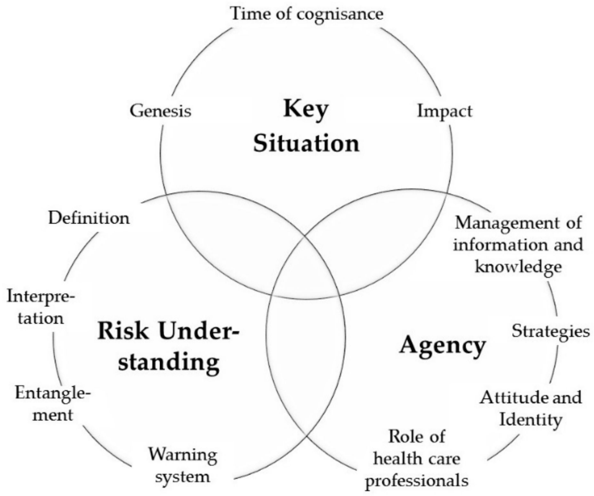

Figure 1. Central categories of dealing with disease risk: key situation, risk understanding, and agency.

3.2.1. Key Situations

In the context of this study, key situations describe a distinct moment or an extended period of the ideational realisation of one's risk. This is determined by a person's biographical background, intuition, and degree of self-reflection. Whether a person is confronted with the risk of developing a disease for the first time or has been confronted with the idea of risk directly or indirectly for years, has an influence on how the risk is dealt with, and on the decision-making processes regarding early diagnostic or preventive measures. In the following, features of key situations identified in the interviewees' narratives will be described. The identified key situations can be differentiated along the process of being confronted with risk, in terms of the emergence of a risk feeling, the time of cognisance of risk, and the impact of key situations.

Genesis

Genesis describes the development that gave the initial impetus for dealing with the concept of risk, and ultimately participating in early diagnostic procedures. Respondents describe an omnipresent risk idea or an intuitive risk perception over a longer period of time to be the reason for the participation in early diagnostic procedures as a form of active engagement with their own health-related future:

> "That's a little strange because, um … that was for me, well breast cancer has always been an issue for me." (FBOCP06)
>
> "Yeah, I kind of want to know what that is and why. [...] Just to have the certainty." (ADP08)
>
> "And it's nothing that has uh just been there for three months, it has always been there. Well, it didn't just appear like three months ago, it has always been there." (PSYP10)

Time of Cognisance

The time of cognisance means the moment or period of time of risk confrontation in which participants became aware of their risk. According to interviewees' descriptions, a moment of confrontation in the sense of a sudden awareness of a risk can be caused by biographical upheavals (relocations, life stage changes, crises) or chance findings during routine examinations. Dealing with disease risk over a longer period of time can be the case due to disease experiences in the family or the observation of symptoms that people may associate with the development of diseases and interpret them as a potential precursor (forgetfulness, changes in perception, cardiovascular complaints): "Sometimes I don't have any problems at all and sometimes I think 'It can't be true that you don't remember this anymore!'." (ADP07).

Facing an increased disease risk, whether in a moment of confrontation or over a period of becoming aware, entails a transition or a turning point in the lives of the participants of this study, with characteristic consequences for their identity formation, lifestyle or future perspectives. The interviewees' narratives contain detailed episodic accounts of the situations or periods of becoming aware and inescapably realising that 'something is wrong'.

> "Um, and then, as really the most relevant moment was when I was at the North Cape and the big turquoise wide sea was in front of me, the people around me were all happy, there were some plants around me you can't find anywhere else, and I just didn't feel anything." (PSYP01)

> "I was still young and thin and thought: 'How could that be, diabetes type two, you get that at seventy or eighty or so and if you get it before then, it's because you're a rather chubby person!' I was really shocked. Because I expected everything, but not that I would become diabetic at the age of fifty or in my early fifties." (CHDP01)

Impact

Respondents described key situations to have an existential impact on their considerations and planning with relevance for their life course, their identity, and their family planning: "The consequence of this, if I think about my husband and myself, would be family planning." (FBOCP10), their professional context: "I already told my superior to consider me as a risk factor" (ADP04) or their view on future life in general: "There are days where I only look at the black side of my future." (ADP07).

The impact of key situations on people's perceptions or actions can be of a positive and motivational nature: "I want to stay healthy you know? So living healthily is my contribution to not getting high blood pressure." (CHDP03). At the same time, key situations can have a negative-destructive impact: "All I feel is fear of getting dementia. [...] It is in every cell." (ADP01).

This is of central importance with respect to patient information and risk communication. Consultation in the context of early diagnostic counselling and intervention planning can be decisive in terms of the extent to which people who seek advice are motivated and enabled to make health-promoting decisions and actively shape their health development wherever possible.

Key situations can also provide information on peoples' preferences, skills, and strategies in researching and selecting risk-related health information. Whether, for example, they have been informing themselves about a possible risk of illness for a longer period of time or whether they do not yet know or have not sought any information on the subject at all, sheds light on the scope and the content of information needed. This provides a starting point for medical consultation.

The identification of key situations can also mean orientation for individuals' lived realities, their biographical experiences, and their socio-cultural embedding of the risk understanding. These background circumstances are pivotal in terms of people's needs concerning health-related information and decisions.

The available data offer an opportunity to define types of key situations. A typology of key situations with respect to their emergence or time of cognisance (e.g., sudden or foreseeable) and their impact (e.g., shock or confirmation), can serve as an orientation framework in the early diagnostics of risk and preventive praxis, helping professionals to provide risk information based on individual needs.

3.2.2. Risk Understanding

The understanding of risk comprises aspects of subjective risk definition and interpretation, as well as the individual's relative meaning of a disease risk. The following issues were identified with respect to the understanding of risk.

Definition – Describing Risk

People have individual definitional concepts of a disease risk. 'Definition' in this context refers to metaphors and descriptions participants use to name their risk. People, for instance, describe their risk as a "time bomb" (ADP09), a "tattoo" (PSYP10) or a "bookmark" (PSYP10) and thereby reveal risk to be experienced as something threatening, stigmatising or permanent. Defining one's personal risk means naming it on the one hand; on the other hand, naming it by using metaphorical terms also means applying interpretational concepts to it. The definition and interpretation of risk are therefore closely interwoven and determined by personal disease conceptions. Threat rhetoric used by interviewees with regard to their disease expectations show that experience-based disease images, which for example are associated with decay, hopelessness, strain on relatives or the loss of the social role and one's own identity, pre-set a definitional framework: "I would like to see my daughter grow up and be an adequate companion for her and not a [. . .] senile one." (ADP03). The metaphorical description of risk perception and disease conceptions emerging in the context of the body maps, both in visual and in verbal form, provide insightful information about risk-related perceptions or visions of one's own state of health. Definitional concepts and interpretations of disease risk are crucial in the process of meaning-making [38] concerning potential future health scenarios.

Interpretation – Appraising Risk

According to the analysis of the interviews in our study, the appraisal of risk, as illustrated by the following exemplary quotations, is largely determined by personal conceptions of a disease, which in turn are influenced by self-inflicted or externally-intrigued experiences of illness. People who have already experienced the course of a disease, for example by caring for a relative, project these experiences onto themselves and define their own future state of health accordingly: "I know lots of people with dementia in my environment. [. . .] Seeing my friends' parents. That's really bad you know." (ADP05) or "I don't want not to be pretty anymore. [. . .] I have seen my cousin dying of cancer, she looked so ugly. That was really bad." (FBOCP05).

Risk knowledge in the present about an anticipated state of health in the future can influence the perceived quality of life. Thus, the boundaries between being healthy and being ill already are blurred by the imaginary confrontation with a disease risk before the actual occurrence or onset of a possible illness. Perceived symptoms, for instance, can entail a disease experience even before the actual manifestation of a condition: "I have all the symptoms!" (ADP01). This influences everyday life and lifestyle: "This fear that they might say 'Ok, there is something.' keeps me getting these panic attacks." (FBOCP02) or "I definitely try my best to live more relaxed, and not to let it get any worse." (PSYP05).

"Healthy" and "sick" are thus redefined and persons at risk are confronted with identity-relevant changes. HL of persons with an increased risk of illness - their resources and motives to deal with and apply risk-related health information - depends on their ability to integrate the risk status into their own reality and to accept or actively reject it as part of their identity.

In the individuals' perceptions, the perceived risk prevails over the actual (statistical) probability score: "And in the end we are people, not statistics." (FBOCP09). For example, the results of early diagnostic examinations may contradict the feelings of those seeking advice: "I was always, um, totally irritated because of these test results, I have to admit. Because they didn't reflect at all what I am feeling for myself." (ADP05). The consequence can be that an existing risk is not perceived as such: „Well, I don't know. I have been told that I am at risk, so to say. But yeah. That's all." (PSYP02). In this case, people face the conflict of making decisions about a situation of which integration into their lifeworld does not correspond to their own perceptions.

Percentages given to respondents were interpreted subjectively. Risks can be perceived as an omnipresent threat even with a low numerical probability of illness. While early risk detection procedures for some persons can imply the positive effect of an "early warning system" (which will be described in more detail in the following), for others these do not convey a sense of security if they pervasively continue to feel that they are facing a health threat despite the "all-clear signal". For example, respondents stated that they did not feel any sense of security, even though the result of their predictive examinations did not reveal an increased risk of developing a disease: "I mean, it was a fact that there was something a way it was not supposed to be." (ADP05). So, the emotional evaluation outweighs the logical interpretation of percentages and factual findings.

Entanglements

In addition to such emotional-intuitive interpretation systems, the analytical-reflective approach is of relevance when dealing with the probability of illness (consistent with the model by Slovic et al. [39] on the emotional and analytical handling of risk). The respondents' statements on the subjectively perceived relativity of risk refer to risk entanglements as well as to vague versus concrete risk conceptions.

For example, the disease risk that respondents were undergoing early diagnostic procedures for, was repeatedly named in connection with parallel existing diseases or disease risks: "Being overweight is part of my biography. I am overweight now [. . .] and I have been overweight as a kid or as a teenager." (CHDP03). Risks are therefore not perceived and processed as isolated entities but understood as interdependencies with other risks: "It could be that my depression has affected my cognitive condition, couldn't it?" (ADP04) or "Sure there is a risk when you smoke and drink alcohol." (FBOCP01).

When dealing with a certain disease risk, persons reflect their own (prospective) health as the totality of various (risk) factors. Reflection in the sense of critical HL [40] goes beyond the differentiated examination of health-related risk information and includes an examination of one's own lifeworld in terms of values, preferences, habitualisation, and social circumstances. As a practical implication for early diagnostic consultations and treatment, these findings can inform starting points for health-promoting or preventive measures.

Vague versus concrete risk conceptions determine to what extent people adopt a "diagnosed" risk probability and include it in their consideration processes and actions. The perceived degree of abstraction of both the risk and the respective image of disease plays a role here. Our data allow the assumption that risk developments and disease progressions with psychological or mental effects are likely to be experienced as more difficult to "grasp" than risk prediction of diseases with physical consequences, the development of which can be – according to respondents' appraisal – specified more precisely by means of biomedical parameters: "Subjective cognitive disorder, my God. You have your aches and pains and that's just one of them." (ADP03) or "I'm not saying that everybody has mental issues but in some way [. . .] other people do struggle with their everyday life, too." (PSYP01).

Warning System

Irrespective of the degree of abstraction of the risk, people who participate in early diagnostic procedures actively deal with their risk. In this context, risk prediction is interpreted as a kind of early warning system and as a resource in the informed handling of one's own health. Respondents describe that the medical prediction of their likelihood of disease gives them a feeling of clarity and therefore the opportunity for active prevention – in terms of medical interventions, organisational preparations or lifestyle changes. The last quotation also underscores the blurring between 'risk' and 'disease' in the interviewees' accounts.

> "That's why I'm glad I was able to deal with my problems now. [...] And I'm just glad that this bang fortunately caused the discernment that I have to let people help me." (PSYP07)

> "That was just another piece of the puzzle for me. It was absolutely out of question. Either you want to know or you don't. I already said before I knew for certain: Just take my breast off!" (FBOCP04)

> "We have decided to downsize a little with respect to our living. Age-appropriate. That as well has to do with my dementia." (ADP06)

Our interviewees' risk narratives reveal the process of understanding, evaluating and applying risk information. Subjective interpretation patterns and relevance systems are crucial for the interpretation of risk and the resulting motivation to act. This negotiation process can be revealed through the narratives of those seeking advice to meet their needs with regard to medical consultation and treatment.

3.2.3. Agency

The category "Agency" refers to individual autonomy and manageability in view of an increased risk of illness. It comprises emotional, cognitive, and behavioural strategies that our interviewees reported in order to (re)construct their capacity to define their situation, to make choices, and to act independently. This includes aspects of information and knowledge management, the role of attitude and identity in dealing with a health-related risk, individual strategies of action, and the role of health care professionals in risk perception and processing.

Dealing with Information and Knowledge

Respondents name various sources of information they use to get informed about their disease risk, including articles, studies, TV and books. They also mention the Internet and the social environment to be central media for the exchange of experiences or personal opinions and the search for risk- or disease-related information: "And when you read something like this, what do you do nowadays? Google." (ADP03) or „I talk to my husband, he is of great help to me." (FBOCP03). The finding and understanding of health information does not refer to an isolated source of information but to a construct of several sources of information, which people individually choose and evaluate. The information medium therefore goes beyond the medical setting and the doctor-patient communication setting in early diagnostic procedures. According to the respondents, the primary information strategy is to obtain health information by oneself: "I can only recommend to get as much information as possible." (ADP04). They critically decide where to look for information: "You have to be careful about where you find your information, right?" (FBOCP01), what information they choose for themselves: "I don't trust my doctors exclusively anymore." (FBOCP01), and which information they want to or do not want to deal with: „Sometimes you just don't want to know it in cold print, you know?" (ADP07). Information seeking and evaluation strategies depend on the individual's systems of experience and relevance.

Attitude and Identity

In terms of attitude and identity, personal competences such as interest, motivation, self-reflection and self-efficacy are essential prerequisites for the way people deal with information about and the personal exposition to health risk. Participation in predictive procedures, for example, is described as self-initiative based on self-observation and self-reflection. With the decision for or against information, examinations, study participation or reporting of findings, a competence for one's own needs becomes visible, which has to be included and taken into account during counselling.

Of equal importance for attitude and identity in dealing with a disease risk is the social environment. Persons within the social network – family, partners, and friends – directly or indirectly influence decision-making processes with regard to early diagnostic procedures as well as the negotiation processes regarding therapeutic measures. Direct influence exists, for example, when relatives actively encourage participation in diagnostic testing: "Well I have to say, my oldest daughter was the one who told me to see a doctor." (ADP07). Indirectly, a feeling of responsibility towards relatives may for instance be decisive for a person's step towards medical risk prediction: "I have three children. I think about them, I don't really think about me." (FBOCP02).

While identity and attitudes determine how health risks are dealt with, they can also be influenced by the way risk is conceptualised.

"I am a risk factor." (ADP05)

"And then you go like: 'Oh shit – this is like a tattoo!' That's gonna stay for now." (PSYP10)

For the promotion of health-literate action in dealing with disease risk, this finding shows that factors such as intrinsic and extrinsic motivation as well as input from the social environment deserve to be taken into account in medical consultations.

Strategies

In dealing with a disease risk, our interviewees reported having developed personal strategies. These include, for example, subjective explanatory models and measures to maintain or improve the subjective quality of life. As elaborated further below, explanatory models are both a strategy to process the origin and development of risk within people's own logical system. At the same time, these models are the starting point for the development of strategies for dealing with a disease risk, which involves the acceptance of a "new" reality and the assumption of the risk status. Health-oriented decisions and lifestyle adjustments can be the result.

With reference to our interviewees, explanatory models of risk were individual and biographical. When negotiating one's own risk, not only information from outside is taken into account, but also theories of justification which are constructed by the individuals themselves. In this way, they explain their own risk by stress and psychological strain due to for example overwork in everyday life: "I think I have been permanently overstrained all my life." (CHDP02), concern for relatives and family: „I have a ten year old daughter. What will happen to her?" (ADP02) or disease burden: "Well, there are two areas that need to be worked on. There is my depression, and these signs of psychosis." (PSYP01).

Strategies described by respondents regarding the management of disease risk relate to actively influencing one's own health and maintaining quality of life by leading a health-promoting lifestyle: "I do my best to live a healthy lifestyle, eat healthy food, do sports." (CHDP03) and by continuing everyday life and one's social role: "Continuing everyday routines, that's what is important." (ADP05). Following on from the central explanatory model of stress as the cause of an existing disease risk, stress avoidance or stress reduction are central strategies, universal to respondents in all clinical areas addressed in this study.

The orientation of strategies is decisively influenced by the therapeutic interventions and preventive options available with regard to the prevention of the onset of a disease or the positive influence on the course of a disease. For three of four indications included in this study (CHD, FBOC, and PSY), these strategies range from surgical interventions and drug therapies to psychotherapeutic and educational approaches. For AD, to date, no effective prevention or cure exists, even at an early stage of risk prediction. However, knowing about the risk can offer the opportunity to make provisions in terms of organisational and existential matters: "Everything is prepared. [. . .] If I got Alzheimer's dementia tomorrow, I would have everything organised." (ADP03).

Role of Health Care Professionals

The handling of information about one's own disease risk and the development of strategies for action are thus decisively related to biographical and personality-related relevance systems, information needs and explanatory models.

Do the data also provide insights into the role of consulting physicians in connection with risk perception, processing and risk-adjusted decision-making? The respondents' comments on the consultation on risk prediction and possible preventive treatment they had experienced ranged from statements of complete satisfaction and feeling well-informed, to the condition of feeling as clueless as before the consultation: "I feel totally well advised." (FBOC08) or "I know just as much as I did before." (ADP08).

Patients critically reflect on the counselling situation and the information content, and compare it with their own needs. The role assignment to health care professionals in dealing with a health risk is also negotiated by patients: "I kept asking what I could do about it but she never really gave me any answers." (ADP08)

A central expectation towards health care professionals in this context is their empathy and understanding with regard to the individual situation of those seeking advice: "A doctor, even if he can't help, a doctor should be a person who is able to listen." (FBOCP05). There is also a desire for communication "at eye level". The power-relation in patient-doctor communication is addressed in various contexts and forms an important category, as it can adversely affect the use of consultation or participation in decision-making processes.

> "But on the other hand, it's actually very important, well it happened now already, um, twice, that something important just showed up in the results .., about which my doctor didn't talk to me." (ADP05)

> "I just don't trust doctors anymore. Oh God, I have experienced so much that I prefer using my own head. [. . .] Things you experience are not always that enjoyable, you know?" (FBOCP01)

With reference to power relations and participatory decision-making in risk diagnostic counselling and preventive treatment, people seeking advice describe how they feel restricted in their freedom to act. For example, they felt that their choices were influenced by strategic rhetoric they experienced in conversations with their doctors: "It would be better if there were people who helped you in your interest, without giving you the feeling of pushing you towards something they want." (FBOCP01). These findings emphasise the relevance of asymmetric power structures between patients and health care professionals, due to an imbalance in medical knowledge and expertise, for SDM in the course of medical consultations.

Positive experiences with medical consultations in the predictive field, however, can enable relationships of trust with medical services in general, and with practitioners in particular:

> "A trusted relationship with my doctor is essential to me. Now I ended up with a doctor I don't have any connection to. And in that case . . . well, with her, I would rather not talk about sensitive stuff." (CHDP03)

> "Where it actually kicked in for me were my therapy sessions. [. . .] Because of them, I was able to see things more clearly." (PSYP10)

These results can contribute to the expansion of the concept of HL by including essential aspects that are relevant for the promotion of HL, especially in the setting of risk prediction. The data emphasise the self-reflected way of persons at risk in dealing with risk information, their own biography and identity in the context of risk, personal definitional concepts of risk and illness, and their perception of risk diagnostic consultations. These results serve as starting points to enable health literate decision-making and action-taking in medical risk context. The reflection of key situations in recognising risk, processes of understanding risk and the negotiation of strategies in dealing with risk are aspects that deserve consideration with respect to identity formation, and with regard to communication strategies in the context of SDM in medical consultations and beyond. Practical implications, both for the expansion of the concept of HL and for early diagnostic consultation practice, will be discussed in the following.

4. Discussion

The data of our study provide unique insight into the tension fields between HL, risk, and predictive medicine by adopting the perspective of our interviewees – the so-called "persons at risk". In this way, our findings can make an important contribution to research on HL, and hereby enrich its theoretical anchoring.

Our findings raise exciting questions about (1) the definition of HL from a bottom-up perspective, (2) the co-construction of HL within the communication process, paying particular attention to the effects of strategic/persuasive communication on SDM, and (3) HL instruments that may have a positive impact on both health system and lifeworld in the context of risk. In the following, we will illuminate each of these fields, grounded in both theoretical and empirical considerations.

4.1. Defining HL from a Bottom-Up Perspective: Jumping the Frame of Dealing with Health Information and Opening up a Space for a More Holistic Approach

Our findings support the definition of HL by WHO [2,3] as a complex human competence, which is impacted by different factors. Especially in the context of risk, HL can be described, from the perspective of respective individuals, as a way of balancing between different sources of risk information: the physician or the health system, the Internet and other media, somatic feelings, explanatory models, biographic experiences, and everyday life (in terms of subjective quality of life) which evolve in the context of their individual lifeworlds.

In the preparation phase of our research, we used the integrated model by Sørensen et al. [2] as a template and an orientation framework for the development of our study design and the interview-guide, assuming that HL in the context of risk would follow the same or a similar logic. Nevertheless, after first data emerged and was analysed, we quickly realised that an interdisciplinary and multidimensional theoretical embedding will be needed in order to grasp the great amount of symbols and meanings generated throughout the research process. We needed to situate our findings within the field of the HL research (individual and organisational, critical and relational) but also in the sphere of health communication and SDM as well as social science research. The interplay between risk information, the individual explanatory model of risk, intuition, and the ability to reflect on all three aspects (Figure 2) clearly illustrates the necessity to merge different theoretical approaches. This model depicts the understanding of HL from a bottom-up perspective.

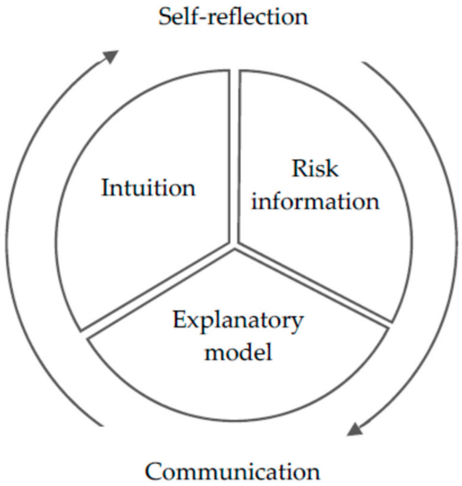

Figure 2. Model of HL in the context of risk– co-construction of risk interpretation and meaning.

On the one hand, this model emphasises the importance of learning more about the patients' explanatory models of sickness [41] and risk as a way to grasp relevant information in the context of their lifeworld. On the other hand, it refers to Slovic's [39] theory on risk mentioned above – risk probabilities as part of the analytical system and intuition as part of the emotional system which both on an equal stance enable individuals to make decisions about risk. Furthermore, the dimension of reflection highlights the importance of different domains of critical HL, as described by Chinn [17]: critical appraisal of information, understanding social determinants of health and collective action. These findings are not pioneering in health research; however, they shed a different light on the field of HL in the context of risk perfectly illustrating the "mismatch between 'biomedical' and 'lifeworld' agenda" [42].

Based on these findings and building on already existing work [7,43,44], we propose a complementary definitional perspective to the concept of HL, employing an ethnographic and health sciences bottom-up approach.

4.2. HL as Communicative Action?

In the process of data analysis, the interaction between lifeworld and system turned out to be central for understanding HL in the context of risk from the interviewees' perspective. For a sound theoretical anchoring of this finding, the philosophical foundations of the theory of communicative action by Jürgen Habermas [45] were considered an appropriate and fruitful background for the theoretical embedding of the empirical data, seeking to bridge action and systems theories. Furthermore, this approach incorporates the notion of power in health communication, which emerged as a central issue when discussing the role of critical HL in the context of predictive and preventive medicine. According to Habermas, actors' coordination of actions based on common norms is not self-evident, but must always first be reached by mutual agreement between the parties involved; the way in which this happens is through linguistic communication.

In the context of HL and risk communication, the existing literature provides insight into the common norms underlying communication or SDM in medical contexts. But what do we know about the way the actors (professionals and patients) coordinate and negotiate their health-related actions?

Categories like self-reflection, agency, interactions (in the context of patients' lives and health system) can be fruitfully used to draw an analogy to the Habermasian tensions between (a) lifeworld and system and (b) communicative and strategic action, and provide an inspiring theoretical framework to contextualise the risk-encounter in terms of HL. In the following, we will relate our findings to the theory of communicative action, arguing that this allows for an additional, practice-related and intervention-oriented approach in operationalising and doing research on HL.

4.2.1. Lifeworld and System

The interviewees' risk narratives play a central role in our empirical findings. On the one hand, we see the personal risk narrative which reveals the social integration of the new status as 'person at risk' within one's own lifeworld. On the other hand, we hear the individuals' interpretations of the professionals' narratives, which provide an insight into the assimilating mechanisms of the health system, giving the 'person at risk' a certain system-relevant role and access to prediction and prevention. Speaking with Habermasian terms, the system is "colonising" the lifeworld labelling a certain statistical probability as risk and attributing to a still healthy person the status of "person at risk". In this sense, we can see HL as communicative action where validity claims about risk are made and negotiated. Therefore, the ability to integrate the systemic knowledge into the individual lifeworld and vice versa is an integral part of HL as a dynamic process in both individuals (including the professionals) and the system. Based on this we are prone to see HL as a communicative action that enables professionals, patients, and their relatives to use the risk consultation for negotiating the lifeworld and system narratives and achieve a social and systemic integration of the condition of 'being at risk'.

In line with the Habermasian theory of communicative action, we therefore believe in the necessity to combine the action- and systems theoretical perspective while doing research on health at risk. Especially in the context of HL, such a theoretical bridge is essential in order to integrate both bottom-up and top-down research perspectives, while addressing the concept and allowing for a holistic approach to health risk and communication.

4.2.2. Communicative and Strategic Action

The Habermasian theory differentiates between two types of rationality – the strategic and the communicative reasoning. Communicative action is oriented towards understanding, consensus and balance; strategic action towards manipulation and personal goal achievement. The interview data also mirror this tension; individuals identified situations in which they felt being persuaded to choose for a certain option of risk prediction or prevention. The empirical data show that individuals describe the communicative action as "communication at eye-level", which harmonises the agendas of both actors – patients and doctors. Individuals also detect and describe in detail consultation situations in which they felt like a victim of strategic action and communication.

In the context of risk communication in predictive medicine, we should address the ethical question of wishful thinking with regard to HL from both patients' and professionals' perspectives – should HL perform a communicative or a strategic role? Our data showed that individuals at risk see HL as a process of communicative action in the context of SDM; it will be particularly interesting to learn more about the perspective of professionals in this context – do they see the goal of the communication in uniting both agendas (in the same sense as SDM), or do they (unconsciously) engage in persuasive rhetoric? Greenhalgh et al. found that:

"Lack of trust, intense pressure of time, mismatch of agendas (biomedical versus lifeworld), firm expectations of a specific outcome (e.g., referral, prescription) and profound power imbalances all promote strategic action (i.e., speech that seeks consciously or unconsciously to manipulate an outcome) rather than communicative action (i.e., sincere efforts to achieve understanding, and reach consensus) by all parties." [42] (p. 1170)

In this sense, we are deeply convinced that the understanding of the concept of critical HL should be expanded with one further aspect or category – the ability to engage in communicative action and to detect and reflect on strategic action in the process of the risk consultation. Communicative action requires symmetry. In the case of health at risk we need to critically review the validity claims of both parties. Carel & Kidd [46] argue that ill persons are particularly vulnerable to *epistemic injustice*, while health professionals are considered to be epistemically privileged, and the structures of the health system encourage this condition of epistemic injustice. We suggest that this concept may be enormously fruitful when discussing HL in the context of risk on both theoretical and practical level, drawing the attention to the ethical dimensions of HL-promotion.

Following this argumentation line, future research needs to ask further questions on the prerequisites for communicative action in the field of predictive medicine, where lack of certainty is omnipresent: Which are the major barriers to HL as communicative action?

4.3. Intervention-Oriented Theory on HL as Communicative Action – Draft and First Ideas

Broadening the definition of HL, emphasising the interaction as the space within which HL is manifested and may be promoted offers a new perspective on the development of instruments for measuring and promoting HL. Based on our findings and the theoretical considerations above, we suggest the following impulses for future research and intervention development.

4.3.1. Interaction as a Target

Based on our empirical findings and their theoretical embedding, we recommend moving the focus on the process of interaction between physicians and patients, not only during the risk consultation itself, but also during preparation and follow-up processing. The results of this study suggest that we should rethink the way of designing HL promotion interventions (especially in the context of risk) which usually aim at contributing to the "accurate understanding" of numbers and statistics. Instead, we should turn our attention also to the consultation encounter itself, enabling patients and professionals to engage in communicative action, detect and disclose strategic communication and reflect on both medical and lifeworld-oriented explanatory models of risk and its consequences.

One possible way to take up the patient's explanatory model on the one hand and encourage him/her to engage in communicative action on the other is to explore the key situation of risk during the consultation process. The nature of the key situation can provide information about the socio-cultural embedding of the individual understanding of risk. The processing of the key situation in the counselling situation can strengthen a person's health competence and support professionals in conveying risk information in a patient-centred manner. Discussing the key situation and the explanatory model of risk behind it can contribute to bridging the space between 'patienthood' and 'physicianhood' [47] (p.352).

4.3.2. (Self-)Reflection as a Tool

One of the key results of the current study is the necessity to add a new, additional dimension to the concept of critical HL in the context of risk – the ability to detect and reflect on strategic communication within the risk-consultation. Furthermore, the competence to integrate the status of being at risk into the individual everyday world and identity, translating medical and systems knowledge into one's lifeworld experience, has turned out to be a central resource for approaching HL from a bottom-up perspective. However, how can both types of competences be promoted in the course of the consultation?

One possible tool is to integrate self-reflection components in the process of providing, receiving and negotiating risk information. In the course of our research, we found that patients' narratives do not only reveal information on their medical risk status, but also on the way they have understood and translated this information into their life-world language. Moreover, their accounts may also provide evidence on the strategies individuals have adopted in order to handle the risk information and its consequences. We believe that integrating these narratives in the risk consultation may lead to an increased patient sovereignty [48], more effective communicative action, and extended HL.

4.3.3. Individual and Organisational HL at Once

Our results show that individuals perceive, define, and analyse the role of the health system in the process of risk negotiation primarily through the lens of their interactions with professionals in terms of communication and treatment. With regard to SDM, our interviewees' experiences of strategic communication by healthcare professionals also underscore the importance of paying attention to prevailing asymmetric power relations in healthcare encounters; 'expert knowledge' concerning risk was perceived as a sole privilege of the professionals' role. In line with other authors, this encouraged us to ask for a more holistic approach to HL promotion on both an individual and an organisational level. For example, Samerski describes individual HL as "a bricolage of different forms of knowledge" [7] (p. 4). Greenhalgh et al. argue that a "failure to play both system and lifeworld roles effectively" [42] (p. 1184) may lead to distorted communication. Carel & Kidd [46] propose a 'phenomenological toolkit' to support symmetry and epistemic justice in encounters between patients and healthcare professionals, and to reconcile the patient's experiential first-person narratives with the 'objective' third-person accounts characteristic of the medical world. We will support and further develop this argumentation line, claiming that 'colonising' individuals' lifeworlds with medical and system-centred risk information is a too narrow interventional concept for HL promotion and we believe that in the doctor-patient relationship, more space should be reserved for communication, and for the patient's lifeworld.

5. Limitations and Reflection

Throughout different stages of the research process, this study faced some challenges and limitations:

5.1. Methods and Setting

Methodologically, the process of theoretical sampling and the definition of the inclusion and exclusion criteria deserve consideration. In this study, only individuals were included who had been attested an "objective" and medical risk (e.g., genetic mutation). Nevertheless, during the analytical process we realised that the perceived "subjective" risk - which is not based on medical factors and statistics, but on lifeworld-knowledge, intuition, and experience – is as important as the "objective" risk. For future research on risk and HL we suggest also including individuals who believe to be "at risk" even if they cannot prove it in terms of medical documentation.

5.2. Recruitment and Sample

By interviewing only people who have participated in early medical diagnosis procedures, the focus of this study is narrowed. In consequence, persons not involved in services of early diagnostics for any reason (e.g., because they do not have access or willingly reject making use of them) are excluded. The findings of this study can therefore not be generalised unrestrictedly to persons 'at risk'. Participants' sociodemographic data showed that the sample of this study was rather homogeneous in terms of educational and social background. Therefore, future research on this subject should incorporate recruitment strategies that ensure a more diverse sampling structure with regard to sociodemographic background and experiences with pre-clinical diagnostics.

5.3. Analysis

This article is based on comparative, interpretative analysis of data from four clinical fields. Contrary to what we expected, we were not able to recruit 10 individuals at risk of developing Coronary Heart Disease, and hence conducted only three interviews. We therefore did not reach thematic saturation [35] in the first analytical step. We were nevertheless able to identify some core themes for this group, relate them to already existing research, and then use the key messages as an orientation framework for interpretative analysis. Our experiences will inform a reflexive, methodological discussion on the criteria of defining individuals "at risk" of developing CHD (currently under preparation).

5.4. Research Environment

Apart from these concrete study limitations, we should pay attention to a more general one, which can be seen as both limitation and challenge – the academic/research environment within which qualitative empirical research on health is being conducted, presented and published. In a medically oriented environment, there is a common sense of doing research in a standardised manner with a linear research process, designed to answer pre-defined hypotheses. A circular research process, defining research questions and using the empirical research to create hypotheses and to generate a theory grounded in data, is still not very common. Researchers hence need to plan additional resources for defending, explaining and legitimising their qualitative exploration-oriented approach within the research environment, and in cooperation with the medical team.

6. Conclusions

In our study, we used a qualitative, open methodological approach to investigate the role of HL among persons confronted with a potentially increased disease risk. We identified three central categories that shape individual HL: key situations of risk awareness, the understanding of disease risk, and risk-related agency. These categories are interrelated and play an important role in the process of making meaning of one's risk, coping with it, and integrating it into one's identity, health-related behaviour, and life plan. There are several implications for clinical practice, theory building, and future research.

In terms of clinical practice and intervention development, our findings are of vital importance with regard to patient information and risk communication. Our interviewees' narratives showed that the process of risk negotiation is characterised by introspection and self-reflection, and is closely connected to individuals' interactions with healthcare professionals. Their rich accounts provide a foundation for the development of practical guidance to support HL in the context of risk in clinical patient-doctor interactions. The way risk is communicated and framed will strongly affect a person's perception of agency in the sense of autonomy and manageability. This includes individual strategies of information management, decision-making, and acting in view of an increased disease risk. These insights emphasise an understanding of HL as a communicative action, and as a co-construction between the individual, the healthcare professional, and the healthcare system. Hence, actively including patients' narratives in risk counselling encounters (e.g., by exploring key situations of a person's confrontation with the respective risk) can be conducive to an effort for more power balance and 'epistemic fairness', and for supporting HL in the context of risk prediction and prevention.

In terms of the theoretical underpinnings of HL and future research directions, the results of our study can contribute to an expanded concept of HL, including essential aspects of relevance for the context of risk prediction. Our findings provide insight into individual manifestations of being health- and risk-literate beyond medical information or statistical skills. The interviewees' risk narratives reveal their very individual journey of understanding, evaluating and applying risk information. We therefore believe that our study will be a valuable complement to the research landscape in terms of theory building and conceptual reflection on the meaning of HL. It can enrich existing work with perspectives on HL grounded in people's narratives and ethnographic data, hereby contributing to the theoretical grounding of the concept. In methodological terms, future studies may benefit from a more extensive consideration of qualitative designs, in particular ethnographic and participatory approaches, in order to allow for a more open, resource-oriented approach to HL. Moreover, the results of our study can serve as a basis for further research on HL as a communicative element between patients or persons in search of advice and medical professionals; and they can offer starting points for communicative action as a means to realise individual and organisational HL.

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Appendix A

Table A1. Institutions involved in the recruitment process.

Familial Breast and Ovarian Cancer: Zentrum Familiärer Brust- und Eierstockkrebs, **Rita Schmutzler und Kerstin Riehm**	**Alzheimer's Disease:** Zentrum für Neurologie und Psychiatrie, Klinik für Psychiatrie und Psychotherapie, **Frank Jessen und Ayda Rostamzadeh**
Coronary Heart Disease: Schwerpunkt Allgemeinmedizin, **August-Wilhelm Bödecker und Jörg Robertz**	**Psychosis:** Früherkennungs-und Therapiezentrum für psychische Krisen, Klinik und Poliklinik für Psychiatrie und Psychotherapie, **Theresa Haidl und Mauro Seves**

Appendix B

Table A2. Inclusion and exclusion criteria in four clinical fields.

Inclusion Criteria	Exclusion Criteria
Coronary Heart Disease Adults (a) with an increased risk of developing coronary heart disease (CHD) or (b) those suffering from clinically manifest CHD (according to the cardiovascular disease risk charts of the European Society of Cardiology [49]). (a) adults without known CHD Age: women > 60 years; men > 50 years Hypertension (blood pressure > 140/95 mmHg) and/or total cholesterol > 200 mg/dl and/or smoking and/or diabetes mellitus (b) adults with known CHD Women and men with known KHK, smoking and/or blood pressure > 140/95 mmHg and/or LDL cholesterol > 100 mg/dl and/or diabetes with HbA1c > 7.5%. Written declaration of consent German language skills that allow the interview conduction	- Age < 35 years - Severe physical disease (except CHD and diabetes mellitus) - Mental illness (e.g., dementia, substance dependence, psychosis)
Psychosis - Adults who fulfill the clinical high-risk criteria for psychosis (basic symptom criteria (SPI-A) and/or the ultra-high risk criteria (SIPS)) - Written declaration of consent - German language skills that allow the interview conduction	- Age < 18 years - Increased risk based only on instruments of self-assessment - Known presence of a traumatic event - Current clinically relevant depressive episode, anxiety symptoms or suicidal tendencies
Alzheimer's Disease - Written declaration of consent German language skills that allow the interview conduction **Clinical Criteria for the Diagnosis of an MCI (According to NIA-AA Criteria):** Cognitive impairment (self or foreign medical history reported) Objective impairment in one or more cognitive domains Maintain daily life activities (ATLs) No dementia	- Dementia Indications of a non-AD neurodegenerative disease such as: Parkinson's disease, Lewy's body dementia, frontotemporal lobar degeneration, very rapid cognitive deterioration within a few weeks or months (classically indicative of a prion disease, neoplasia or metabolic disorder) or brain tumour

Table A2. *Cont.*

Inclusion Criteria	Exclusion Criteria
Clinical Criteria for the Diagnosis of an SCD (According to the Criteria of Jessen et al. 2014): Subjective and persistent (not acute) deterioration of cognitive performance compared to the original starting level Neuropsychological test battery, which is used for MCI or prodromal AD, shows a positive response within the age range, gender- and education-adjusted norm group lying findings	- Current clinically relevant depressive episode (GDS >11), other serious psychiatric disorders or suicidal tendencies - MCI, prodromal AD or dementia - impairments caused by a psychiatric* or neurological disease (excluding AD), somatic disease, medication or substance abuse can be explained * mild subsyndromal depressive symptoms or anxiety symptoms are not considered an exclusion criterion
Familial Breast and Ovarian Cancer - Group 1: Carrier of a BRCA1 or BRCA2 mutation - Group 2: Carrier of a mutation in a moderate risk gene (e.g., CHEK2) - Group 3: No mutation detection in one of the known risk genes, but increased mathematical risk of disease due to own and family anamnesis - Written declaration of consent - German language skills that allow the interview conduction	- Age < 18 years mild cognitive disorders or Alzheimer's dementia - Current clinically relevant depressive episode, anxiety symptoms or suicidal tendencies

Appendix C

Table A3. Sociodemographic sample description per clinical field.

		FBOC (n = 10)	**PSY (n = 10)**	**AD (n = 10)**	**CHD (n = 3)**	**TOTAL (n = 33)**
Gender	Female	10	4	3	1	18
	Male	-	6	7	2	15
	Other	-	-	-	-	
Age	18–30	1	9	-	-	10
	31–40	5	1	-	-	6
	41–50	3	-	-	1	4
	51–60	-	-	1	1	2
	61–70	-	-	8	1	9
	≥ 71	-	-	1	-	1
Marital Status	Not specified	-	-	1	1	2
	Single	3	9	1	2	15
	Married	6	1	5	-	12
	Widowed	-	-	1	-	1
	Divorced	1	-	2	-	3
	Separated	-	-	-	-	-
Living Conditions	Alone	1	2	2	1	6
	Shared apartment	-	4	-	-	4
	With partner	5	1	5	2	13
	With relative	1	2	2	-	5
	With partner and relative	3	-	1	-	4
	Other	-	-	-	-	-
Cultural Background	German	7	7	9	3	26
	Bi-cultural	2	3	1	-	6
	Other	1	-	-	-	1
Mother Tongue	German	7	8	9	3	27
	Bi-lingual	2	2	1	-	5
	Other	1	-	-	-	1
Education	Abitur [1]	8	8	4	2	22
	Fachhochschulreife [2]	-	-	3	1	4
	Mittlere Reife [3]	2	2	1	-	5
	Polytechnische Oberschule [4]	-	-	-	-	-
	Haupt-/ Volksschulabschluss [5]	-	-	2	-	2
	No school certificate	-	-	-	-	-
	Other	-	-	-	-	-
Employment Status	Full-time	5	6	1	-	12
	Part-time	4	-	2	2	8
	In training/study	-	3	-	-	3
	Homemaking	-	-	-	-	-
	Retirement	-	-	5	-	5
	Jobseeker	-	-	1	-	1
	Unemployed	-	-	1	1	2
	Work disability	1	1	-	-	2

FBOC—Familial breast and ovarian cancer. PSY—Psychosis. AD—Alzheimer's disease. CHD—Coronary heart disease. [1] Abitur = Highest degree of German school system, general or subject-specific higher education entrance qualification. [2] Fachhochschulreife = Degree of German school system qualifying for general or subject-specific upper secondary school entrance. [3] Mittlere Reife = Middle degree of German school system qualifying for vocational school or comparable. [4] Polytechnische Oberschule = School form of former German Democratic Republic, comparable to degree of "Mittlere Reife" [5] Haupt-/Volksschulabschluss = Qualification of a general school form of middle education.

Table A4. Sociodemographic sample description per interview partner.

Clinical Field	Sex	Age	Marital Status	Living Conditions	Cultural Background	Mother Tongue	Religious?	Highest School Leaving Certificate	Branch/ Profession-al Activity/ Education	Employment Relationship	Long-Term Med. Treatment	Chronic Disease
FBOCP01	Female	41 to 50	Divorced	With rel.	German	German	No	Abitur [1]	Social area	Fulltime	Yes	No
FBOCP02	Female	31 to 40	Unmarried	With partner	German	German	Yes	MR [3]	Economics	Part-time	Yes	Yes
FBOCP03	Female	31 to 40	Married	Partner & rel.	Bi-cultural	G. & others	Yes	Abitur [1]	Social area	Part-time	No	No
FBOCP04	Female	18 to 30	Unmarried	With partner	German	German	No	Abitur [1]	Art & culture	Disabled	No	No
FBOCP05	Female	41 to 50	Married	Alone	Bi-cultural	G. & others	n.a.	Abitur [1]	IT	Fulltime	Yes	Yes
FBOCP06	Female	31 to 40	Married	With partner	German	German	Yes	MR [3]	Health area	Fulltime	Yes	No
FBOCP07	Female	41 to 50	Married	With partner	German	German	Yes	Abitur [1]	Other	Fulltime	Yes	Yes
FBOCP08	Female	51 to 60	Married	Partner & rel.	German	German	Yes	Abitur [1]	Health area	Part-time	Yes	Yes
FBOCP09	Female	18 to 30	Unmarried	With partner	Other	Other	Yes	Abitur [1]	Health area	Part-time	No	No
FBOCP10	Female	31 to 40	Married	Partner & rel.	German	German	Yes	Abitur [1]	Health area	Fulltime	Yes	No
ADP01	Female	61 to 70	Divorced	Alone	German	German	Yes	FH-Reife [2]	Health area	In pension	Yes	Yes
ADP02	Female	61 to 70	Married	With partner	German	German	No	Abitur [1]	Social area	In pension	Yes	Yes
ADP03	Male	61 to 70	Married	Alone	Other	Other	No	Abitur [1]	Other	In pension	Yes	Yes
ADP04	Male	61 to 70	Married	Partner & rel.	German	German	Yes	FH-Reife [2]	Health area	Fulltime	Yes	Yes
ADP05	Female	61 to 70	n.a.	With partner	German	German	No	MR	Admin.	Part-time	Yes	Yes
ADP06	Male	61 to 70	Married	With partner	German	German	Yes	Abitur [1]	Science	In pension	No	Yes
ADP07	Female	61 to 70	Widowed	With partner	German	German	Yes	HS [5]	Other	Unemployed	No	No
ADP08	Female	61 to 70	Married	With partner	German	German	No	Abitur [1]	Admin.	Seeking work	Yes	Yes
ADP09	Female	51 to 60	Single	With rel.	German	German	Yes	FH-Reife [2]	Social area	Part-time	Yes	No
ADP10	Female	71 or older	Divorced	With rel.tives	German	German	Yes	HS [5]	Health area	In pension	No	No
PSYP01	Male	18 to 30	Unmarried	Alone	Bi-cultural	G. & others	No	Abitur [1]	IT	In training	Yes	Yes
PSYP02	Female	31 to 40	Married	Partner & rel.	German	German	No	Abitur [1]	Social area	Fulltime	No	No
PSYP03	Female	18 to 30	Unmarried	With rel.	German	German	No	Abitur [1]	Social area	In training	Yes	No
PSYP04	Female	18 to 30	Unmarried	Shared app.	German	German	No	Abitur [1]	Social area	Fulltime	No	No
PSYP05	Male	18 to 30	Unmarried	With partner	German	German	No	Abitur [1]	Social area	Fulltime	Yes	Yes
PSYP06	Female	18 to 30	Unmarried	Shared app.	German	German	Yes	MR [3]	Other	Disabled	Yes	Yes
PSYP07	Male	18 to 30	Unmarried Unmarried	With rel.	German	German	Yes	Abitur [1]	Other	Fulltime	Yes	No
PSYP08	Male	18 to 30	Unmarried	Shared app.	German	German	No	Abitur [1]	Social area	In training	No	Yes
PSYP09	Male	18 to 30	Unmarried	Shared app.	Bi-cultural	G. & others	Yes	Abitur [1]	Art & culture	Fulltime	Yes	Yes
PSYP10	Male	18 to 30		Alone	Bi-cultural	German	No	MR [3]	Social area	Fulltime	No	No
CHDP01	Male	51 to 60	Unmarried	Alone	German	German	n.a.	Abitur [1]	Trade	Unemployed	Yes	Yes
CHDP02	Female	61 to 70	n.a.	With partner	German	German	Yes	FH-Reife [2]	Economics	Part-time	Yes	Yes
CHDP03	Male	41 to 50	Unmarried	With partner	German	German	Yes	Abitur [1]	Other	Part-time	No	No

FBOC—Familial breast and ovarian cancer. PSY—Psychosis. AD—Alzheimer's disease. CHD—Coronary heart disease. [1] Abitur = Highest degree of German school system, general or subject-specific higher education entrance qualification. [2] Fachhochschulreife = Degree of German school system qualifying for general or subject-specific upper secondary school entrance. [3] Mittlere Reife = Middle degree of German school system qualifying for vocational school or comparable. [4] Polytechnische Oberschule = School form of former German Democratic Republic, comparable to degree of "Mittlere Reife" [5] Haupt-/Volksschulabschluss = Qualification of a general school form of middle education.

Appendix D

Table A5. Data material used for analysis.

	Audio Material	Transcripts	Questionnaires	Body Maps
FBOC	10:00 h	351 pages	10	10
AD	09:20 h	325 pages	10	8
CHD	04:10 h	60 pages	3	3
PSY	10:20 h	300 pages	10	10
Total	**~34:00 h**	**1036 pages**	**33**	**31**

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Indication-specific Risk Perceptions – HL- and SDM-relevant Aspects for Patients

Harzheim, L.*; Lorke, M.; Rostamzadeh, A.; Jessen, F.; Woopen, C.; Jünger, S. (2023a): **The Promotion of Health Literacy: An Ethical Task in the Prediction of Alzheimer's Dementia Risk.** In: *GeroPsych*, Artikel 1662-9647/a000310. DOI: 10.1024/1662-9647/a000310.

This article covers an in-depth analysis of risk perceptions of people facing an increased Alzheimer's disease risk and thereby sheds light on patient experiences with predictive medicine in the field of neurodegenerative diseases, allowing to derive conceptual and practical recommendations on how to promote HL and SDM in that context.

Drawing on the data corpus of the RisKomp project, 10 narrative interviews, body-maps, and sociodemographic data of patients who had participated predictive procedures and were diagnosed with Mild Cognitive Impairment or Subjective Cognitive Decline, as well as the researchers' reflexive field notes were analyzed. The concept of individual HL – the finding, understanding, appraising, and applying of health information (Sørensen et al., 2012) – in the context of cognitive impairments, the interplay of self-perception and subjective quality of life in the face of a life-altering disease, and ethical challenges that come along with the prediction of AD were illuminated.

The key findings presented in this article are depicted in a category system of HL-relevant aspects from the perspective of the interviewees, revealing their risk perceptions, individual competencies and resources in dealing with risk, their way of negotiating information and knowledge and how their health-related perceptions and decisions form, and personal strategies in explaining and dealing with their risk. The concepts of HL and SDM are theoretically extended by identifying 'self-literacy' as a central HL-relevant component, especially in the field of risk prediction and early detection of neurodegenerative diseases. Touching upon ethical implications of AD research and prediction, issues such as self-determination, informed consent, decision-making with relatives, and balancing patients' wellbeing with the disclosure of risk information were also discussed in this article.

In contribution to the overall aim of this thesis, the article pronounces empirically based recommendations on how to promote individual HL of persons facing AD risk and on how to support SDM in this vulnerable context. These recommendations are to serve as a base for the development of communication strategies, teaching material, and tools for an individual-sensitive information and communication in the predictive setting. The findings presented in this article reframe communication and decision-making about disease risk, underlining the relevance of communication with others and oneself, respecting the normative character of risk diagnosis and its impact on a person's perception of being (still) healthy or (already) ill. Key conclusions derived from this study are: (1) the need to emphasize the medical encounter in predictive procedures as a space for HL and SDM to evolve, the need for HCPs to follow communication strategies that respect the informational and emotional needs and capacities of patients (and their relatives); and (b) the necessity to incorporate the teaching of value- and capacity-sensitive, individualized risk communication in (medical) education and training.

Respecting the ethical dimension of AD risk prediction, the discussion of this article's findings addresses, among other things, key ethical issues such as the potential harm of risk prediction (the risk of knowing), the balancing of patients' and relatives' perceptions and needs (wellbeing, autonomy, and self-determination in diagnostic procedures), and self-hood in the context of risk prediction and the early onsets of cognitive impairments (critical HL and (continuous informed consent).

This article’s results also contributed to the alignment and the design of the subsequent sub-study on HCPs’ experiences and perceptions with respect to HL and SDM in predictive consultations.

Full-Length Research Report

The Promotion of Health Literacy

An Ethical Task in the Prediction of Alzheimer's Dementia Risk

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Abstract: Progress in predictive medicine has increased the challenges to navigating complex risk information for patients and healthcare professionals. This contribution investigates how people facing the risk of developing Alzheimer's dementia perceive risk, what aspects are relevant to their health literacy, and how to promote individual health literacy in predictive medicine. We conducted a qualitative study analyzing narrative interviews, body maps, and sociodemographic data from persons who had undergone early predictive procedures in a memory clinic. We understand the promotion of health literacy as an ethical task in predictive medicine and argue for (1) emphasizing personal resources to promote subjective health literacy, (2) reframing communication and decision-making about disease risk, and (3) teaching skills for value-sensitive, individualized risk communication.

Keywords: Alzheimer's disease, risk prediction, health literacy, ethical aspects

In an aging population, age-related neurodegenerative diseases are becoming more prominent in medical research and care (Albert et al., 2011). Ongoing medical-technical progress allows the prediction of the risk for the development of neurodegenerative diseases as well as the detection of their early stages to enable preventive measures (Jessen, 2019). This opportunity means people undergoing early prediction procedures are particularly challenged in dealing with risk information (Newsholme, 2015). Understanding and critically evaluating risk information is important to making informed choices about preventive interventions or adopting a health-promoting lifestyle (Harzheim et al., 2020; Sørensen et al., 2012). Likewise, healthcare professionals (HCPs) are challenged to establish an environment adequate for shared decision-making (SDM) in predictive consultations, although there are presently no well-established communication models for this setting (Rostamzadeh & Jessen, 2020). To promote a health-literate approach to risk information, empirical research on health literacy (HL)-relevant factors in the context of neurodegenerative disease could substantiate implications for predictive practice.

The aim and methodological approach of this study stem from the predictive diagnosis of Alzheimer's disease (AD) as an example of a neurodegenerative disease, the relevance of HL in the context of cognition, and ethical issues in the field of predicting Alzheimer's dementia risk.

The Predictive Diagnosis of Alzheimer's Disease

AD is the most common neuropathologic etiology of dementia, with an increasing prevalence in older age. Along with demographic developments, a growing incidence of AD implies a substantial public health challenge (Ferri et al., 2005). AD is characterized by amyloid and tau pathology as well as consecutive neurodegeneration, which finally leads to a progressive cognitive decline (Blennow et al., 2006). Its pathophysiological processes can be detected in early disease stages using biomarker-based analysis (Rostamzadeh & Jessen, 2020; Sanroma et al., 2017). Subjective cognitive decline (SCD) and mild cognitive impairment (MCI) may be Alzheimer's dementia at-risk stages

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(Albert et al., 2011; Jessen et al., 2014).[1,2] There are increasing efforts to predict dementia risk at preclinical or prodromal stages of AD to enable preventive actions: People affected can adapt their life plans, address modifiable lifestyle aspects (e.g., diet, physical activity, cognitive training) to decelerate disease progression (Basu et al., 2019; Li et al., 2020; Livingston et al., 2020; Ngandu et al., 2015), or decide for early medical interventions, which are hoped to slow disease courses by maintaining cognitive functions (Jessen, 2019). Decision-making in the context of early AD detection and risk prediction hence implies particular demands on health literacy (HL) in terms of navigating and appraising complex health information (Rostamzadeh et al., 2020; Sørensen et al., 2012).

Health Literacy and Cognition

HL refers to assessing, understanding, appraising, and applying health information. Given the growth of predictive medicine, risk-related HL[3] is essential for health promotion (Sørensen et al., 2012). HL and decision-making in predicting Alzheimer's dementia risk are challenged by the complexity of information about anticipated health events and by (beginning) cognitive constraints. Also, knowledge about being at risk itself can impact health-related outcomes (Harzheim et al., 2020) and increase the risk of disease progression (Jessen et al., 2014; Roehr et al., 2017). It, therefore, constitutes an ethical challenge in risk communication (Davies & Savulescu, 2021; Götzelmann et al., 2021).

For cognitively impaired individuals, the challenge of dealing with complex health information amplifies since they may face more difficulties than nonimpaired persons in applying the above-mentioned attributes of HL (Rostamzadeh et al., 2020). Studies have distilled a bidirectional relationship between cognitive functions and HL: Deterioration of memory is associated with regressive HL (Federman et al., 2009; Liu et al., 2019), and a "low HL" may increase the risk of cognitive impairment (Oliveira et al., 2019).

Ethical Aspects

A vivid ethical debate is going on about the predictive diagnosis of AD (Gauthier et al., 2013; Porteri & Frisoni, 2014; Schicktanz et al., 2021). Conducting genomic research or analyzing biomarkers to predict a life-altering disease raises questions about patients' well-being, normativity, autonomy, and self-determination (Götzelmann et al., 2021). With all the benefits of risk prediction, its potential harm and the possible psychological effects of a risk diagnosis are being discussed in the scientific literature (Andorno, 2004; Berkman & Hull, 2014; Cook & Bellis, 2001; Davies & Savulescu, 2021). This also results from the normative potential of predictive medicine: Predicting disease risk potentially shifts the perception of being healthy to being ill (Lorke, 2021; Meier et al., 2017); especially in the context of neurodegenerative diseases, diagnostic labeling entails the risk of stigmatization and discrimination (Götzelmann et al., 2021). Autonomy and self-determination in the context of AD research are especially delicate subjects in the face of (beginning) cognitive constraints (Burlá et al., 2014; Cascio & Racine, 2018; Silva et al., 2020). The ethical asset of informed consent needs to be preserved by guaranteeing the patient's understanding of disease risk information and enabling them to make informed choices (Kim, 2011). These ethical aspects are elements of communicating about and dealing with the disease risk inherent to HL (Harzheim et al., 2020). They need to be empirically investigated and theoretically reflected when conducting research on HL and risk prediction of Alzheimer's dementia.

Aim

Concerning the epidemiological and ethical relevance of the risk prediction of Alzheimer's dementia, the importance of HL in dealing with complex risk information, and the lack of patient-centered, inductive HL research in the context of predictive medicine, this contribution aims at identifying the patient perspective. The research questions we address are as follows: (1) How do people facing Alzheimer's dementia risk perceive disease risk? (2) What HL-relevant aspects are important to them? (3) How to best promote the HL of people facing Alzheimer's dementia risk?

Methodological Approach

We employed a qualitative, mixed-methods research design, including narrative interviews, body maps, and sociodemographic data. The data stem from a research

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[1] While MCI is defined by a slight functional impairment without yet meeting dementia criteria (Petersen, 2004), SCD is described as a state of self-perceived cognitive deterioration that cannot be objectively identified. SCD may represent the earliest manifestation of Alzheimer's dementia or other forms of dementia (Jessen et al., 2014; Roehr et al., 2017).

[2] Alzheimer's disease (AD) refers to the pathological changes addressed by early diagnosis procedures; Alzheimer's dementia refers to the clinical syndrome investigated in risk prediction.

[3] Risk-related HL in terms of self-efficient management of risk information and risk-adjusted decision-making and behavior (Sørensen et al., 2012).

project about HL in predictive medicine, analyzing HL-relevant aspects for people facing disease risk in four exemplary clinical fields (Harzheim et al., 2020).[4]

Sampling and Recruitment

Participants had been diagnosed with SCD (Jessen et al., 2014) or MCI (Albert et al., 2011) during the diagnostic work-up at the Centre for Memory Disorders of the Department of Psychiatry and Psychotherapy at the University Hospital Cologne. We recruited them in collaboration with the Centre for Memory Disorders according to predefined inclusion and exclusion criteria[5] and provided written and verbal informed consent. The interviews were conducted between April 2018 and August 2019 by one of the authors (LH, SJ, or ML).[6] Ethical approval was granted by the medical faculty of the University Hospital Cologne.[7]

Data Collection and Analysis

The mixed-methods approach (Kelle, 2014) enabled a comprehensive analysis of the participants' perceptions: A triangulation of data sources served for a more in-depth analysis of different layers of risk appraisal (verbal and nonverbal; declarative, procedural, and embodied). Therefore, we conducted 10 narrative interviews (Nohl, 2017) and asked participants about their experiences with and perception of disease risk and predictive procedures. To investigate HL-relevant aspects from the interviewees' perspectives, we asked in-depth questions concerning their access, understanding, appraising, and application of risk information. At the end of each interview, we invited the participants to draw their dementia risk perception on a body sketch.[8] Body-mapping, as "the process of [. . .] using drawing, painting, or other art-based techniques to visually represent aspects of people's lives, their bodies and the world they live in" (Gastaldo et al., 2018, p. 5), proved helpful for nonverbally assessing perceptions of people experiencing cognitive constraints or difficulties with verbal descriptions (Dew et al., 2018). We also assessed sociodemographic data like age, living conditions, and healthcare experiences to contextualize the participants' personal situations.

We analyzed the verbal (interviews), visual (body maps), reflexive (field notes), and contextual (sociodemographic questionnaire) data following the principles of the reflexive grounded theory[9] (Breuer et al., 2010; Corbin & Strauss, 1990). We transcribed audio recordings of the interviews verbatim and analyzed them line by line (open coding), abstracting the codes and condensing them into categories and subcategories (axial and selective coding). This category system illustrates the main findings of this study (Table 2). We used the field notes for documenting, disclosing, and minimizing the subjectivities of the researchers and for reflecting upon their role in the research process (Breuer et al., 2017). We analyzed the body maps together with the verbal explanatory information provided by participants, analyzing the sociodemographic data using descriptive statistics (Table 1).

Theoretical saturation (Breuer et al., 2017) was reached when the repeated examination and triangulation (Denzin, 2012) of the data did not lead to theoretical amplifications in the category system.

Results

We included 10 interviews in the data analysis[10]; five participants were diagnosed with MCI and five with SCD. MCI patients were communicated an increased Alzheimer's dementia risk compared to people of their age without signs of cognitive impairments; SCD patients were communicated that most people with SCD do not develop Alzheimer's dementia compared to a minority that does.

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[4] The project RisKomp (Health Literacy of Persons at Risk – From Information to Action) was conducted at the Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health (CERES) of the University of Cologne from 2016 to 2019, in cooperation with clinics of the University Hospital of Cologne.

[5] Inclusion criteria met the NIA-AA guidelines for the diagnosis of MCI (Albert et al., 2011) and diagnostic criteria for SCD (Jessen et al., 2014). Exclusion criteria were, among others, a diagnosed dementia or an impairment stemming from a psychiatric or neurological condition.

[6] Laura Harzheim (LH), Saskia Jünger (SJ), Mariya Lorke (ML).

[7] Registration number from ethical approval: 18-014.

[8] With drawings showing participants' handwriting, the body maps were technically replicated true to the original for anonymity protection.

[9] The grounded theory methodology (GTM) is an approach of qualitative social research, describing a set of systematic procedures to generate inductively derived theories about certain phenomena. (Corbin & Strauss, 1990). Subjective relevancies uncovered through the interviewees' narrations can be abstracted into theoretical considerations about the phenomena of interest, following the assumption of social realities based on subjective relevance systems. This employs individuals' risk perceptions as a basis for theoretical considerations about HL-relevant aspects for people at risk.

[10] Despite a controversy discussion, there is no gold standard for the sample sizes in qualitative studies (Guest et al., 2016; Saunders et al., 2019). The sample size of this study is justified by the research question, the choice of the analysis method, the field access, and given research resources (Corbin & Strauss, 1990). In line with its design, this study does not aim for representativeness but for empirically founded theory building (Flick et al., 2010).

Table 1. Sociodemographic sample structure

Characteristic	Distribution
Sex	Male (3); female (7)
Age	≥ 71 years (1); 61-70 (8); 51-60 (1)
Family status	Married (5); divorced (2); widowed (1); single (1); *ns* (1)
Living with ...	Partner (5); partner and relatives (3); alone (2)
Cultural background	Bicultural (1); German (9)
Religious	Yes (6); no or *ns* (4)
Educational background	Higher (7); middle (1); lower (2) school graduation
Professional background	In health care (3); social services (2); science (1); administration (2); *ns* (2)
Experience with health conditions/involvement in the healthcare system	Have been medically treated (7); suffering from chronic disease (7)

Table 2. HL-relevant aspects in predictive diagnosis of AD

Risk interpretation	Information and knowledge
– Risk perception	– Seeking and reflecting
– Disease images	– Explanatory models, uncertainties, and meaning-making
Personal competencies and resources	**Strategies**
– Self-perception and -reflection	– Self-determination, proactive engagement
– Intuition	– Information, communication, interaction
– Disease experience	– Health-promoting lifestyle
– Personal environment	

Both groups were recommended to take all available preventive measures and to return every 6–12 months for check-ups. All participants completed the sociodemographic questionnaires, eight completed the body maps.

We identified four main categories that capture the participant's perceptions on accessing, understanding, appraising, and applying AD risk information (Table 2): individual ways of interpreting risk, dealing with risk information and knowledge, personal competencies and resources, and strategies for dealing with disease risk.[11] All categories touch on ethical aspects in predicting Alzheimer's dementia risk (discussed later on).

Risk Interpretation

How participants interpreted their Alzheimer's dementia risk was linked to their risk perceptions and disease images. Interviewees described perceiving the risk as a threat, as something omnipresent, or as something relative. They associated AD risk with degeneration, dysfunction, cognitive capacity loss ("[...] your body wears out," ADP02) and with declining social connection ("cut off," ADP02). Patients also referred to their risk with "fear" (ADP01), "concern" (ADP05), and as a "safety warning [of something] the increase [of which] would be the worst" (ADP04). They visualized swirls and question marks around the heads and bodies, verbally expressing confusion and insecurity (Figure 1).

Participants perceived AD risk as multidimensional, locating it in the head and body (physical), affecting cognitive functions, as well as on a spiritual level (metaphysical), affecting and being affected by the mind (Figure 2).

Risk was perceived as omnipresent, affecting participants' well-being when they constantly worried about their families, about becoming a burden, and about not being able to live life as usual: "And I can't get this diagnosis out of my mind. It's in my every cell. [...] I'm just terrified of getting dementia" (ADP01). The communicated estimated risk for developing Alzheimer's dementia (SCD vs. MCI) did not necessarily affect the degree to which participants perceived it as a threat or as omnipresent.

However, interpreting risk as something relative was a form of negotiating it: "Subjective cognitive decline – dear God, you've got your little aches and pains, and that is just one of them" (ADP02). Mentioning health-related contexts

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[11] Exemplary quotes from participants are presented to illustrate the anchoring of (sub)categories in the empirical data. Participants were pseudonymized (from ADP01 to ADP10).

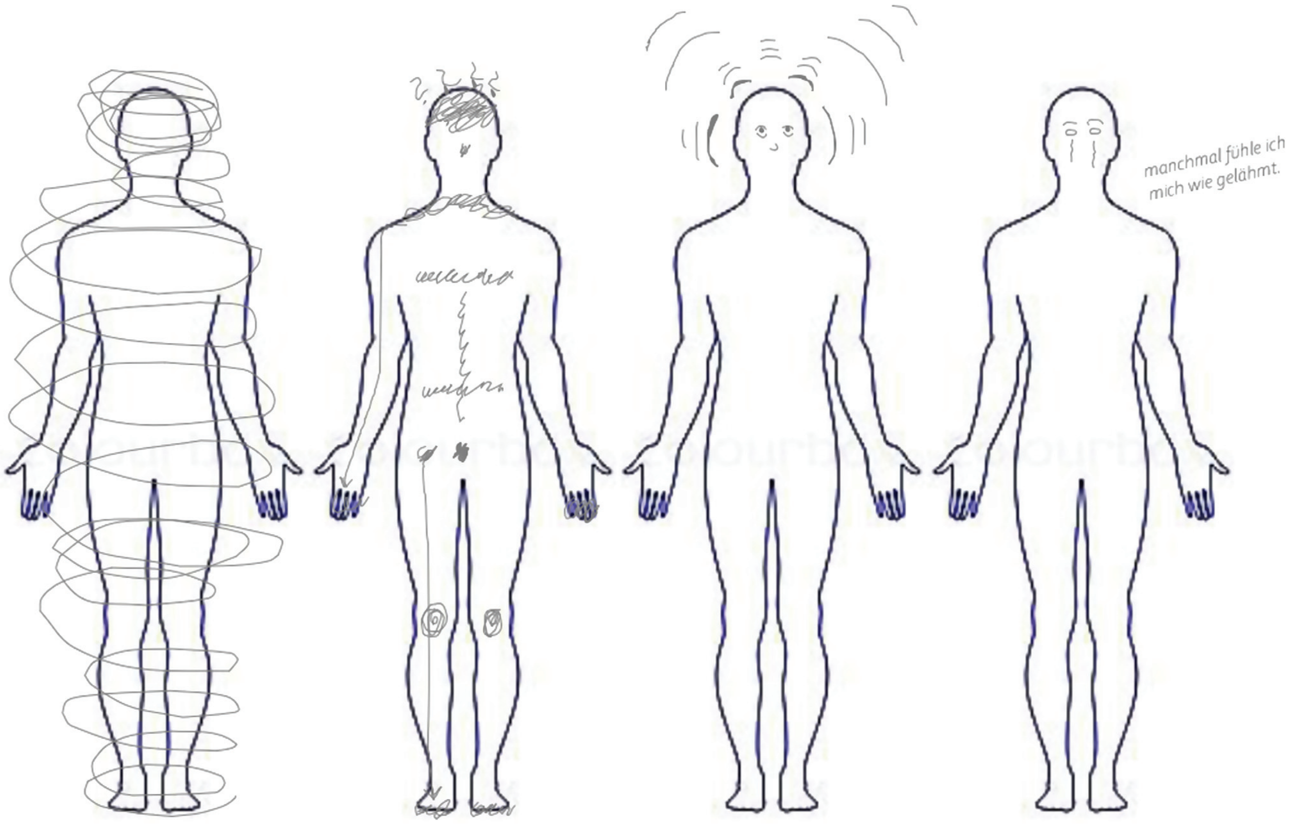

Figure 1. Body maps: emotional risk perception.

along with their Alzheimer's dementia risk indicated that risk was not interpreted separately: "When I took the first test [...], I was still in a job that really burdened me" (ADP08).

Participants' risk interpretations were also informed by their disease images – shaped by personal experiences (family history) or socially formed imprints (stigma), which induced fearful anticipation and preemptive strategies to regain control. For instance, participants associated AD with the loss of cognitive capacities and identity, but also – in most negative extremes – a life not worth living: "If I feel there's no way out, I'll go to Switzerland and kill myself" (ADP01).

Information and Knowledge

The participants' ways of searching for and assessing risk information, explanatory models, and uncertainties in the meaning-making (Park & Folkman, 1997) of risk information shed light on how they were dealing with risk information and knowledge of risk.[12]

Regarding seeking and reflecting on risk information, participants named public sources like online articles and TV broadcasts as well as their social environment. They furthermore emphasized being critical about risk information provided by their HCPs: "Well, it happened twice now that my medical report said something important my doctor hadn't even mentioned" (ADP05) and having difficulties with navigating through the variety of information on health, risk, and disease. Having worked in healthcare was reported as helping to deal more confidently with risk information.

Participants explained how they experienced divergences between the risk status communicated to them and their feeling of being at risk: "Well, I'm not really certain if I know for sure that I am not at risk" (ADP02). Not only when their perceptions contradicted the risk communicated to them did participants complement information from predictive consultations with (autobiographical) explanatory models: "[My job loss] bothers me constantly. [...] I think this is the main cause for my beginning dementia" (ADP06).

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[12] The term "information" describes the process of getting informed and the information itself, meaning bundled and contextualized data that contribute to gaining knowledge on a subject (Schreyögg, 1996; Seiffert, 1971); "knowledge" refers to the individual integration and interpretation of information (Schreyögg, 1996) when dealing with disease risk.

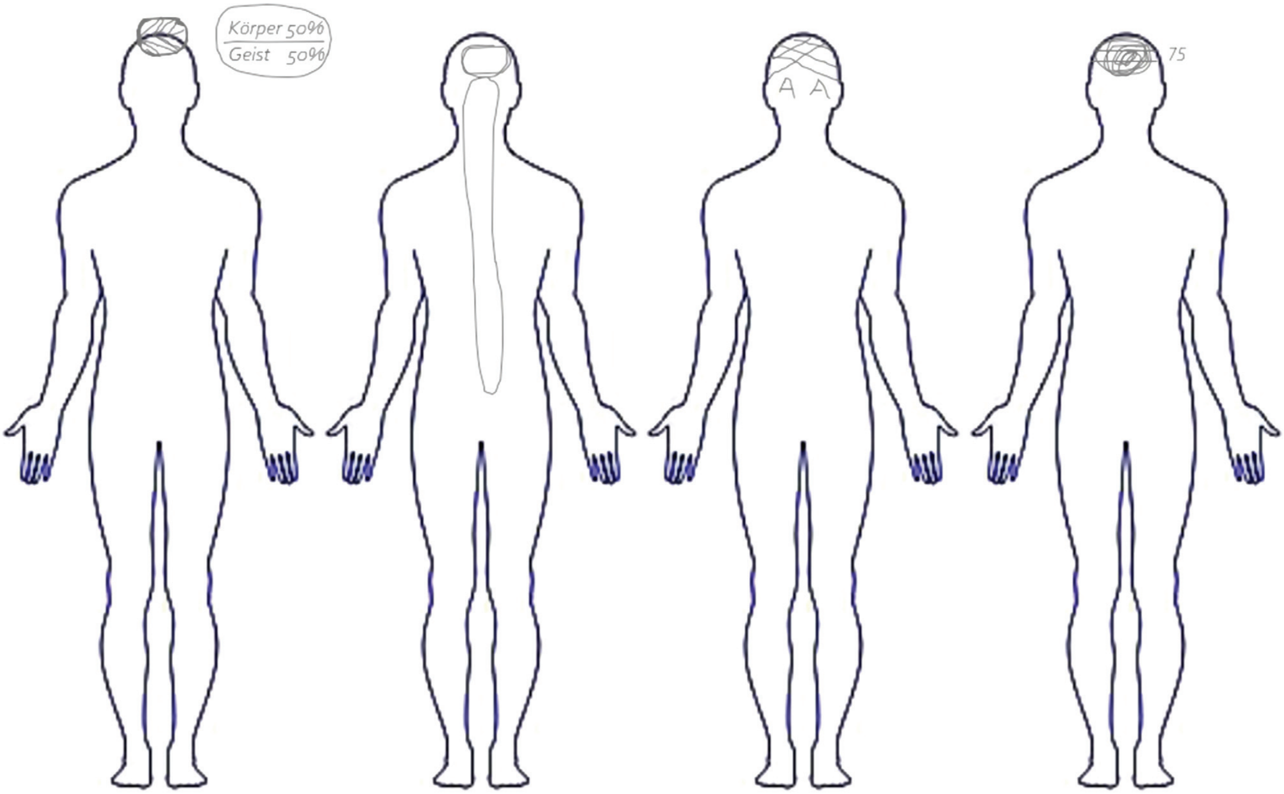

Figure 2. Body maps: location of risk perception.

Personal Competencies and Resources

Self-perception, intuition,[13] experience, and communication were personal competencies or resources participants restored when dealing with risk.

Observing changes in their cognitive capacity, for instance, led them to undergo predictive procedures: "It was my initiative actually. Because I had the feeling that I have become more forgetful" (ADP02). Intuitively feeling an imbalance between communicated and perceived risk contributed to the negotiation and inner communication about risk: "So, basically all the tests you can make [...] were all ok. [...] I just don't have a good feeling" (ADP05, SCD patient, no signs for an increased Alzheimer's dementia risk).

Having (directly or indirectly) experienced disease was described as influencing engagement in predictive procedures: "I witnessed [...] [my grandma's] condition getting worse [...], and that was also the reason why I came here" (ADP10). Interviewees seemed to project what they had witnessed to their future health vision: "And if you have witnessed the end of dementia [...] that cannot be a life goal for me" (ADP04). Disease experience, therefore, was either a competence (when leading to health-promoting choices) or a burden (when leading to approach risk in a fear-driven manner).

Participants designated their social environment as another personal resource in dealing with disease risk; relatives and friends served as a reflection and warning system, leading participants to seek professional advice: "That was when I started [noticing] – when my kids and my husband said something" (ADP07).

Strategies

Self-determination, information, communication, and a healthy lifestyle were strategies pursued by participants when dealing with disease risk.

Undergoing a predictive procedure was a form of proactively dealing with risk: "Everything you can do [...] against it needs to be done" (ADP04). With this, participants expressed autonomy, self-determination, and agency. A contrary example depicting the same principle is the choice to withdraw from risk information. Not wanting to know was described as a form of self-protection against the potential harm of knowing, when knowledge was perceived as a deterministic certainty about what to expect and a lack of

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[13] The term "intuition" is used in the sense of an intelligence not based on logic coherences or conscious reasoning (Gigerenzer, 2007).

hope for things to develop differently: "To know means knowing exactly how things will be. Not knowing [...] – I can lie to myself a bit longer" (ADP07). What may appear to be health illiterate was a well-considered, self-determined measure of protection against harm that subjectively outweighs the occurrence of alternative damage.

Communication and exchange with peers was a form of understanding, sorting, and coping with risk information: "Yes, we talk a lot about it. [...] Because really good friends are affected, too, you know?" (ADP05). Using another strategy of actively engaging with risk, participants consciously opted for a healthier lifestyle (e.g., memory training, physical activities, healthy diets, meditation): "Mindfulness training, meditation. [...] And I also read that cognitive training is helpful, right?" (ADP04).

Discussion

The main categories identified in this study showed various HL-relevant aspects in the course of Alzheimer's dementia risk prediction. HL has already been differentiated as multidimensional, situational, and a form of social practice, implying various forms and sources of health knowledge (Samerski, 2019). Expanding on these facets of HL, based on our findings, we wish to discuss the following implications for the promotion of HL in the context of risk prediction: (1) emphasizing personal competencies and resources, (2) reflecting the way of communication and decision-making in predictive procedures, and (3) incorporating preference-sensitive, individualized risk communication competencies into the education and training of HCPs. Concerning these implications, we elaborate on the significance of HL as an ethical task in predictive medicine.

Emphasizing Personal Competencies and Resources

The interviewees' perceptions showed the relevance of emotional-intuitive resources in the context of risk. Self-literacy in terms of a sense of personal well-being, discomfort, or physical and psychological changes determined the participants' decisions on preventive measures.

Indeed, that emotional-intuitive aspects are more relevant for health decisions than rational facts is already being discussed in HL research (Schaeffer et al., 2019). Situational awareness, "gut-feeling," and self-perception are considered at least as important as factual knowledge for evaluating and making sense of health information (Champlin et al., 2017; Naccarella et al., 2016). Slovic et al. (2004) emphasized intuition as an equally relevant component of a rational-analytical approach (experiential vs. analytical) that people resort to when dealing with risk. To strengthen HL in the context of Alzheimer's dementia risk prediction, it is, therefore, crucial to consider individual resources – such as intuition – as essential parts of selfhood and identity (Brown, 2017), since identity and health may be regarded as interwoven[14]: A resource-oriented approach to promoting HL acknowledges and respects the patient's capacities and relevancies. Value-sensitive communication – e.g., by considering the degree to which patients desire to learn about their risk – may be understood as respecting their autonomy and self-determination. Therefore, social intuition and emotional intelligence on HCP's behalf are required.

Another means of resource-oriented HL promotion can be building on existing health, disease, and risk concepts. Since participants attended medical consultations with certain levels of knowledge, attitudes, and visions of their (future) health, ignoring these may lead to a preoccupation with statistics, which is known to be not necessarily decisive for decision-making (Holmberg et al., 2015; Reyna, 2008). Considering existing concepts may help to establish health-promoting strategies that already grew reasonable to patients. Asking "What do you know about Alzheimer's disease?" or "What is most important to you regarding your health?" or "What are your hopes and worries?" may help to incorporate preexisting knowledge into predictive consultations.

In other words, rather than operationalizing skills and competence levels with standardized criteria ("objective" HL), the focus of promoting and evaluating HL should lie on people's appraisal of their individual health-related resources (subjective HL) and on supporting them in critically appraising information (critical HL): "We need to change the focus of health literacy research by studying which approaches to dealing with health literacy result in the best outcomes for patients [...]" (Weiss, 2015).

Reframing Communication and Decision-Making

Following the assumption that HL forms and evolves in social interaction and communication (Harzheim et al., 2020), how risk is communicated can be key. Communicating with others and themselves helped participants to understand their risk. Therefore, intuitive-emotional

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[14] Identity potentially *affects* health – e.g., when identity-relevant changes lead to someone undergoing preventive measures (Strohminger & Nichols, 2015) – and identity potentially *is affected* by health – e.g., when cognitive decline impacts someone's perception of self and identity (Brown, 2017; Caddell & Clare, 2010).

aspects should be reflected in the way HCPs communicate in predictive encounters – how can intuition and biographical experience be acknowledged instead of being devalued as "irrational"?[15] Participants' struggling with understanding risk information may conflate with cognitive constraints or with an interview being a potentially stressful event. However, their difficulties need to be taken seriously, considering a more individualized, value-sensitive communication strategy for predictive procedures.

Irrespective of probabilities, risk can be perceived "[...] as highly normatively charged [and] as an emotionally significant threat" (Wöhlke et al., 2019, p. 1). This is connected to the suggestion of considering the ethically relevant risk of knowing along with the medically identified risk (Sarangi et al., 2003) as well as the potential epistemic confusion that may come along with risk information (Samerski, 2015).[16] Because AD is a disease that cannot yet be cured or prevented, predicting it may impact the psychosocial well-being of patients (Rostamzadeh & Jessen, 2020), which is of ethical relevance for the research field (Götzelmann et al., 2021).

HCPs who consult people facing Alzheimer's dementia risk are also familiar with communicating with relatives accompanying their partners or parents. Relatives and friends proved to be decisive for patients to undergo predictive consultation, suggesting the social environment to be an HL-relevant component. HCPs may consequently face the need to mediate the patient's and the relative's perceptions alike, needing to widen their communication spectrum, covering informational, emotional, and mediation-technique aspects, and considering the patient's cognitive capacities (Chiong, 2013; Wolfs et al., 2012).

Teaching Value-Sensitive, Individualized Risk Communication Competencies

Communication as a source for HL gets addressed more closely by Harzheim et al. (2020), particularly referring to Habermas' theory of communicative action (Hofmann, 2016). Cherry (1996) stated that patients and HCPs jointly construct medical-social reality. Key elements in this creational process are communication (information) and interaction (relationship), which is also in line with Samerski's (2019) notion of HL being co-created in social practice.

To operationalize this study's findings, we interpreted them with a focus on the setting of predictive consultations, where patient-HCP interaction and communication constitute a central encounter for individual HL promotion (Mullan et al., 2017).

The importance of teaching communication skills in HCPs' education has long been acknowledged (DasGupta & Charon, 2004). Yet, in predictive medicine, HCPs face a communicative situation for which no established orientation exists – the consultation for disease prediction (Schwegler, 2021). Specific communication guidance should therefore be offered for HCPs in predictive procedures. A two-level communication strategy (rational-analytical and emotional-intuitive) appears to be beneficial, since both systems operating in parallel are considered holistic and sufficient: "[...] each [system] seems to depend on the other for guidance. [...] analytic reasoning cannot be effective unless it is guided by emotion and affect" (Slovic et al., 2004, p. 1).

Still, risk-communication training in medical education is considered underrepresented (Baessler et al., 2020), although this study and other research identified it as crucial for HL promotion in predictive medicine (PreDADQoL[17]). Communication guides, checklists, or HCP training could be offered, covering standardized, indication-specific information about risk and prevention, along with guidance on individually adaptable tips for preference- and capacity-sensitive communication.

Considering HL-Relevant Ethical Aspects in Predicting AD Risk

Risk perceptions, personal competencies, and strategies in dealing with risk are categories entangled with ethical issues in the context of AD research distilled by Götzelmann et al. (2021) and Silva et al. (2020).

In this study, we addressed the risk of the potential harm of Alzheimer's dementia risk prediction, its identity-relevant impact on individuals, their autonomy and self-determination, and their empowerment in decision-making are matters. We wish to reflect on this in light of the ethical

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[15] Greenhalgh et al. (2015) address low status of patient experience in evidence hierarchy as a potential bias in evidence-based medicine.

[16] Samerski (2015) describes the challenge of translating a statistically constructed risk status into an individual's life world as "epistemic confusion" and thereby also addresses the potential imbalance between risk communication and perception. Molewijk et al. (2008) shed light on the same potential confusion by pointing out the misinterpretation of statistically generated recommendations as "individualized" risk information.

[17] As part of the BMBF-funded research project (2016–2021), colleagues from CERES and the Centre for Memory Disorders are investigating the ethical and legal framework for carrying out predictive diagnostics of AD in order to develop guidance for informing, advising, and caring for patients dealing with an increased risk Alzheimer's dementia (Rostamzadeh et al., 2021).18Ethical debates in AD research may differentiate between genetic and biomarker-based risk prediction. We apprehend ethical considerations of predicting Alzheimer's dementia risk in general, to distillate recommendations for both directions of predictive practice.

guidepost for AD research (Götzelmann et al., 2021; Silva et al., 2020).[18] The ethical issue of potentially harming people with risk information lies within the nature of risk prediction, since communicating a risk entails imposing uncertainty upon a person (Davis, 2017). Information on biomarker testing is considered potentially harmful knowledge that can negatively affect patients' well-being, for instance, leading to depression or anxiety (Karlawish, 2011). It has been suggested to balance patients' desire to know their risk profile with the necessity to prevent harm resulting from this information (Karlawish, 2011). This implies the challenge of balancing patients' autonomy and well-being and the need to minimize the harm of risk disclosure by guiding patients through uncertainties (Götzelmann et al., 2021).

The status of being at risk has shown to be an identity-relevant shift from a person's self-perception as healthy to (soon-to-be) ill. This normative potential of risk prediction is addressed by "healthy-sick debates" (Meier et al., 2017) and elaborations on the power of definitional dynamics in risk prediction (Lorke et al., 2021). This is of high ethical relevance when a person's health and liberty are disregarded by overseeing psychological factors of public perceptions of at-risk statuses (Perhac, 1996). Silva et al. (2020) address the "acknowledgment of lived world," that is, calling for understanding and respecting the implications of risk diagnoses on an individual's life, their social experiences, and their interaction with others.

Respecting holistic personhood (Silva et al., 2020) also entails respecting autonomy and self-determination. Self-determination (living one's own will, making self-effective decisions; Burlá et al., 2014) implies respecting a person's choices, despite potential cognitive impairments (Cascio & Racine, 2018). When addressing self-determination in the context of dementia research, ethical debates on informed consent in medical practice are prominent (Kim, 2011). Because the potential compromising effect of memory loss on someone's cognition, their conscious self and thereby their decision-making can be impacted (Buller, 2015; Davis, 2017). Efforts to empower persons with (beginning) cognitive constraints should aim at maintaining their autonomy (Silva et al., 2020). Seeking "ongoing consent" is a strategy of continuously reassuring that diagnostic procedures and preventive options are being understood and agreed to (Silva et al., 2020). Relatives can be potentially valuable in negotiating solutions in line with the patients' values (Kim, 2011). At the same time, sensitivity is needed concerning the extent to which relatives may be included in the decision-making process, balancing out the patients' best interests with their relatives' concerns (Götzelmann et al., 2021).

Conclusion

This study's findings emphasize the complexity of HL-relevant factors in risk prediction, revealing crucial ethical aspects that need to be addressed in medical practice. Approaches to promote self-determined decision-making should incorporate individual experiences, perceptions, relevancies, and (cognitive) capacities. HL should be understood as a subjective concept, where "good" or "bad" HL is not defined mainly from an objective point of view but rather regarding the extent to which individual values are being met. Supporting subjective HL can be seen as an ethical task in the prediction of Alzheimer's dementia. For this, we consider the direct communication between patients and HCPs to be the smallest but most crucial unit in predictive medicine. Once the patient's perspective on the subject matter has been analyzed, experiences and perceptions of HCPs working with people seeking advice in predictive procedures must also be considered, to account for the bilateral co-emergence of HL.

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Conflict of Interest
The authors declare no conflict of interest.

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HCPs on HL and SDM in Predictive Practice

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This article displays and discusses the findings of the observation of HCPs' perceptions, experiences, and recommendations with respect to the interaction with patients facing disease risk in predictive procedures. Drawing on the results of the preceding study part, the focus of this article lies on the communicational aspects of HL and SDM and its integration into medical training and practice.

After having observed the patients' perspective on the subject matter, the results of the first empirical phase of this thesis were translated into the conceptualization and design of the investigation of HCPs' perspective, respecting the reciprocity and the interactional dimension of the realization of HL and SDM in medical encounters. Using qualitative, semi-structured expert interviews, HCPs who consulted patients in predictive procedures about their risk profile and preventive measures were asked about how – from their perspective – HL of individuals facing disease risk could be promoted within the predictive setting; what aspects were relevant for SDM in that encounter; and which communication strategies had proven to be beneficial in their practice. Complementary surveys were used to learn about HCPs' background and whishes with respect to (medical) education and training, especially in patient information, risk communication, and SDM in predictive procedures.

Key findings introduced in this article were the identification of factors HCPs considered relevant for the promotion of HL and SDM in predictive consultations and the discovery of challenges HCPs commonly faced in their practice when communicating with patients (and their relatives) as well as resources they noticed in their interaction with patients that can be used for promoting HL and SDM in that setting. Furthermore, communication strategies HCPs regarded helpful were disclosed; the education and training of risk communication, patient information, and SDM was considered underrepresented in predictive medicine and identified as a starting point for promoting value-sensitive, demand-oriented communication in that field. Concrete implications and recommendations for the practice transfer of the findings could be derived and were discussed in this article.

This article in particular discusses the suitability of communication tools and medical training for HL- and SDM- promotion in predictive medicine and theoretical concepts behind the practical implications, such as the role of communication in disease risk perception and the reciprocity of risk/disease perceptions and health outcomes.

Contributing to this thesis' aim this article empirically and theoretically connects the perspectives of patients and HCPs. Practical guidance to promote HL and SDM in predictive consultations covers relevancies of both life worlds – of medical lay people, whose personal, health-related life is affected by the confrontation with disease risk, and of (medical) professionals whose occupational responsibility it is to enable patients to health-literate, informed decisions upon their risk and preventive measures. This article provides an empirical base for the development of strategies, tools, and teaching concepts and material for medical education and training, addressing HL and SDM promotion in predictive medicine.

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ORIGINAL ARTICLE

Health literacy and shared decision-making in predictive medicine — professionals' perceptions and communication strategies

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Abstract

Aim This contribution empirically analyses and theoretically reflects health literacy (HL) and shared decision-making (SDM) in the context of predictive medicine, taking in the perspective of healthcare professionals (HCPs). The aim is to identify ways to promote HL of persons dealing with disease risk, and to support SDM in predictive consultations.

Methods The perspectives of HCPs consulting patients at early prediction centers and advising them with respect to preventive therapies or further diagnostic procedures were examined using semi-structured, qualitative expert interviews and a complementary survey.

Results The data reveal resources and challenges regarding risk communication and the empowerment of patients for informed and health-literate decisions upon their disease risk. They also show potentially useful communication strategies and prerequisites for demand-oriented decision-making in the predictive setting. Furthermore, the findings highlight that risk communication and patient information in predictive medicine are considered to be underrepresented in medical education and training. Therefore, this contribution provides implications and suggestions for educational concepts and practical tools for medical education and predictive practice.

Conclusion We emphasize communication and interaction between HCPs and patients as crucial for health-literate decision-making in the specific context of predictive medicine. This study's results indicate relevant aspects of social and communicational skills that need to be considered in consultation guides and integrated into medical education and training, to provide individual-sensitive consultation and HL promotion for people at risk.

Keywords Health literacy · Shared decision-making · Predictive medicine

Introduction

With continuous medical–technical progress, individual disease risks prediction is getting increasingly advanced; likewise does the scope of preventive therapeutical options in predictive medicine[1]. Patients confronted with disease risk are challenged to navigate complex risk information, needing to decide upon anticipated health developments. Health literacy (HL)[2] is crucial for risk-adjusted decision-making (Schmidt-Kaehler 2016; Sørensen et al. 2012). Being able to critically evaluate risk information is necessary to make informed choices towards preventive

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[1] Predictive medicine or early diagnostic procedures refer to consultations, assessments, diagnostics, and therapeutic interventions to identify and respond to disease risk factors or early disease states, to prevent disease development or to moderate its onset.

[2] HL describes the ability to critically access, understand, appraise, and apply health information (Sørensen et al. 2012). It addresses the individual, organizational, and system levels (Schaeffer et al. 2018; Sørensen et al. 2012). Additionally, we share the understanding of HL as a form of multidimensional knowledge and social (Samerski 2019) and communicative practice (Harzheim et al. 2020).

measures or health-promoting lifestyles (Oliveira et al. 2018). This requires HCPs to inform their patients extensively on disease probabilities and enable them to make sound decisions. Especially in the context of predictive medicine, HL and shared decision-making (SDM)[3] are interwoven (Altin and Stock 2016; Hauser et al. 2015; Joseph-Williams et al. 2014). Simultaneously, there is a shift from traditional medical consultation models towards co-creative encounters between patients and HCPs (Clayman et al. 2017; Stiggelbout et al. 2015), emphasizing the demand for promoting HL and SDM in medical consultations (Altin and Stock 2016; Shen et al. 2019; Smith et al. 2009). Therefore, an individual-sensitive communication culture needs to be practiced (Jorm 2015), for which HCPs need to be equipped by incorporating communication skills into their education (Clayman et al. 2017; Schmidt-Kaehler 2016; Shen et al. 2019; Stiggelbout et al. 2015). While there is a lot of teaching material on general patient information in medical education (Langewitz 2012), literature does not provide specific concepts of teaching risk communication in predictive medicine, nor is there research on what resources HCPs resort to when communicating with patients in the context of risk. There are studies investigating aspects of HL (Wagner et al. 2009) and SDM (Woudstra et al. 2019) in the context of medical screenings. However, studies like these focus on the perspective of patients, examining correlations of educational levels or objectively defined HL states with the utilization of screening procedures. What has not been investigated to this date is the perspective of HCPs on the challenges and requirements of risk communication and decision-making in the field of predictive medicine. While HL and SDM are mostly investigated quantitatively and standardized[4], there is a lack of qualitative–inductive research, exploring what aspects are relevant from the perspective of HCPs.

Building upon a study on the perspective of patients (Harzheim et al. 2020), this contribution investigates the perceptions and experiences of HCP's regarding HL and SDM in predictive medicine, focusing especially on risk communication, patient information, and decision-making.

Aim & research questions

This study's aim is to enhance HL of persons partaking in early diagnostic procedures, to support SDM in predictive medicine, to provide empirically grounded recommendations for communication in the predictive setting[5], and to suggest strategies to translate the findings into practice and medical education.

Research questions addressed are: (1) how can HL of individuals facing disease risks be promoted, (2) what aspects are relevant with respect to SDM, and (3) which communication strategies have proven to be beneficial from the perspective of HCP consulting patients about disease risk predictions?

Methods

To inductively explore HCP's perspectives, a qualitative research design was chosen.

First, semi-structured expert interviews (Helfferich 2011) were conducted, followed by a short, complementary survey. The interview guide contained questions about HCP's experiences and perceptions about HL- and SDM-relevant aspects in predictive consultations. HCPs were asked about how they experienced communicating with patients about disease risks, what aspects they considered relevant to support patient's HL, and what challenges they faced in the decision-making process about disease-preventing measures. Due to its open structure, the interview guide allowed for participants to address any other subject of relevance to them in the context of the research topic. The guide was conceptualized incorporating findings from the preceding study on the patient's perspective, where risk communication, patient information, and decision-making were central aspects for patients with respect to HL and SDM in predictive procedures (Harzheim et al. 2020). Therefore, these categories were used as focus themes in the conceptualization and the analysis of this study (Kuckartz 2018). The additional survey was conducted to learn about participants' professional background and their experiences and needs regarding medical education and training on patient information, risk communication, and SDM. It comprised a combination of multiple-choice questions and free text fields on participant's professional profile and work experience, as well as their experiences and wishes regarding training and further education within these domains.

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[3] This work aligns with the definition of SDM as a process in healthcare where patients and HCPs mutually find health-relevant decisions by critically negotiating treatment options and possible outcomes (Hauser et al. 2015).

[4] An investigation of the HL in German society, for instance, used the HLS-EU-Q47, consisting of 47 questions on self-estimated ('inadequate' to 'excellent' HL) differences in dealing with information on health-related activities and tasks (Hurrelmann et al. 2020).

[5] Predictive communication or consultations mean the medical encounters between patients (and their relatives) and HCPs in the course of the medical determination of individual disease risk. The communication of the diagnosis determines therapeutic interventions or preventive measures, and is a key situation for people affected and their future health decisions (Harzheim et al. 2020).

The interviews were audio recorded, transcribed, and analyzed using qualitative content analysis; for the purpose of this study, a topic-centered cross-case analysis was chosen (Kuckartz 2018). Following this method, in a first step the interviews were summarized, disclosing key aspects and contexts. The transcripts were then coded, using a category-based, deductive–inductive approach. For resource-efficient reasons, the coding procedure was conducted by the first author (LH). Triangulation between researchers (Flick 2011) was applied to ensure the quality of data analysis; the codes and all following analysis steps were critically reviewed by the co-authors (LH, SS, SJ) and discussed among all authors. With this open yet thematically oriented process, key categories and subcategories were identified, which will be introduced in the following. The survey was analyzed using descriptive statistics.

Recruitment & data collection

In line with the study design, recruitment followed a criteria-based sampling strategy (Kuckartz 2018). Included were HCPs who conducted risk diagnostics and consultations in specialized early prediction centers and medical teaching practices of the University Hospital Cologne. This setting was chosen because it is one option for people seeking medical advice concerning disease risk to get diagnosed, informed, and advised with respect to preventive alternatives. It represents one encounter between patients and HCPs, where HL and SDM can be investigated and promoted; with university hospitals being a linkage for evidence-based practice, this setting also provides a ground for research–practice–transfer. As examples of indicational fields, the disease risk prediction of Alzheimer's disease (AD), coronary heart disease (CHD), familial breast and ovarian cancer (FBOC), and psychosis (PSY) were chosen. The selection of these clinical fields is rooted in their epidemiological relevance and in how their prediction or early detection affect future healthcare services. They cover a broad clinical spectrum (psychiatry, neuropsychiatry, oncology, and cardiology) and imply different preventive and therapeutic options (surgical, medicinal, psych-educative, behavioural). Also, they reveal diverse notions of risk (bodily, as in the case of FBOC, where risk is located in certain organs, vs abstract, as, for instance, in PSY, where risk is related to mental manifestation of the disease. This makes it possible to observe the understanding of and dealing with risk-probability statements about physical as well as mental disease manifestations.

In total, 262 HCPs were invited to partake in the study (interviews and surveys). They were contacted in cooperation with the collaborating institutions.[6] Recruitment and data collection took place from December 2020 to April 2021. While the survey was conducted via online-inquiry, the interviews were carried out via telephone or face-to-face at the respective center or with video-telephony.

Results

Of the contacted HCPs, seven agreed to being interviewed and to completing the survey (one FBOC, three AD, three PSY), 32 filled in the survey (one FBOC, three AD, two PSY, 26 CHD). Lack of time, the small number of professionals conducting predictive consultations at the respective clinic, and pandemic-related adjustments were reasons named by contacted HCPs who did not participate in the study or who only agreed ot complete the survey. Strengths and limitations of the sample size will be addressed in the discussion of this study.

Main findings from expert interviews

Based on the participants' experiences, three thematic foci were identified: (1) the communication of risk, challenges, and strategies, (2) HL in predictive medicine, communicating risk and negotiating previous knowledge, and (3) the decision-making on disease risk, recommended communication tools. A selection of pseudonymized quotes shall illustrate these categories introduced in the following.

The communication of risk — challenges and strategies

HCPs reported recurring challenges when communicating risk to patients. Explaining disease probabilities to medical lay people was described as being complex, requiring medical knowledge and emotional sensitivity in equal measure. HCPs stated that there are disease-specific facts but also individual concerns and emotions that need to be addressed. Risk perceptions thereby differed. HCPs pointed out that they faced extended requirements in communication skills, considering a dynamic development of the HCP–patient relationship, patient empowerment, and individual-sensitive communication:

> *"It's essential, that people are fundamentally different in how they deal with situations like this. […] Whether a glass is half full or half empty depends on someone's character."* (Expert Interview (EI) 07)

The potential of stoking fear when communicating disease risks to patients was also emphasized. Especially regarding particularly stigmatized diseases such as psychosis or Alzheimer's disease, patients attended predictive consultations with strong preconceptions or trauma. Rigid disease images were described as potentially hindering constructive

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[6] The collaborating institutions were the (1) Centre for Memory Disorders (AD) and the (2) Early Detection and Therapy Center for Mental Crises (PSY) of the Clinic and Polyclinic for Psychiatry and Psychotherapy, the (3) clinic for general medicine (CHD), and the (3) Center for Hereditary Breast and Ovarian Cancer (FBOC) the at the University Hospital Cologne.

dealing with risk information. The 'risk of knowing' was depicted, when fearing risk led to the progression of symptoms or the onset of a disease:

> *"We witness patients […] getting into mental crises. Such as depression, anxiety, isolation […]. And that […] has a negative effect on the onset of the disease. […] It compromises the quality of life. It worsens the course of disease."* (EI 02)

Disagreements between patients and their relatives were also mentioned as having a complicating effect on predictive consultations. Differences in self- and external perception challenged HCPs to mediate, needing to conciliate both parties. In cases of low symptom understanding or motivation on behalf of the patient, communication was experienced as being harder than with proactive and intrinsically motivated patients whose perceptions aligned with those of their relatives:

> *"It's rather [challenging] with patients who don't recognize any symptoms, coming to us because their family members […] asked them to. […] and then they come here with a bunch of symptoms but without being motivated for any treatment."* (EI 05)

The interviewees shared communication strategies they had developed to navigate the challenges named: considering the emotional level, communicating in an opportunity-oriented manner, and using imagery language had proven to be beneficial in their practice. Mediating a diagnosis carefully, asking about the patient's fears and worries, and being transparent and empathic helped to constructively convey communication. Building a trusted environment and responding to individual needs before communicating a diagnosis were explained as putting patients at ease and preparing them best for discussions on how to proceed:

> *"First, it is about building trust. […] You have to mediate very carefully."* (EI 01)

The earlier disease probabilities are identified, the more preventive options there are — from medical or surgical interventions to psychotherapeutic or educative approaches. HCPs described it as being essential to emphasize the chance that lies within risk prediction. An opportunity-oriented communication style helped to focus on possibilities, encouraging patients to preventive measures:

> *"I always try to come to therapeutic options as soon as possible. 'All right, what can we do about it?'"* (EI 02)

HCPs used imagery language, illustrations, or pictures to decrypt complex statistical risk parameters. Self-made drawings, graphs, or prints from imaging techniques were used to communicate medical findings. Metaphors also helped to make certain conditions more acceptable for patients:

> *"And I always try to destigmatize by naming neurobiological causes […]. I have my standard metaphor of a broken leg […]. The comparison with a physical condition is often easier to accept for people."* (EI04)

Health literacy in predictive medicine — communicating risk and negotiating previous knowledge

According to the interviewees, challenges in navigating risk information lie in the complexity of health information in general and in explaining and understanding risk probabilities in particular. 'Incorrect' self-gained knowledge and pre-assumptions based on, for instance, stigma, hindered a constructive communication and challenged the HCP to realign patients' perceptions of risk.

> *"With all that information available it is really hard [to distinguish good and bad sources]. And all this external information has a strong impact on patients […]. During the consultations you only contribute a small part as an expert."* (EI 01)
> *"People do their research on the internet. And it's difficult because they name symptoms they have read […], they adopt a terminology that isn't correct, and they use certain buzz words but the content behind those is actually different."* (EI 04)

HCPs stated that in general, disease prognoses, preventive options, and symptom characteristics were pieces of information asked for in predictive consultations. When disclosing a positive risk finding, HCPs found themselves being asked about the next steps, potential courses of the disease, and available preventive options. Patients also showed relief when having their symptoms explained and being introduced to preventive and therapeutic measures:

> *"People want to know what they can do to prevent the disease from breaking out."* (EI 04)
> *"Many of them are relieved that their symptoms are explicable. That they then finally know, their symptoms are nothing totally out of the ordinary."* (EI 04)

Individual resources and competencies of patients were also named as being central components in the communication and negotiation of risk. HCPs experienced patients' risk perceptions as depending on internal and external resources and competencies: intuition, self-reflection, and motivation were named as important internal resources. Individuals' social environment and being appropriately informed were external resources HCPs associated with a constructive dealing with risk:

> *'Some know the factors that aren't good for them. They intuitively know that they should quit smoking weed and that stress does no good for them. A lot of them know what they need right now.*' (EI 04)

> *' I feel like those who came here motivated by themselves, […] are well reflected and have observed themselves over a longer period of time."* (EI 05)

> *"One of the most important things is family, the social situation. When patients are settled, it's one of the best preconditions."* (EI 01)

Decision-making on disease risk — recommended communication tools

Depending on the clinical field, HCPs were involved to a different extent in the decision-making process on preventive measures. In an early prediction center that is specialized on the diagnostic process alone, the communication between patients and HCPs is limited to the diagnosis disclosure. However, when there are follow-up concepts, the encounters involve further decision steps. Yet the decision-making was described as resting more strongly on part of the patients, once the HCPs had introduced them to different treatment options:

> *"You name all options to the patient and then they decide for themselves."* (EI 04)

> *"And I ask them what option they prefer from the bouquet I introduce to them. And I always say that we make a recommendation but as a reasonable, mature person, they need to make the decision themselves."* (EI 05)

Interviewees reported communication tools such as brochures to help in disease risk consultations. They recommended differentiating between the factual, indication-specific level and the communication–strategical level. As examples, they named standardized guidelines/protocols with information about the predictive procedure, disease characteristics, treatment options, and topics such as social and legal issues. As well as adaptive, situational coaching tools for individual-sensitive communication:

> *"It is important to differentiate between the content and the way you communicate. […] How to communicate can be learned in non-specific communication-training sessions. […] Basic information about disease, treatment options and everything around it should be standardized."* (EI 01)

Although teaching material was stated not to replace experience, participants emphasized that risk communication had been neglected in their academic studies or further education. There were training elements in medical education on delivering diagnoses in general, but not on communicating risk in predictive medicine in particular:

> *"In medical practice, there is a lot about learning by doing. You can be trained to a certain extent, but in the end, it is about professional experience…"* (EI 01)

> *"I would benefit from some training on how to talk to relatives in this context."* (EI 03)

Depending on the academic background (psychological vs medical education) and the specification of the institution with respect to risk communication and SDM in the predictive setting, the awareness of and the need for tools and education regarding risk communication skills varied between participants. It was also indicated that aspects such as communication, empathy, and sensitivity are of varying relevance in medical and psychological curricula:

> *"The training in psychology, especially when it comes to communication, empathy, and sensitivity for people, is completely different from what you can learn in medical school."* (EI06)

Main findings from the survey

Complementary to the interviews, the survey made it possible to highlight HCPs' experiences, needs, and impulses with respect to professional training and further education on the three topics (1) patient information, (2) risk communication, and (3) SDM in the context of disease risk prediction (Table 1). It discloses implications for the operationalization of the study findings in medical practice.

Participants specified: *"Consultations [about risk] and how to conduct them should be trained intensively"* (Question (Q) 20). Participants who stated that there was not enough respective education in their professional field, added that *"too little practical training"* was offered or that *"frequent training would be desirable"*. *"I didn't realize that the offer for professional training was so scarce."* (Q 15).

Wishing for more professional training and further education on risk communication, SDM, or general patient information, one participant added: *"I find it useful to be taught basic communication skills and competencies that can be transferred to various clinical fields in the [medical] studies. Indication-specific training sessions should be offered by the respective professional association."* (Q 20).

Table 1 Main findings from the survey

Survey participants	
In total	32
Clinical field during data collection…	
CHD	26
AD	3
PSY	2
FBOC	1
Educational background	
Studied medicine	31
Studied psychology	1
Did NOT get input on the three topics during education	17
Did get theoretical (not practical) input	1
Studied more than 10 years ago	19
Studied 5–10 years ago	3
Studied less than 5 years ago	2
Professional training and further education experience	
Frequently take part in training and further education	16
Training and further education they received were offered by...	
External providers (e.g., medical association)	15
The clinic they worked for (e.g., guest lecture)	10
Others (not specified)	4
Training and further education they attended covered the topics…	
SDM	13
Patient information in general	8
Risk communication in particular	5
The input was provided in form of…	
Presentations	11
Articles, digital and print media	10
Practical exercises and simulations	6
Need for training and further education for disease risk consultations	
Education on the three topics is missing in their profession	7
Wish for more training/education with respect to...	
SDM	13
Risk communication in particular	10
General patient information	6

The following table (Table 2) summarises all findings and implications. It provides suggestions on how to implement the findings and implications introduced into (medical) education and predictive practice.

Discussion

In the following, the findings and implications will be discussed in the light of previous research and existing literature. With this work's overall aim to contribute to promoting HL of people confronted with disease risk and to support SDM in predictive medicine, there is a need to critically reflect whether the implications derived from the results are suitable for operationalization and transfer into practice — are the suggested approaches appropriate to support HL and SDM in predictive medicine, especially with respect to their practicability and their effectiveness? What does previous research indicate with respect to the implications derived? To address these questions, the benefit of tools in medical practice as well as the effectiveness of incorporating communication and interaction skill training into medical education should be critically discussed.

Communication tools and medical training as suitable for HL and SDM promotion in predictive medicine

Recommending tools such as prompts, checklists, handouts, and explanation instruments can only be fruitful if they can be incorporated into medical practice effectively. While there is a lot of research on instruments to *assess* HL, there is no systematic evaluation on how to *promote* HL or SDM in predictive consultations in particular. However, there are a few studies that address questions about whether it is reasonable to offer communication tools in medical encounters, and whether they show a positive effect on patient's HL and/or the SDM. An interview study investigating HCPs' perceptions with regard to communication and SDM with patients with limited HL in the palliative setting revealed that teaching communicational skills and using tools in consultations were concepts that effectively supported HL and SDM (Roodbeen et al. 2020). A review on the effectiveness of question prompt lists in general medical consultation, in terms of patients actively partaking/asking questions in consultations, showed that more content was shared in consultations when using such a tool. However, the quality of the consultation or the effect of a question aid on the HL of patients was not evaluated (Sansoni et al. 2015). In addition, using tools to visualize risk probabilities and to introduce possible outcomes to patients is recommended for use in a trusted environment and for informed choices about disease risk (Paling 2003). With tools potentially being an effective measure, HCPs' resources to implement them need to be considered. The work environment needs to provide structures for the use of tools (e.g., management support, time, coaching, supervision, etc.).

With regard to our recommendations for medical training and further education, we wish to discuss (a) the potential of teaching-to-practice transfer in general, and (b) the benefit of training and education for HL and SDM promotion in particular. Participants wished for input on risk communication, SDM, and patient information. But even if the curriculum of medical studies would cover these areas, there is the risk that input on communication, interaction, and mediation skills is given little priority by medical students,

Table 2 Summary of findings, implications, and suggestions for implementation

General findings	The results give an orientation on aspects HCPs find to be relevant with respect to HL, SDM, and communication concerning disease risk prediction. They highlight the needs of HCPs with regard to professional training and education in predictive medicine. (Medical) education and training is important for individual-sensitive and demand-oriented communication in predictive medicine.
Implications for education and training	There is a wish for input on risk communication, SDM, and patient information in (medical) education, professional training, and further education for predictive consultations. Input on communication in predictive medicine should be two-levelled, addressing 'facts & feelings': standardized, indication-specific material as well as adaptive guidance on communication strategies
Communication resources and strategies	As equally beneficial for medical practice as education and training, tools such as guides, protocols, and handouts were named. For fruitful communication strategies and HL-/SDM-promotion in predictive consultations, approaches such as (1) considering informational and emotional needs of patients and relatives, (2) incorporating previous knowledge, fear, and stigma, (3)communicating in an opportunity-oriented manner, (4) using imagery language, (5) providing time and empathy, and (6) enabling for informed choices were suggested.
Transfer to practice	Shared perceptions and experiences (e.g., the duality of risk communication, the 'risk of knowing', the need for mediating competencies, the relevance of emotions, pre-assumptions, and internal resources) should be incorporated into the conceptualization of teaching materials and tools. Findings should be integrated into a training concept for medical curricula and further education programs. For example, by the development of practical exercises, focusing on risk prediction (simulations of predictive consultations) in different clinical areas, and on communication with patients alone and with their relatives. Examples of tools could be: prompts or checklists for HCPs, handouts and questions lists for patients, graphs, figures, and explanation instruments to draw on in a medical encounter.
Implementation	A 3-moduled pilot project could be developed: (1) a teaching concept for the undergraduate medical curriculum, (2) a further education program for practicing HCPs (indication-specific, using the example of one clinical field at first), and (3) tools and materials for patients and HCPs in medical practice. Following a participatory approach, the pilot project would need to be co-created by scientists (conceptual framework, evaluation, transfer to medical curriculum), patients (content and assessment), and HCPs (content, assessment, and implications with regard to medical practice). During and after implementation, materials and teaching concepts needed to be empirically evaluated. For example, with a mixed-method approach, incorporating interviews, surveys, participatory observations, and/or workshops with students, HCPs, and patients. The evaluation study should be re-incorporated in further developments of the materials and teaching concepts. After that, the modules might be expanded to other universities/training facilities/clinics/medical offices to cover a broader variety of clinical fields.

considering the massive amount of material to be learned and the biomedical focus of the curriculum. Our participants' engagement with these subjects possibly correlates with their specification in predictive medicine and their work at an early diagnostic center. Yet, an educational concept focusing on competencies in the named areas could be beneficial for medical students, preparing them for individual-sensitive communication and SDM. To our knowledge, there are no evidence-based teaching concepts for the training of HL competencies in HCPs, nor have there been investigations on how professionals manage to incorporate acquired competencies into their medical practice (Lippke et al. 2020). There is, however, a study showing that teaching risk communication and SDM skills in clinicians is effective, meaning that participants engaged more confidently and that they showed a higher objective knowledge on SDM and risk communication after having undergone some online teaching (Hoffmann et al. 2021).

There are theories on the practice transfer of learned contents and thereby on the effectiveness of further education and professional training. Literature primarily discusses the learning–practice–transfer in a business educational context (Tonhäuser 2017). Yet, general theories can be transmitted to the medical practice as well. The theory of identical elements by Thorndike and Woodworth (1901), for instance, suggests that in order for learned material to be translated successfully into practice, the learning and application situation need to be as similar as possible (Woodworth and Thorndike 1901). So, when wanting to sensitize HCPs in predictive consultation for both the informational and emotional needs of patients and relatives, communication simulations need to replicate a patient–relative–HCP interaction as truly as possible to the original. Experiences shared in this study could serve to replicate sample scenarios, e.g., by creating case vignettes for simulated advice seekers, to confront students or professionals with challenges in risk communication. Behaviorist approaches such as this focus on stimulus–response processes mostly depend on external components of environment. Cognitivist transfer theories, however, centralize inner processes/mechanisms of the learner. With regard to individual problem-solving strategies, general principles are introduced to the learner, who then deductively interprets and transfers these general sets of rules to the practice (Singley and Anderson 1989). Following this theory, introducing general information on aspects such as fear or stigma to (medical) students and HCPs, may enable them to transfer this knowledge into their practice. Grounding on these and other theoretical approaches, Tonhäuser (2017) summarizes three categories that determine a positive learning–practice–transfer process: personal factors (motivation, volition, cognitive capacity etc.), organizational factors (such as supporting colleagues and superiors or application opportunities in the workplace), and measure-specific factors (e.g., similarity of learning material to practice reality and applicability). Simplified, this means that teaching materials need to be target group-oriented, applicable, and close to reality. The module-box for the development of culture-sensitive communication trainings in predictive and preventive medicine by Lorke (2021) offers one possibility for a complementary conceptual framework, empirically covering patients' perceptions in the context of health, risk, and culture.

When delving into the literature about medical education and HCP training on HL and SDM, *'professional health literacy'* is a central term one may come across. The concept includes the competence of a HCP to communicate and listen in a way that centers the patient's individual interests (Lippke et al. 2020). There is a reciprocal effect implied, demanding health-literate professionals in healthcare in order to provide an environment to support a patient's HL (Mullan et al. 2017). It is emphasized that a health-literate interaction with patients should be taught in medical education and training, and that teaching communication skills may enable HCPs to appraise and respond to their patients' HL (Lippke et al. 2020). Educational concepts that are considered beneficial in teaching HL competencies of HCPs are, for instance, interactive communication loops (Schillinger et al. 2003), motivational interviewing (Miller and Rollnick 1991) or the health action process approach (Schwarzer et al. 2011).

Previous research and theoretical concepts on implications

We address the duality of risk communication respecting factual and emotional aspects that need to be considered when communicating about disease risk; also, emphasis is placed on the requirement for predictive consultations to be individualized and preference-sensitive, incorporating previous knowledge, fears, and needs.

The two-levelled approach of addressing facts (standardized) and feelings (individualized) in a medical consultation has already been addressed by others. Studies have shown that emotions often overweigh statistical aspects in decision-making processes and therefore need to be taken seriously in medical encounters (Holmberg et al. 2015; Lorke et al. 2021). Recognizing and replying to emotions potentially creates an environment for more productive interactions. Respecting emotions as valuable in decision-making eases the decision-making process and comforts people in their choices, reducing relational conflicts (Gengler 2020). Meeting the emotional element in medical encounters is also considered to be beneficial with respect to people's HL (Roodbeen et al. 2020). With predictive medicine being primarily grounded on statistical and numerical information, a balanced risk communication is needed, considering facts and feelings individually. Kaldjian (2017) gives valuable focus on the duality of communication in healthcare by discussing different concepts of health in SDM processes. He opposes the biostatistical concept of health (such as absence of disease, objective, value-free) and the well-being concept of health (such as value-oriented, socially determined, individual-specific), arguing that attributes of both systems need to be negotiated in SDM processes, where care goals have to be identified individually (Kaldjian 2017). Chirchirez and Purcărea (2018) go beyond encouraging HCPs to be trained in incorporating feelings of patients, but to analyze and consider the complexity of their mindsets, emotions, and reactions to "[…] diagnose not only the health state but also the patient's typology level [meaning the set of a patients' personal characteristics], their cultural and mental state." (Chichirez and Purcărea 2018). We share the idea that medical encounters should be a sensitive, nurturing environment where beneath the communication of facts, personal issues, and concerns are integrated for effectively promoting HL and SDM. Going beyond this, we suggest encouraging HCPs also to analyze and consider *their own* mindsets, emotions, and cultural and mental state. This would be a prerequisite for critically reflecting on one's own fears, values, and preferences, since it has been shown that it is hardly possible to present decision-relevant medical information in a neutral manner (Molewijk et al. 2003). Moreover, it would be a means to overcome the strict separation of 'physicianhood' and 'patienthood', allowing for truly 'shared' decision-making (DasGupta and Charon 2004), since it can be argued that in medical encounters, not only the patient has emotions and culture (Napier et al. 2014).

We consider stigma, fear, and previous knowledge to be potentially relevant for predictive consultations. Conditions affecting the mental state (e.g. Psychosis or Alzheimer's disease) are especially stigmatized. With predictive procedures alone being a potentially fearful event (Chiolero 2014), needing to deal with health-related stigma or fear may facilitate negative health outcomes (Jessen et al. 2014), less participation in healthcare services in general, and preventive measures in particular (Kane et al. 2019). Being sensitive towards what is known about or feared about a disease may help to counteract misconceptions. This reciprocity of risk/disease perceptions and health outcomes implies the importance of understanding factors such as stigma, fear, and previous knowledge in predictive consultations. This consideration interrelates with the above mentioned 'risk of knowing' which is being given credit by the controversial debate on potential harms of risk prediction and 'the right not to know' in predictive medicine. In genomic research and the prediction of life-altering diseases for instance, ethically highly relevant impulses with regard to aspects such as individualized communication, patients' autonomy, and normativity in healthcare are contributing to the mentality of future healthcare (Andorno 2004; Berkman and Hull 2014; Cook and Bellis 2001; Davies and Savulescu 2021).

When recommending an opportunity-oriented communication style (e.g., using imagery language or practicing empathy), questions for communication strategies that have proven to be effective in predictive medicine arise. Although there is literature on communication in medicine in general and on concepts such as individualized and preference-sensitive communication, publications rather indicate research desiderata than empirical evaluation of communication models with practical implications (Balducci 2014; King and Hoppe 2013; Koul 2017). There is, however, evidence concerning the use of graphical images in medical consultations showing that patients who saw explanatory images when being consulted about disease were more satisfied with the encounter (Vilallonga et al. 2012). Complementing the use of graphical images, imagery language (metaphors) may be a relevant tool for explaining disease risk. Schwegler (Schwegler 2021) has described the risk consultation encounter as a novel communication genre that confronts both advice seekers and HCPs with new and particular challenges. Future research on HL and SDM in predictive medicine could therefore benefit from linguistic approaches, analyzing the effectiveness of imagery language in predictive encounters for patients and HCPs alike.

In order to operationalize this study's results, deductive concepts and practical tools integrating the abovementioned implications should be developed, introduced to patients and HCPs in the predictive practice, and systematically evaluated — most preferably using a participatory research approach. Respecting the idea of medical reality being co-created by patients and HCPs (Cherry 1996), previous research on patients' perceptions (Harzheim et al. 2020; Lorke et al. 2021) should be included in conceptualizing tools and teaching material.

Strengths and limitations

Due to the heterogeneity of HCP's specialty (e.g., CHC vs FBOC) and the varied data corpus (more surveys than interviews), an overarching data analysis, without the intention to provide indication-specific findings, was conducted. The focus was based on identifying similarities across clinical fields, so that early predictive procedures in general may benefit from the findings. The sample size is adequate for the research question, the study design, and the given project resources, following the principles of purposive/theoretical sampling (Corbin and Strauss 1990). This study's sample allowed for HCPs to share experiences and views on the topics of interest, and for deriving theoretical approaches and orienting cornerstones for further research. However, all participants worked at specialized early prediction centers and therefore were sensitized to the topics addressed. Investigating the perceptions of HCPs consulting about risk in less specialized environments might reveal insights which a broader audience in predictive medicine could relate to.

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Availability of data and material All data used for this contribution are available to the journal upon request and in in a pseudonymized form.

Declarations

Ethics approval Ethics approval to this study was granted by the ethics committee of the Medical Faculty of the University of Cologne on December 8, 2020 (registration number: 20-1290_1). The study aligns with the Helsinki Declaration of 1964, as revised in 2013, respective human and animal rights. All participants consented their participation verbally and in writing.

Consent to participate and for publication Informed consent to participate in this study and to having their data published was obtained from all participants included in this study.

Conflicts of interests There are no conflicts of interests to declare.

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Summary of Findings

The results of this study allow to empirically undergird and theoretically reflect on the concepts of HL and SDM in the specific context of predictive medicine and to derive recommendations for transfer into practice. To operationalize the findings for HL and SDM promotion in predictive procedures, key findings and their practical and theoretical implicational shall be collated.

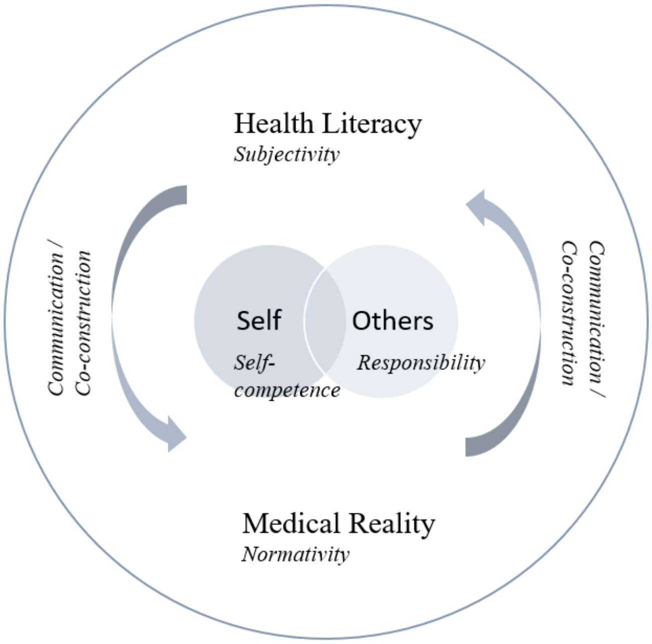
Participants' risk perceptions, interpretations, and strategies of dealing with risk show how risk perceptions individually differ on the one hand, but also how risk is being perceived as an identity-relevant complex by all participants (Harzheim et al., 2020; Harzheim et al. 2023a). The disclosure of risk diagnoses in predictive procedures epitomizes a key situation, affecting patients' self-perception and their choices regarding preventive measures and participants' ways of living (Harzheim et al., 2020; Harzheim et al. 2023a). Disease images (e.g. through experience or stigma), preventive options (psychotherapeutic, educative, behavioral, pharmaceutical, or surgical), the prognosis (curable vs. not curable disease manifestation), and the conception of risk (abstract vs. physical disease manifestation) were central aspects named by the participants of this study (Harzheim et al., 2020; Harzheim et al. 2023a).

HCPs highlighted challenges they experienced in their predictive practice, like the complexity of risk information and the necessity to incorporate both factual and emotional aspects into consultations. They addressed conflicts between the perceptions of patients and their relatives that need to be mediated; and they emphasized the potential harm of predictive procedures or the disclosure of a risk diagnosis on people affected. Being engaged and proactive with respect to preventive measures, as well as internal (intuition, motivation, self-reflection) and external (social environment) resources were, on the other hand, assets to resort to when negotiating risk. With communication being central in the perception of and dealing with risk, strategies reported as helpful for predictive consultations were an opportunity-oriented communication style, the use of imagery language and a two-leveled communication strategy, addressing facts and feelings alike. With respect to risk information and SDM in the predictive context, HCPs expressed their wish for education, suggesting these matters to be included in medical training and practical guidance (Harzheim et al. 2023b).

With this study's aim to (a) identify HL- and SDM-relevant aspects in the context of predictive medicine from the perspectives of people involved and to (b) conceptualize instruments for HL and SDM promotion in the predictive practice, the above mentioned key findings shall be illustrated with a focus on their theoretical contribution to the concepts of HL and SDM in predictive medicine (Figure: "HL and SDM in Predictive Medicine") and on their implications for the predictive practice (Figure: "Three-pillared Approach of Promoting HL and SDM in Predictive Practice").

Figure 4

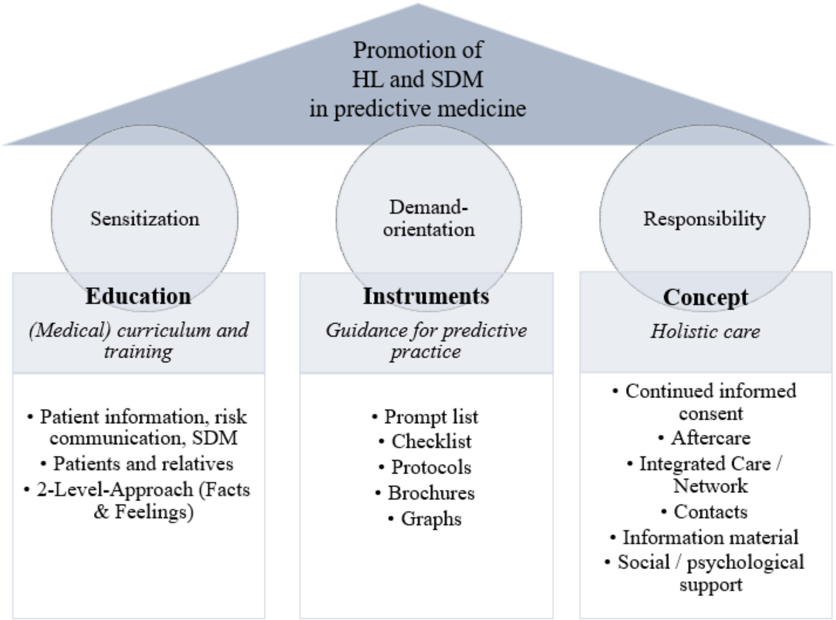
HL and SDM in Predictive Medicine



Addressing the level of individual HL on the example of predictive procedures, ‘persons at risk’ (patients) and others (here: HCPs as well as relatives or friends) were shown to be the key player in the negotiation and meaning-making of disease risk. Aspects like self-awareness and self-competence, in terms of being able to recognize and reflect upon health-related changes, wishes, and capacities of oneself, were identified as relevant for building a subjective HL – the competence of dealing with health information in a manner that contributes to one’s health to an extend this person subjectively prefers. ‘Important others’ may be understood as equally relevant in the process of dealing with health (and risk) information, being meaningful for the negotiation of a risk’s meaning for someone’s life. Communication with oneself (through self-reflection and intuition) and with others (through conversations in the private setting, within predictive procedures, but also through communicated signals from the outside, like stigma) are inherent to dealing with risk information; the co-creation of health-related (medical) reality by the exchange about and the negotiation and meaning-making of risk information with oneself and others reflects the significance of communication for the evolvement of someone's HL and for the way people perceive health, disease, and risk and its impact on their lifeworld. The results of this study indicate that, due to their identity-relevant impact, predictive procedures have a normative potential. Within this potential lies the medical-ethical responsibility of the healthcare system in general and HCPs in particular to critically consider how disease risk is being defined and communicated to patients. These conceptual considerations depicted in figure 4 will be one point of view discussed in the following.

Figure 5

Three-pillared Approach of Promoting HL and SDM in Predictive Practice



Collating this study's results to operationalize them for the predictive setting, a three-pillared model for practice transfer is postulated. (1) HCPs' wish for education on patient information, risk communication, and SDM in predictive procedures is one approach derived from the data. To sensitize HCPs for HL- and SDM-relevant factors in disease risk prediction through education and training can be one way to prepare them for meeting patients' informational and emotional needs in a crucial health-related moment in their lives. (2) HCPs' suggestion to provide instruments for the use in predictive consultations (such as prompt lists for patients, protocols for HCPs, or explanatory graphs) may help accompany conversations between patients (and their relatives) and HCPs in predictive procedures, assisting them to communicate in a demand-oriented manner. (3) As a third pillar, a holistic consultation concept may serve early diagnostic centers in guiding patients and their relatives throughout predictive procedures and does also provide an organizational structure for HCPs to develop, practice, and maintain HL- and SDM-relevant competencies. Measures like assuring continued informed consent (especially within the field of cognitive impairments) or an aftercare road-map (e.g., contact information for social or psychological support) are logical consequences of the insight of patients being potentially overwhelmed with their (new) health-related reality and of statements describing risk diagnoses to be a momentary encounter that does not necessarily equip persons in search of advice sufficiently for health literate decision-making. Accompanying patients throughout their journey of meaning- and decision-making about their disease risk, may be understood as a form of enabling the shared decision-making process, since a decision may not be worked out during one medical encounter alone; at the same time, the medical-ethical responsibility of ensuring a patient's wellbeing in the context of a medical consultation is being met when patients are not left alone without orientation after an event like a risk-diagnosis/disclosure. The illustrated three-pillared approach for HL and SDM promotion in predictive procedures will be discussed in the following.

Discussion

In the following, the overarching value gained from the summary of findings for the research field, the conceptual broadening of the HL and SDM concepts within the predictive setting, and the feasibility and applicability of the practical implications derived for medical education and practice will be discussed. While the results of the two empirical phases are discussed in detail in the respective publications, key findings consolidated in this thesis' findings section will be translated into hypotheses/deliberations that will be reflected in the light of previous research and theoretical concepts: What is the innovative knowledge and the added value to be concluded from the analysis and interpretation of this study's findings?

The differentiators of this research work are (1) the empirical investigation and theoretical reflection of the concepts of HL and SDM within the specific context of early risk prediction and (2) the exploration of the perceptions of people involved and affected by the research context, applying an inductive, participatory mixed-methods approach.

In light of its conceptual, methodical, and practical characteristics, this research work allows to pronounce hypotheses that will be discussed in the following and may serve as practice-oriented impulses, and as a ground for further research, namely:

- HL and SDM are interwoven concepts – for promoting them in predictive medicine, their reciprocity needs to be understood.
- Subjectivity and normativity in predictive medicine contribute to the framing of HL and SDM in risk prediction.
- Self- and role-perceptions affect the negotiation of risk and prevention and therefore reason a holistic view on the protagonists in predictive practice.

- A three-pillared approach may support the promotion of HL and SDM in predictive practice, involving education and training of HCPs, practical instruments for predictive consultations, and holistic care concepts of early prediction centers.

HL and SDM as Interwoven Concepts

– Understanding Reciprocities for Their Promotion in Predictive Medicine

With accessing, understanding, critically appraising, and applying health information being central to the definition of HL (Sørensen et al., 2012), the concept inherently entails decision-making of an individual on his or her dealing with health. *Shared* decision-making (Kasper et al., 2010) brings in the aspect of (at least) a second party being involved in the negotiation of health information and related behavior. With this thesis understanding HL as a co-created construct (Harzheim et al., 2020), the communication of (at least) two parties (Self and Others) is an integral characteristic of the concept. Since this communicational process contributes to a mutually created (medical) reality (Cherry, 1996), decisions following this process are developed in a shared manner.

A Decision Space Model by (Lippa et al., 2017) approaches decision-making in medical encounters the same way this thesis reflects the concepts of HL and SDM: Both actors (patients and HCPs) frame the situation based on personal perceptions and strategies; there are external and internal components that impact the evolvement of a decision, such as norms, values, and personal capacities, but also physical parameters like diagnostic and treatment options (Lippa et al., 2017). Just like with the evolvement of HL, this approach of SDM respects the relevance of personal and professional values and preferences; addressing the "[…] culturally defined notions of health care, illness, and quality of life considerations." (Lippa et al., 2017, p. 1036). Physicians and patients – both being imprinted by their (professional) lifeworlds – ideally find an intersection in a co-created construct that reconciles a solution both parties can stand for. SDM is thereby negotiated between patients and HCPs; patients' and HCPs' reasoning needs to be integrated into the decision-making process to avoid adverse outcomes (Lippa et al., 2017). This is in line with this thesis' consideration of respecting and integrating both lifeworlds of patients and HCPs when wanting to promote HL and SDM in medical encounters. Zoffmann et al. (2008) emphasize a person-centered, reflected communication strategy in SDM processes, where professionals gain insights into the motives of patients, instead of the other way around. They thereby re-define HCPs' role in the concept of SDM. Seeing SDM as a dynamic that involves co-creational knowledge (Zoffmann et al., 2008), HL, as a form of knowledge contributing to health-related decisions, again appears to be an inherent part of the SDM concept; the responsibility of HCPs that comes along with the need of understanding the decision-making of patients also intertwines the two concepts by seizing professional and organizational (Baumeister et al., 2021) HL as essential in SDM processes. The conceptual model defined in this thesis (Figure: "HL and SDM in Predictive Medicine") suggests the communication with oneself and others to be central for the evolvement of HL and SDM from the perspective of the patient. Having the idea of HCPs' (self-) reflection as a competence within SDM processes in mind, this model may also serve for the theoretical reflection of professional HL.

Elaborating on the communicational aspect within the concepts of HL and SDM as a primarily binary construct, focusing on the relationship between patients and HCPs alone, undervalues the role of relatives or proxies for the decision-making and the evolvement of HL – especially in the context of predictive procedures. Remembering the findings of this thesis, relatives can play a crucial role in negotiating disease risk (Harzheim et al., 2020; Harzheim et al. 2023a), opening up the concept of SDM to a process where not only the perceptions, wishes, and capacities of patients and HCPs affect the dynamics, but also the presence and influence of a third party. The component of the outward communication with others in the conceptual model (Figure 4) introduced in this thesis, in distinction to the inward communication with oneself, therefore specifically understands ‘others’ as everyone directly or indirectly contributing to the creational space of HL and SDM.

When acknowledging the impact of the individual lifeworlds of patients, HCPs (Cherry, 1996), and others on the evolvement of HL and SDM, the subjectivity constituting these concepts reinforces the question of whether there is at all a way of objectively assessing one of each. If decisions are based on some form of competence, what does competence consist of? How does it evolve and in how far do unquantifiable aspects like intuition contribute to someone’s competences – competences that are relevant for decisions that may then be evaluated as literate or not? Deliberations like these oppose objective HL (objectifiable, performance-based) and subjective HL (perception-based, self-reported) (Schulz et al., 2021). This thesis rather argues for respecting the validity of both approaches (Schulz et al., 2021), understanding objective and subjective HL as two separate but reciprocal concepts. This may help with finding appropriate evaluation strategies that credit the respective natures of the two concepts. Using multivariable assessment methods, considering a variety of influencing aspects on the evolvement of HL rather than single parameters (Martin et al., 2009), would be an approach that meets the multidimensionality of the investigated phenomenon with a multidimensional study design. Samerski also emphasizes to respect the “bricolage of different forms of knowledge” (Samerski, 2019, p. 8) in HL research by considering the multidimensionality of HL in a study design.

In the same way, questioning the generalizability of the SDM concept, Baldt and Slunecko found out that pre-defined categories of decision-making (such as patient-driven, physiciandominated and so forth) are not applicable to every encounter between patients and HCPs; they emphasize SDM to be a situational and individual-dependent dynamic (Baldt & Slunecko, 2022). Just like this thesis argues, there are more variables than the dominance of patients or HCPs that may affect the decision-making process.

When aiming to promote HL and SDM in the context of predictive procedures, understanding the interplay of the two concepts is important: The evolvement of competences that lead to a decision as well as to someone's positioning in a decision-making process with other parties involved, is individual-specific and multidimensional. When wishing to contribute to a competent decision-making about a disease risk, there is no way around exploring, disclosing, respecting, and negotiating the values, wishes, and reasons of patients and their relatives as well as organizational, motivational, and cultural aspects (Cherry, 1996) that determine the role of HCPs within that construct.

Subjectivity and Normativity in Predictive Medicine

– The Framing of HL and SDM in Risk Prediction

One central finding of this thesis is the understanding of HL as a communicative practice (Harzheim et al., 2020). Communication is a central aspect of the evolvement of HL (Harzheim et al., 2020) and efforts to promote HL should address the quality of communication between patients and HCPs (Coleman, 2020; Wynia & Osborn, 2010) as one interactional component in the decision-making process with respect to disease risk.

How communication is valued within SDM processes is connected to underlying concepts of health and ethical alignments in personal interactions. Keeping the binary view on perceiving health (and disease risk) on a factual and emotional level (Harzheim et al., 2020; Harzheim et al. 2023a), a two-pillared conception of health may help to exemplify attitudes that determine health communication: (1) Understanding health as a biostatistical concept, health is defined by the absence of disease. Disease is described in statistical, biological labels, health and disease are value-free and objective. Consequently, healthcare is to free from physical abnormalities (Kaldjian, 2017). (2) Opposing this, a well-being oriented concept of health sees health as the ability to live life in a subjectively fulfilling manner. According to this, disease is a reducer of this ability. Health and disease are value-bound, social constructs, and healthcare is to promote this subjective, well-being-oriented form of health, enabling a person to pursue their life goals (Kaldjian, 2017). Although the term 'well-being' may also be inherent to the absence of disease in a biological-statistical sense, the core of this idea is the subjectivity of health, wellbeing, disease, and also disease risk, leaving the perception of and the dealing with these concepts to the individual. For communication characteristics in SDM, a well-being oriented approach means adjusting the course of communication to subjective goals of care, contributing to a subjective form of health. Whereas it is more common to determine a disease (risk) and treatment options first, aligning communication goals on an objectively desirable health outcome, a value-oriented communication determines personal health goals first and adjusts the SDM process to it in the following (Kaldjian, 2017). Looking at the model introduced in this thesis (Figure: "HL and SDM in Predictive Medicine"), communication can be understood as a medium to negotiate the subjective understanding of health and disease (risk) and a (medical-) objective understanding of these concepts. Communication should therefore be about respectfully explaining one's own perspective and interests to the other and negotiating a solution that does not necessarily – in this context – need to meet the HCPs' interests, but that grounds on a mutual understanding of the factors contributing to a respective outcome.

This individual negotiation of health-relevant parameters that determine decisions on disease risk centralizes communication in HL-research and -promotion; it also accentuates how health, risk, and disease are subjectively constructed on an individual level (Harzheim et al. 2023a). Following the belief that medical reality is being co-created by patients and HCPs (Cherry, 1996) is close to the theory of social-cultural constructivism, where reality is socially constructed within a pre-defined, historically evolved social-cultural context (Schmidt, 2000). Translating this thought into the setting of HL in predictive medicine, the communication and interpretation of disease risk information is happening on an individual, social-culturally framed level.

However, creating medical reality in a medical encounter alone does not cover the whole spectrum of contributing factors to this reality. What the above-mentioned example depicts on the micro level of two individuals (patients and HCPs), can nevertheless be projected onto a higher level: the creation of (medical) reality on a system-level. The normative character of predictive medicine has been addressed in the findings of this thesis (Harzheim et al. 2023a; Harzheim et al. 2023b). As shown above (Figure 4), complementing the individual-driven approach of interpreting health and disease information, a normative understanding of reality-creating dynamics emphasizes the deductive impact of exterior systems, disease images, and stigma on individuals' perceptions and interpretations of medical contexts (Silva et al., 2020; Harzheim et al. 2023a). A definition of health, risk, and illness may be attributed to the nature of healthcare services, the increase of predictive and preventive options, and reimbursement policies of health insurances, which all together shift the focus from an individual understanding of health and disease towards an externally imposed health status. Historically grown norms in healthcare define being healthy and being ill and thereby co-determine individuals' perceptions of their health status (Meier et al., 2017). The shift towards a preventive health system has been critically reflected by Daphne Hahn, who sheds light on the misleading potential of modern healthcare to impose the status of being at risk to everyone who is not undergoing preventive measures (Hahn, 2010). Following this idea, the status of being at risk is inevitable to all of us; if consecutively being at risk *feels* like being (almost) ill, the prediction of risk did make you feel (subjectively) ill in the first place.

Deficit-oriented health norms like these push towards a self-responsibility-centered agency of patients, whereas ‘self-responsibility’ is connotated with taking preventive actions and living a lifestyle that promotes an objective-normative imposed understanding of health (Hahn, 2010). This interesting debate on normativity and subjectivity in healthcare invites to reflect upon meanings of the self, roles, and responsibilities within the framework of disease risk prediction.

Self- and Role-Perceptions in the Negotiation of Risk and Prevention

– A Holistic View on Protagonists in Preventive Practice

The findings presented in this thesis as well as their discussion to this point have underlined the relevance of approaching HL and SDM on the individual and organizational level. Patients and HCPs interact as individuals within an organizational frame, holding different roles. When wanting to promote HL and SDM in this complex, it is important to reflect upon prevailing mechanisms and role understandings.

The already mentioned normativity of predictive medicine does not only refer to the dynamic in self-perception through the definition and disclosure of a risk status; but also to the power relations and role distributions in a medical encounter, where patients appear as advice seekers and HCPs as providers (Joseph-Williams et al., 2014). This seizes role-relevant aspects like the evolution of ideal SDM-scenarios from paternalistic to reciprocal approaches (Stiggelbout et al., 2015) and communicational processes in negotiating risk and health-realities. When speaking of role and power relations in a medical encounter, a common contrast depicted is the power difference between patients and HCPs with respect to knowledge and the perceived capacity to impact the decision-making process (Joseph-Williams et al., 2014). This captures this thesis' findings of patients finding themselves confused by the risk prognosis they were communicated, not feeling enabled to make an informed choice with respect to preventive measures (Harzheim et al. 2023a). Although the concept of SDM itself entails the homogenization of roles within the decision-making process, rescinding asymmetric communication between patients and physicians (Kasper et al., 2010), the phenomenon of epistemic injustice is being discussed as inherent to the role-structure of patient-HCP-relationships, awarding HCPs as 'epistemically privileged' (Kidd & Carel, 2017). Asymmetric power distributions with respect to knowledge and decision-making are central when looking at promoting HL and SDM because they indicate power-dynamics that were cultivated by the development of healthcare systems to be a starting point for interventions. A multi-dimensional approach, incorporating education and holistic care concepts therefore may be effective in sensitizing individual but also organizational mindsets with respect to epistemic asymmetries.

The predictive setting emphasizes the aspect of power-relationships, role-understandings, and responsibilities in medical encounters as crucial, because it entails the complexity of identity-shifts and changes in self-perceptions (Harzheim et al., 2020; Harzheim et al. 2023a), but also the potential of role-ambiguities (Harzheim et al. 2023b). With HCPs being the dominant part with respect to knowledge and information on the medical-factual aspects of predictive procedures, the phenomenon of epistemic confusion (Samerski, 2015) or injustice holds to a potential disadvantage of the patient (Kidd & Carel, 2017). However, there may also lie the possibility of a role-confusion on the HCPs' side, since they communicated being challenged to cover a broadening spectrum of responsibilities within the predictive encounter, needing to understand, incorporate, and negotiate emotional and informational needs of patients and their relatives (Harzheim et al. 2023b). Scientific elaborations indicated HCPs to hold conflicting roles (such as therapists, economic agents, members of social and occupational cultures) (Cherry, 1996) long before the healthcare system developed to its today's extent. The demand for teaching HCPs value-sensitive, ethically responsible risk communication- and SDM-skills (Harzheim et al. 2023b) also goes in hand with an expanded role-understanding of the medical profession. Requirements and expectations towards the role of an HCP thereby grow. This needs to be mediated carefully, respecting its psychological effect on medical professionals and students, minding an appropriateness and reasonableness with respect to work load and professional responsibility.

Respecting role perceptions of patients and HCPs alike may help to understand the dynamics of HL and SDM evolvements; both parties are situated in a socio-cultural and professional-cultural setting that defines their action spectrum but also pre-sets their capacities of taking time and empathy for understanding the person in front of them. Efforts to promote HL and SDM in predictive encounters therefore need to be reflected on the individual and organizational level.

A Three-Pillared Approach of HL- and SDM-Promotion in Predictive Practice

– Education and Training, Practical Instruments, Holistic Care Concepts

Having explored individual perceptions of disease risk and HCPs experiences with predictive procedures, the three-pillared approach to promote HL and SDM in predictive medicine is one key finding of this thesis (Figure: "Three-pillared Approach of Promoting HL and SDM in Predictive Medicine"). Before discussing its dimensions, it shall be prepended that one model alone will most likely not cover all challenges inherent to the field. HL-associated aspects and SDM-determining parameters were extracted by this thesis' results and discussion as diverse as individuals interacting in the predictive context themselves. As it was argued that there is no gold standard of evaluating HL and SDM sufficiently, there may not be one way of promoting the two concepts either. However, the model introduced offers guideposts to sensitize for the subjective, self-reported, and unquantifiable aspects of HL and SDM (value-sensitive alignment of (medical) education and design of healthcare services) and respects the literacy-related, rational, and objectifiable aspects (standardized practical guidance) of the two concepts alike.

Curricula and professional trainings should be an environment where values, ethics, and working morale that sensitize (future) professionals for challenges of their working domain are imparted. Taking the 2-Level-Approach (facts and feelings) suggested in the introduced model (Figure: “Three-pillared Approach of Promoting HL and SDM in Predictive Medicine”) as an example, the education on informational and emotional aspects in risk consultations may shift the (medical) education towards a more holistic approach of healthcare, nurturing a multidimensional perception of health in the mindset of practitioners and organizations. The model for integrating a binary concept of health (biostatistical- and well-being-oriented) into SDM (Kaldjian, 2017) could for instance serve as a basis for teaching concepts.

There is a demand for incorporating HL-relevant teaching into the initial education of HCPs but also into the continuous training accompanying their professional path (Nutbeam & Lloyd, 2021); and even though there are systematic evaluations of such trainings on HCPs, demonstrating a positive effect on their practice (Saunders et al., 2019), there are no standardized, comprehensive education and training concepts (Nutbeam & Lloyd, 2021).

Leaning towards the model of the conceptual expansion of HL and SDM and related literature, HL is a concept comprising patients and professionals alike. Professional HL can be understood as the competence of HCPs to listen to and communicate about patients’ health beliefs and wishes (Kickbusch et al., 2005), their ability to communicate in a personally effectual and socially appropriate manner, and their skill to recognize when patients have difficulties in dealing with health or disease risk-information and to meet these difficulties by negotiating diagnoses and treatment options in a patient-centered manner (Lippke et al., 2020). Professional HL is said to be especially important for HCPs who are in direct contact with patients (physicians, nurses, social workers, psychiatrist, psychotherapists and so forth) (Lippke et al., 2020); in a predictive consultation this contact entails the disclosure of a risk-diagnosis, the negotiation of preventive measures, and ideally the planning of (social, psychological, therapeutic) support after the predictive procedure. A health-literate communication on behalf of HCPs can have a positive impact on patients' HL (Lippke et al., 2020). Also, HCPs with a distinct HL should be better equipped to use and effectively form healthcare services. In this lies the responsibility of HCPs to actively promote individual HL in medical encounters (Rosenblatt & Myers, 2016). This interrelation of being educated and contributing to the 'education' of others in HL- and SDM-relevant concerns is an extended assignment to the profession of HCPs that needs to be mediated and accompanied continuously by education and training.

Lorke for instance suggests a culture-sensitive communication training within the field of predictive medicine, with an understanding of culture going beyond ethnicity and nationality, but covering also dimensions like medical, professional, and lifeworld-related culture (Lorke, 2021). By this she credits the cultural imprints of HCPs on a personal and professional level, just like cultural effects on patients are respected in literature. As patients, HCPs are affected by biographical, cultural, and social influences of their environment; they are also impacted by their professional environment and the culture of the institution they practice in (Lippke et al., 2020). How much capacity can be used for promoting HL and SDM in predictive procedures is also determined by the work-related infrastructure, the acceptance towards these matters, and the practicability in HCPs' everyday practice. Cultural diversity holds a wealth from which individuals and society can prosper. In a medical encounter cultural differences need to be mediated in order to identify mutual motivations, goals, and strategies with respect to the patients' health. HCPs need to be prepared and equipped for this challenge. Potential hindrances that may challenge the establishment of a good, health-literate communication between patients and professionals are introduced in a model by Kickbusch et al. (2005), modified by Lippke and colleagues (2020). It opposes scenarios with 'low' HL in patients and HCPs and its communication related impact, seizing aspects like cultural differences, financial worries, language barriers, lack of time, and the influence of relatives, all of which need to be covered in preparation for these challenges (Lippke et al., 2020).

While "Communication in medicine is considered as a fundamental clinical skill to establish a relationship with the patient, paving a way to successful diagnosis and treatment." (Ferreira-Padilla et al., 2015, p. 313), the failure to communicate in an demand-oriented manner was linked to insufficient training in medical school (Baessler et al., 2020).

Respecting the workload, the extending responsibilities, and role-perceptions of (future) HCPs, it is a responsibility on the system level to re-define values and foci within the conceptualization of medical curricula, grading systems, trainings, and working environments.

To support communication in a HL- and SDM-oriented manner during the course of a medical encounter, this research work recommends the incorporation of tools into predictive practice. In the context of a variety of aspects to consider in these consultations, tools and handouts may help to recall suggested communication strategies. There are communication concepts (assumptions on the reciprocity of impulses (communicated information) and reactions (perceived information)) that are considered to promote professional HL (Lippke et al., 2020). To name examples, the four pillared communication model (Schulz von Thun, 2022) reminds the user of considering content-, relationship-, self-disclosure-, and appeal-related aspects in the communication; interactive communication loops (“Close-the-Loop”) (Schillinger et al., 2003) are a strategy where the recipient of an information is encouraged to repeat the essence of this information. In comparison to this thesis’ suggestions, the first model respects the factual and emotional level of informational processes within a medical encounter; the second example is a tool that can be beneficial especially in the context of (continued) informed consent, where patients’ understanding of information shared is continuously reassured throughout the entire process of decision-making.

There are assumably countless handouts, brochures, and information material accompanying everyday practice. These materials are valuable to inform patients about standardizable information like facts on diseases, therapeutic options, or procedures of care (Harzheim et al. 2023b). They can serve patients as an orientation when the medical encounter is over and they wish to recall some information or want to share it with their relatives and friends. There are also information services that provide ‘subjective experiences’ complementing ‘factual knowledge’ on health issues, such as patient journeys or testimonials (gesundheitsinformation.de, 2023). How patients use information material and if it is of help to them is outside the reach of professionals (Harzheim et al. 2023b). Using tools like question checklists, protocols, or graphical explanation aids on the other hand is something HCPs can draw on during their interaction with patients (and their relatives). The effectiveness of practical aids like these on a positive outcome for patients and the SDM process has been shown (Boyd et al., 2017; Gluyas, 2015). In light of the benefits of participatory approaches (Harzheim et al., 2022) the development of prompt lists, checklists, and protocols would best be conceptualized in co-creation with patients and HCPs. The knowledge gained in this thesis concerning patients' and professionals' needs and wishes with respect to risk communication (Harzheim et al. 2023a; Harzheim et al. 2023b) could serve as an empirical base for the design of these tools.

The third pillar of the suggested model for HL and SDM promotion in predictive medicine implies a holistic care concept for exercising the responsibility of ensuring a patients' wellbeing. The concept of holistic healthcare originates in the ideal of holistically caring for a patient's "[…] physical, emotional, social, economic, and spiritual needs […]" (Ventegodt et al., 2016, p. 1935). Incorporating aspects like these, holistic care is designed for accompanying patients along a range of disciplines and (potentially) long time services (Ventegodt et al., 2016). The concept can be seen from the perspective of offering a comprehensive caring model or as an approach to improve patients' wellbeing (Jasemi et al., 2017). The idea of this thesis' model (Figure: "Three-pillared Approach of Promoting HL and SDM in Predictive Medicine") is to improve patients' wellbeing by offering comprehensive caring models. Since there are predictive procedures that are reduced to a momentary encounter by design (e.g., when they end with the disclosure of a (risk) diagnosis), others are meant for accompanying patients for a longer period (Harzheim et al. 2023b). The extent to which HCPs, medical institutions, or confined predictive procedures have the capacity to accompany patients holistically therefore varies. However, providing contact information or organizational support for an aftercare, encouraging patients to make use of psychological or social support and introducing them to contact points, can be incorporated low-threshold into the conception of predictive procedures. Especially when there are only little resources like time or personnel, standardized procedures like a defined (holistic) caring concept or efficient communication tools may be key to accompany patients appropriately. This again leads to the centrality of organizational HL in providing the frame for a health literate environment and decision space.

Research on holistic care revealed three main factors for an effective establishment of a respective system: education, professional environment, and personality characteristics (Zamanzadeh et al., 2015)

Strengths and Limitations

When methodologically and conceptually reflecting this dissertation, strengths and limitations arise. While strengths and limitations of the two empirical phases are discussed in the respective publications, there are remarks to make with respect to the overall research project, addressing (1) the sample character and data corpus included in this thesis, (2) the research setting this study is situated in, and (3) the role of the doctoral candidate during the data collection and analysis process of this research project.

Sample character and data corpus: The samples of the two empirical phases of this dissertation are reasoned by the research intent, the study design, the field access, and given research resources. This approach of purposive sampling (Corbin & Strauss, 1990) is common in qualitative research projects in social sciences. The predefinition of inclusion criteria and recruitment strategies, however, excludes potential participants this study may have benefited from. Patients who participated in this study had all undergone predictive procedures and therefore had already decided to consult objective measures to determine their disease risk; the dealing with disease risk of people who subjectively feel being at risk without having it medically investigated therefore fell under the radar or this study. A similar selection bias lies in the inclusion of HCPs who worked in practices or centers specialized for early disease risk prediction. To explore the negotiation of and the decision-making upon disease risk outside specialized institutions, further investigations would be needed.

The sampling also accounts for a heterogeneous data corpus. For instance, there are more qualitative interviews with patients than there are with HCP; on the other hand, there are more HCPs who completed the survey than there were patients participating in the study. This is due to the availability, the resources, and the willingness of contacted patients and professionals to participate in this study – a dynamic that cannot be foreseen or influenced by a researcher. Heterogeneous data corpuses are characteristic for multimethod research approaches. Mixed methods approaches bring the benefit of revealing different perspectives on a subject of interest, aligning a set of research methods to different aspects of a research question (Burzan, 2016; Harzheim et al., 2022). Central to this study is its interest in the subjective lifeworlds of the participants. It thereby offers *one* way of interpreting the phenomenon of interest, without intending to find a ‘truth’ representative for all individuals in this setting (Mey & Mruck, 2010).

Research setting: Reflecting upon the sampling entails the critical discussion of the research setting. The field access happened in cooperation with the centers and medical practices associated with the research institution. Through their affiliation to a university and their specialization in predictive procedures, these centers and medical practices were sensitized for the participation in research projects and for the subjects addressed in this particular research project (such as HL, SDM, patient information, risk communication, and so forth). Aspects like the given examples thereby could not be examined in the context of non-specialized institutions. To define a setting for which the study results could be operationalized for, this ‘narrowing’ of the setting allowed a derivation of implications tailored to the (medical) education and training as well as for the predictive practice. The results may serve as a ground for the conceptualization of following research on the dealing with disease risk outside the predictive setting.

The researcher's role: Another aspect worth discussing is the subjectivity of the doctoral candidate as a participant of the research work (data collection and analysis) (Bergold & Flick, 1990; Strübing et al., 2018). Subjectivity is a manifold discussed issue in qualitative research and is being addressed by the use of scientific quality criteria (Strübing et al., 2018). Amon others, reflexivity and triangulation were quality criteria considered particularly in this thesis. The researcher's role was for instance reflected by using systematic reflection tools that documented personal perceptions, experiences, and interpretation schemes of the researcher throughout the research process (Breuer et al., 2010; Stamer et al., 2015). By disclosing these reflexive records during the data analysis with fellow researchers, principles of transparency, comprehensibility, and triangulation were being met (Denzin, 2012; Stamer et al., 2015). Triangulation (Denzin, 2012) of the data material between the involved scientists ensured an independent, consolidated interpretation of the data material.[11] Continuous reflexivity and peer review ensured the quality and relevance of this thesis' findings throughout all phases of the research process.

However, the limitations addressed may also be interpreted as strengths, considering the scope and context of the research project. The results of the thesis provide useful implications for predictive practice and a fruitful ground for further research.

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[11] The respective contribution of the researchers involved in the data collection and analysis of this thesis' empirical phases is depicted in detail in the findings section (Table 4).

Conclusion

Predictive medicine entails a normative component with an effect on individuals' self-perceptions, the conception of healthcare services, and the organizational and ethical framing of health professions (Hahn, 2010).

To credit these dimensions, this dissertation addresses (1) the meaning of disease risk prediction for individuals, (2) the role of healthcare professionals in the context of predictive medicine, and (3) the responsibility of health organizations within that setting.

The value this thesis adds to the research field lies in its thematic foci, the research questions addressed, and the methodological approach of the study: the concepts of HL and SDM were investigated in the context of predictive medicine, qualitatively exploring the perceptions of people involved and affected; theoretical considerations and practical implications were derived in a step-wise approach, following a reflexive, dynamic study design (Corbin & Strauss, 1990) – the analysis of risk perceptions of patients who underwent predictive procedures emphasized communication and interaction to be central aspects in the negotiation of disease risk and health-relevant decision-making; as one relevant counterpart in this communicational setting, HCPs were asked about their experiences and concerns with respect to patient information, risk communication, and SDM in predictive consultations – combining a mixed-methods approach and participatory elements (Harzheim et al., 2022) in the study design is also new within the research field. It allowed for the different aspects of interest to be addressed with appropriate research methods (e.g., risk perceptions were explored with narrative interviews, profession-related experiences were examined with expert interviews, educational backgrounds were assessed with surveys). As a result, specific implications for how to promote HL and SDM in predictive procedures could be identified. These implications apprehend a holistic view on the setting, addressing the individual level of people facing disease risk, the professional and educational level of HCPs consulting these people, and the framing level of healthcare organizations that provide predictive procedures.

Future research could benefit from widening its focus on a broader spectrum of communicational and interactional determinants of the predictive setting, such as relatives and other social support systems of patients or the organizational structures HCPs are situated in. Building on the ”Three-pillared Approach of Promoting HL and SDM in Predictive Practice” (Table 5), the design of a future research project could combine the principles of implementation science with a participatory approach. Including patients, HCPs, relatives, and other relevant players would allow to translate the model into practice and develop, apply, and evaluate interventions that are tailored to specific predictive settings and sensitive for individual lifeworlds.

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