Quality criteria for patient information material and assistance in decision-making using the example of the interprofessional, cross-sectoral treatment pathway for colorectal cancer

Summary

Joint project of the Interdisciplinary Institute for Ethics in the Health Care System of the Foundation Dialogue Ethics and the Swiss Medical Association “FMH”

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Publisher information

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Acknowledgments

This study was made possible by the support of the Swiss Medical Association (FMH). Our thanks also go to all 10 medical and 10 non-medical organizations via which the evidence-based quality criteria developed over the course of the project – in the context of the implementation of the interprofessional and cross-sectoral treatment path for colorectal cancer – were established and adopted.
Summary of the project

1 Background

In a pilot project, the Swiss Medical Association (FMH) developed an interprofessional and cross-sectoral pathway with critical key interventions¹ for patients suffering from colorectal cancer. For each key intervention in the crucial disease-specific, diagnostic and therapeutic steps, the FMH has compiled tools and patient information materials (PIM), which are intended to support the dialogue between the physician and patient in the implementation of the treatment pathway. Before the tools and patient information materials can be integrated in the treatment pathway, overarching quality criteria must be defined that the tools and patient information materials must meet in order to be recommended as part of the treatment pathway.² The following sections provide a summary of the report on the study.

2 Requirements

The results of the study conducted on the quality criteria of a wide range of patient information materials as part of this project revealed that there is a need for objective informational materials that are based on current, evidence-based research and that can be easily understood by the patients. The diversity and the varying quality of the patient information materials in a complex, fragmented health care system pose a huge challenge in this regard. In terms of the entire system of care, these patient information materials contribute to closing the gaps in the communication process. The evidence-based quality and process criteria reveal what is relevant from the patient’s perspective and how the quality of care depends on functioning and transparent interprofessional collaboration.

3 Definition

Patient information materials (PIM) are information media with health and illness-related content addressed to patients and their family members.³ In easily understandable terms, they describe the possible course of a disease and options for treatment (screening, diagnostic procedures, treatment, prevention, support and follow-up care) in accordance with the state of the art of the respective field of medicine. They also include the information that patients can refuse medical interventions. The PIMs give patients and their family members access to expert knowledge relevant to their health and illnesses. The PIMs can be used regardless of the theoretical reference framework on which the care relationship is based. The reference framework can thereby range from sheer conveyance of information to shared decision-making.

4 Patient Expectations

Due to the patients’ right to self-determination, patients are entitled to understandable, adequate information corresponding to their requirements and their individual needs – which enables patients them to make informed decisions in the first place. This includes enabling the patients to include their own situation as well as their expectations, fears and hopes in the decision-making process, so that not only the disease, but also the experience of being ill with its impact on the lives of those concerned can be taken into consideration. Thus, the subjective experience of the patients is brought into the dialogue as cumulative experiential knowledge. As the basis for successful communication between the patient and the physician, pertinent information about the disease, the diagnostic tools, screening and treatment can have a decisive influence on the quality of the decision-making. The provision of valid, current and easily under-

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¹ Key intervention refers to the “necessary diagnostic or treatment steps to obtain a treatment of high quality, standardized and optimally coordinated, based on recognized (inter)national guidelines, independent of the place of residence”. Quoted from Kraft, E.; Nadig, J.; Pfisterer, J.; Project team (2018): Milestone reached in treatment pathway for colorectal carcinoma! Swiss Medical Journal, 99 (7), pp. 198–201 (here: p. 200).


³ Patient information materials (PIMs) are aimed not only at patients who are already undergoing a treatment process, but also – particularly in the case of information about screening – at healthy individuals or interested lay people who want to learn more about a procedure or treatment. These people are included in the references to patients in the following sections.
standable PIM along the entire treatment pathway helps patients to better understand their individual situations. Moreover, they make it easier to assess possible risks and benefits of a treatment and the available and planned options for treatment more accurately. The PIMs should support the patients in better adapting to their changed life situation which results from their illness. Figure 1 describes this adaptation process.

5 Quality criteria matrix

To ensure good, factual information – and to support the adaptation process of the patient – a quality criteria matrix was developed (see tables 1.1 and 1.2). The informational materials created in compliance with these criteria are intended to support patients in their own considerations and decision-making as well as in their preparation for consultations with relevant specialists. In turn, the quality criteria are supplemented with questions on orientation, design and decision-making and tips with regard to the individual stations along the treatment pathway, the individual subject areas of a disease, and the different medical specialties (nutrition, physiotherapy, nursing, etc.). This results in an extended PIM+, with varying sequences of events, depending on the initial situation: (a) questions for the specialists, (b) questions for the patients themselves to clarify, and (c) tips for ongoing consideration and decision-making. For example, prior to the screening of a patient who is asymptomatic, the first questions will not be directed to specialists, but (a) will be questions for the patients to clarify themselves, (b) tips for further consideration and decision-making and finally (c) questions for the specialists. The quality criteria in the matrix apply very generally to the development of PIM+ for all specialties, i.e. including the specialist PIM+, as shown in figure 2.
Quality criteria for the development of PIM+, additional questions for the preparation of the consultation, as well as for reflection and decision-making

Specific PIM+ e.g. for medical treatment
(a) for the respective stage on the treatment pathway, (b) for the individual aspects of a clinical picture and (c) for the specific medical field with suggestions and questions for the adaptation process to the changed daily life conditions.

Specific PIM+ e.g. for care
(a) for the respective stage on the treatment pathway, (b) for the individual aspects of a clinical picture and (c) for the specific medical field with suggestions and questions for the adaptation process to the changed daily life conditions.

Specific PIM+ e.g. for physiotherapy
(a) for the respective stage on the treatment pathway, (b) for the individual aspects of a clinical picture and (c) for the specific medical field with suggestions and questions for the adaptation process to the changed daily life conditions.

Figure 2: Quality criteria for the development of specific PIM+

Table 1.1: Superordinate general criteria for the evaluation of patient information material (PIM)

1 Procedural criteria

1.1 Preparation process
   1.1.1 Situational inclusion of the individual concerned in the preparation process
   1.1.2 Situational inclusion of relatives in the preparation process
   1.1.3 Participating organizations and expertise
   1.1.4 Quality assurance
      1.1.4.1 Compliance with internal quality criteria
      1.1.4.2 Review by external experts
      1.1.4.3 Information on the translation process (for multilingual PIM)

2 Ethical and legal criteria

2.1 Reference to patient rights

2.2 Neutrality of presentation
   2.2.1 Value neutrality of the language
   2.2.2 Objectivity and scientific/scholarly character
   2.2.3 Balanced presentation of facts
   2.2.4 Listing of several scientific sources

2.3 General accessibility
   2.3.1 Accessibility to information
   2.3.2 Accessibility to the medium

3 Formal criteria

3.1 Comprehensibility
   3.1.1 Goal orientation
   3.1.2 Target group orientation
   3.1.3 Active writing style
   3.1.4 Easily understandable language
   3.1.5 Conciseness and cogency
   3.1.6 Clear outline
   3.1.7 Font and layout
   3.1.8 Visual support
   3.1.9 Presentation of figures (absolute instead of relative numbers)

3.2 Formal/structural aspects
   3.2.1 Addressees
   3.2.2 Publication date
   3.2.3 Authors
   3.2.4 List of references
   3.2.5 Copyright
   3.2.6 Further information

4 Technical criteria for Internet information

4.1 User-friendliness of websites
   4.1.1 Navigation assistance
   4.1.2 Search function
   4.1.3 Print function
Table 1.2: Criteria concerning the content of patient information
(a) for the various stations on the treatment path
(b) for the various subject areas of a disease and
(c) for the various fields in PIM+

5 Content criteria

5.1 Information on disease and diagnosis

<table>
<thead>
<tr>
<th>Content criteria</th>
<th>Stage 1a: Screening</th>
<th>Stage 1b: Staging</th>
<th>Stage 2: disease probably curable</th>
<th>Stage 3: disease probably not curable</th>
<th>Stage 4: End of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.1 Etiology of the disease</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>5.1.2 Symptoms</td>
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<td>x</td>
<td>x</td>
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<td>x</td>
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<tr>
<td>5.1.3 Diagnostic procedures</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>(x)</td>
<td>x</td>
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<tr>
<td>5.1.4 Incidence</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>5.1.5 Prognosis and Diagnosis</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>5.1.5.1 Impact on individual life situation</td>
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<td>x</td>
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<td>5.1.5.2 Mortality</td>
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<td>x</td>
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<td>5.1.6 Prevention</td>
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<td>5.1.6.2 Secondary prevention</td>
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<td>5.1.6.3 Tertiary prevention</td>
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<tr>
<td>5.2 Introductory questions for orientation, design, decision-making</td>
<td>x</td>
<td>x</td>
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</tbody>
</table>

5.3 Information about screening

<table>
<thead>
<tr>
<th>Content criteria</th>
<th>Stage 1a: Screening</th>
<th>Stage 1b: Staging</th>
<th>Stage 2: disease probably curable</th>
<th>Stage 3: disease probably not curable</th>
<th>Stage 4: End of life</th>
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<tr>
<td>5.3.1 Epidemiology</td>
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<tr>
<td>5.3.2 Goal of the screening</td>
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<td>5.3.3 Method</td>
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<td>5.3.3.1 Procedures involved in the screening process</td>
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<tr>
<td>5.3.3.2 Outcome</td>
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<tr>
<td>5.3.3.3 Benefits of screening</td>
<td>x</td>
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<tr>
<td>5.3.3.3.1 Prognosis and course of the disease with/without screening</td>
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<td>5.3.3.3.2 Numbers needed to screen/treat/harm</td>
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<td>5.3.3.3.3 Absolute risk reduction</td>
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<td>5.3.3.3.4 Personal risk profile</td>
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<td>5.3.3.4 Risks of screening</td>
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<td>5.3.3.4.1 False negative/false positive results</td>
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<td>5.3.3.4.2 Overdiagnosis</td>
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<td>5.3.3.4.3 Complications and side effects</td>
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<td>5.3.3.4.4 Impact on individual life situation</td>
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<tr>
<td>5.3.4 Orientation, design and decision-making issues/questions</td>
<td>x</td>
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<tr>
<td>5.3.4.1 Questions to be clarified/reflected upon by the patient</td>
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<tr>
<td>5.3.4.2 Tips for further considerations and decisions</td>
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<td>5.3.4.3 Questions for the specialist</td>
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</tbody>
</table>

5.4 Information on treatment

<table>
<thead>
<tr>
<th>Content criteria</th>
<th>Stage 1a: Screening</th>
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</thead>
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<tr>
<td>5.4.1 Goals</td>
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<td>5.4.2 Treatment options</td>
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<td>5.4.2.2 Evidence and efficacy</td>
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<td>5.4.2.3 Risks and damage/side effects</td>
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<td>x</td>
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<tr>
<td>5.4.2.4 Impact on individual life situation</td>
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<td>x</td>
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<td>5.4.2.5 Compulsory health insurance coverage</td>
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<td>5.4.3 Orientation, design and decision-making issues/questions</td>
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<tr>
<td>5.4.3.1 Questions for the specialist</td>
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<td>x</td>
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<td>5.4.3.2 Questions to be clarified/reflected upon by the patient</td>
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<td>x</td>
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<td>x</td>
</tr>
<tr>
<td>5.4.3.3 Tips for further considerations and decisions</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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</tr>
</tbody>
</table>
6 Uniform structure for the PIM+

The PIM+ are designed with identical content structures for all medical, nursing and therapeutic subject areas, and differ only in the respective information provided and the format. The following structure is used for PIM+:

- Introduction
- Factual information presented appropriately for the target group
- Supplementary questions and tips for self-clarification for patients and for preparing for discussions with the relevant specialists.

7 Patient support

The study showed that patients want to and should be actively involved in medical and therapeutic decision-making processes. The right to complete and balanced information on the basis of the best scientific evidence is anchored as an ethical standard in the European Union regulations governing patients' rights. Good factual information is necessary but not sufficient for good analyses. Patients must be able to collate the information regarding their health status in a deliberative process in accordance with their wishes and needs with or without the relevant specialist to arrive at a coherent and inherently consistent decision in line with their plans for their own lives. Based on this requirement, the evidence-based PIM were supplemented with tools for reflection and decision-making to create PIM+. On the basis of the literature review carried out, evidence-based and additional ethical elements – analogous to the decision-making process of the “7-step dialogue model” \(^4\) – were developed for deliberative reflection and decision-making to create a cross-sectoral, interprofessional 7-step guide. In turn, this interprofessional guide is intended to promote and support the development of high-quality, subject-specific counseling tools by providing a common structure and foundation for decision-making. Both the medical evidence (facts) and the personal values of the patients as well as the professional tenability should all be included in a balanced manner in the design and decision-making process, which the patients complete together with the relevant specialist. The cross-sectoral, interprofessional guide is theoretically justified with the reference model of the “patient coach as a supportive partner” (see section 8) developed in the course of this project, which respects and incorporates the life situation, the life plan and the living environment of the patients as well as the health care specialist’s duty of care.

The guide assumes a respectful, trustful and caring relationship between the specialist and the patient, which also includes a relationship to the patient’s family members. Most of the design and decision-making processes are completed within the framework of the relationships of the health care specialists and the patients naturally, plausibly and without explicit reflection on values. In complex, profound and diverging processes, on the other hand, explicit reflection on the adaptation process and the decision-making is required for every specialty. Figure 3 shows the process steps in three possible decision-making situations for reaching a decision on treatment in seven steps (see also step 3 in figure 3). To match the
PIM+, specific patient counseling tools for health care specialists are to be developed with this common structure using this cross-sectoral, interprofessional seven-step guide (see figure 4). These subject-specific patient counseling tools are intended to support the dialogue with the patient (or with a patient representative in the event of the patient’s incapacity).

8 The patient coach as a supportive partner

In view of the fragmented treatment, nursing care and support, when it comes to the clarification of overarching therapeutic goals, patients require a specialist that must be defined in more detail who will take on the role of “patient coach as a supportive partner”. The specialist who assumes this role will have access to all relevant information about the patient’s health status as well as his or her treatment, nursing care and support situation, which the specialist will analyze and discuss with the patient. The specialist assumes full responsibility for the management of the treatment, nursing care and support processes of the patient. The specialist to be appointed in this capacity – regardless of whether this person may change situationally – is thus responsible for all case management and the clarification of the superordinate therapeutic goals. The model of the patient coach as a supportive partner places tough psychological, communicative, ethical and interprofessional demands on the health care specialists who accompany and support the patients during their process of adaptation. The model of the “patient coach as a supportive partner” is a guide to shaping the relationship between patients and health professionals in treatment, nursing care and social care in the health care and social services systems that encompasses the individual as a whole as well as all participants, thus contributing to an integrated system of care.

Purchase of the full study

The full study in German, entitled “Qualitätskriterien für Patienteninformationsmaterialien und Entscheidungshilfe am Beispiel des interprofessionellen, sektorenübergreifenden Behandlungspfads Kolorektalkarzinom. Schlussbericht” can be purchased via www.dialog-ethik.ch/pim. Via this website you can also purchase Issue No. 138 (December 2018) of the journal “Thema im Fokus”, entitled “Qualitätskriterien für Patienteninformation und Beratung im Gesundheitswesen – gegenseitig informiert und orientiert entscheiden” with extensive background information and interviews about the project.
Participants from the Foundation Dialogue Ethics (authors)

Andrea Abraham, born 1978, completed her studies in social anthropology in Berne between 1999 and 2005, and received her doctorate in social anthropology in 2012 with her thesis entitled “Doing质量. Constructs of medical quality in Swiss family medicine.” From 2012 to 2017 she was a research associate at the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics. Since 2017 she has worked as a research associate at the University of Applied Sciences of Berne.

Ruth Baumann-Hölzle, born 1957, completed her studies in theology between 1977 and 1983 in Zurich and Geneva, following them up with research at Harvard Divinity School in Cambridge, Massachusetts and the Hastings Institute in New York from 1984 to 1986. In 1989 she received her doctorate in theology; the subject of her thesis was “Genetic engineering in humans and modern society”. In 1999 she became the head of the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics. From 2001 to 2013, Mrs. Baumann-Hölzle was a member of the “National Ethics Committee in the field of human medicine (NEK-CNE)”. 

Carmelo Di Stefano, born 1974, initially trained as a metallurgy laboratory technician and then completed the secondary school diploma and university entrance qualification for adults. In 2015 he completed his university studies with a major in philosophy and minors in Italian literature and sociology in Zurich. In his thesis he examined the influence of Orphism and the philosophy of Friedrich Nietzsche on the literary works of the poet Dino Campana using qualitative and quantitative methods. From 2016 to 2017 he worked as a research associate at the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics. Since 2017 he has been responsible for communications, marketing and IT at the institute.

Daniel Gregorowius, born 1979, completed his studies in geography and his teaching degree in biology and geography in Bochum and Zurich between 1999 and 2006. He received his doctorate in natural sciences from the University of Zürich with a thesis entitled “Genetically modified crops in Switzerland: ethical discourse and public perception.” In 2017 he joined the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics as a research associate and is responsible for the “Research Department” there.

Hildegard Huber, born 1956, received her degree in general nursing in 1977 from the Schwesternschule Theodosianum in Schlieren, and then completed her specialty in intensive care nursing and resuscitation. Between 2001 and 2005 she completed advanced training as a nursing expert and from 2007 to 2009 the MAS program in “Ethical Decision-making in Organizations and Society” at the School of Social Work of the University of Applied Sciences of Northwest Switzerland. In 2008 she joined the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics, and since 2014 she has been a research associate in the “Research Department” of the Foundation Dialogue Ethics and an instructor for ethics in nursing.

Patrizia Kalbermatten-Casarotti, born 1963, completed her studies in the educational sciences at the University of Geneva between 1986 and 1991. In 2006 and 2007 she completed a correspondence course as a “Consultant for Ethics in the Health Care System” in Nuremberg and a MAS in “Ethical Decision-making in Organizations and Society”. In 2008 she joined the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics and is the head of the “Patient Directives and Physician-Patient Dialogue” unit there. In 2013 she became a branch manager at Palliativ Luzern, a palliative care services network in the canton of Lucerne.

Mirjam Mezger, born 1984, completed her studies in religious studies with a minor in sociology between 2004 and 2011 at the University of Zurich. She received her doctorate in religious studies from the University of Zurich in 2017, and wrote her thesis on the topic of “Alternative Spirituality in Palliative Care”. In 2016 and 2017 she worked as a research associate at the Interdisciplinary Institute for Ethics in the Health Care System at the Foundation Dialogue Ethics in the research
unit. Since 2018 she has worked as a research associate at the University of Applied Sciences of Zurich.

2 Participants from the Swiss Medical Association (FMH)

Esther Kraft, born 1981, completed her studies in economics at the University of Berne between 2001 and 2006. After a traineeship in federal administration (Swiss Federal Office of Statistics), Ms. Kraft joined the Swiss Medical Association as a research associate in autumn 2006. In 2011 she became the deputy head of the Department of “Data, Demographics and Quality (DDQ)”. In 2013 Ms. Kraft was appointed as the head of DDQ. Esther Kraft completed the course entitled “HTA as a Tool for Priority Setting” taught by Professor Finn Borlum Kristensen at the Lugano Summer School in Public Health Policy as well as the Certificate of Advanced Studies (CAS) in “Business Intelligence and Data Management”.

Jürg Nadig is a specialist in internal medicine and medical oncology, and holds a master’s degree in applied ethics. He has a medical practice in Bülach and was a consultant and hospital-affiliated physician until 2018. He was the president of the Swiss Society for Oncological Medicine from 2004 to 2016 and of the umbrella organization of non-invasive specialists (“Swiss Federation of Specialties in Medicine”) from 2009 to 2016. He was the initiator of the “Swiss Cancer Network”, and is a member of the steering committee of the “Swiss Academy for Quality in Medicine” (SAQM).

Jürg Pfisterer-Graber has had his own practice in internal medicine since 1982 in Affoltern am Albis and was a member of the management board of the “Swiss Society for Internal Medicine” (SGIM) for many years and a member of the executive board from 2008 to 2015. He is also a fellow of the American College of Physicians. As a member of the “Swiss Academy for Quality in Medicine” (SAQM), he was an initiator, together with Jürg Nadig, of the pilot project “Interprofessional, cross-sectoral treatment pathway for colorectal cancer.”

3 Publishing organizations

The Swiss Medical Association (FMH) is a professional association representing over 40,000 members. At the same time, the FMH is the umbrella organization for more than 70 physicians’ organizations; various bodies carry out the work required for successful association policies. The competences are regulated in the legal documents such as the statutes. The General Secretariat is responsible for the coordination between the operational and strategic-political levels; with more than 90 staff members, it functions as the liaison between the physicians and the public.

The Foundation Dialogue Ethics (Stiftung Dialog Ethik) is an independent and politically neutral organization in Switzerland that has been committed to the search for the best ways of working for the best interests of the patients and stakeholders in the health care and social services systems for nearly 20 years. Their focus is on ethical issues that are of interest to society in general. The Foundation Dialogue Ethics conducts its own research studies, supports and advises health care and social services professionals, patients, hospitals, retirement and nursing homes and various organizations in the health care and social services sectors. The work of the foundation is based on an integrative ethics of responsibility in accordance with the principles of autonomy, justice, human dignity, solidarity and respect.