

Assessing the personal perspective

Professor Silke Schicktanz and Sabine Wöhlke discuss their medical ethics research and the importance of a socioempirical and ethical analysis of patients' expectations and attitudes towards prognostic tests in cancer

PROFESSOR SILKE SCHICKTANZ & SABINE WÖHLKE



Could you explain why it is important to investigate the patient's perspective?

When it comes to therapy and decision making, the views of clinicians, psychologists and ethicists are not sufficient; experts claim to speak on behalf of their patients but this hides a risk of paternalism – the restriction of freedom and responsibilities by those in authority, in the supposed interest of those subordinate or otherwise dependent on them. While patients legally have the right to make an informed decision, sociological research has shown that



information, communication and decision making are often biased by the behaviour of professionals. From an ethical perspective this fundamentally undermines the liberal and democratic principle of self-determination.

We aim to explore what patients want to know, what their need for communication is and how we can improve their personal deliberation regarding important but sometimes conflicting values; weighing up the desire to prolong life against quality of life, or self-determination against blind trust

in doctors. We want to enable the exploration of self-esteem, agency and power relations to define the crucial conditions for a free and properly informed decision.

What questions does the new paradigm of individualised medicine raise for the physician-patient relationship?

There are three major questions. The first of these is: how can we make future medicine truly more individualised and avoid rhetoric framing of genetics as personal? The latter would be a radical misleading of patients and professionals.

Second, how can we bring together different kinds of expectation? For many professionals, individualised medicine is associated with increasing evidence-based treatment, while for patients it means that the person is treated as a whole. The concept of 'individualisation' needs broadening for medicine to integrate both of these views.

Third, how can we avoid the increasing complexity of medical and genetic information in individualised medicine hampering informed decisions? Our research shows that in the current situation, informed consent is rather a formalistic ritual. The increasing complexity is no justification for paternalism or for



juridification of informed consent procedures, so we need alternative communication strategies.

How does this project build on previous work?

This project is integrated in a broader clinical research network funded by the German Research Foundation (DFG). The first phase clarified the needs and scope of biomarker research, but during the second it became clear that, for more translational research, ethical reflection is vital.

We have longstanding expertise in methodologies to integrate empirical studies with patients or laypeople into medical-ethical considerations and have conducted several international projects where we systematically explored patient and layperson attitudes towards genetic testing or other current developments in biomedicine. These projects also explored how such lay moralities are embedded in cultural frameworks; therefore, we conducted comparative research, eg. between Germany and Israel, and between different European countries.

You aim to identify the roles of information, autonomy and trust in patient's experiences. Why are these factors central?

Information is essential for making an informed decision, while protecting the patient's autonomy is, according to ethicists and lawyers, an important condition in modern society to overcome paternalistic tendencies in clinical settings. Trust, on the other hand, is fundamental for enabling patients and doctors to establish relationships with good communication. Hence we analyse the values indirectly hidden in a patient's description of their agency, their factual understanding and their experience of the communicative ability of their doctor. We also juxtapose and compare how patients and doctors differently assess those interactions and identify situations of disinformation, mistrust and diminished self-determination.

Could you highlight some general findings of your preliminary results?

Several interviewed physicians and researchers mentioned various concerns about current and future forms of rectal cancer therapy. On the one hand, a fundamental dissatisfaction emerged on the part of the professionals; on the other, we found indications that the assumptions of physicians about the preferences of their patients are highly questionable.

Our qualitative data indicate age, class and gender differences in how patients deal with information, respond to various communication strategies and experience side-effects. In general, however, the expectations of patients about individualised medicine are different from those of doctors. Science and research are commonly associated with finding a more efficient and effective cure for cancer, not with stratifying patients as responders and non-responders, which is what experts are aiming to do.



Research from the **University Medical Center Göttingen**, Germany, is exploring the attitudes of patients and professionals towards biomarker tests for cancer therapy; an understanding of which is necessary for the ethically acceptable development of individualised medicine

'INDIVIDUALISED MEDICINE' has recently become the buzzword of 21st Century biomedicine. Thanks to the advancements in human genome research, it is increasingly possible to precisely classify diseases and patients into more defined subgroups, thus improving the chances of more targeted therapeutic success.

Oncological research is leading the way in this field, as the need for patient-tailored cancer therapy has become increasingly compelling. While treatment regimens such as chemotherapy and radiotherapy have improved the prognosis of many cancer patients, responses to treatment are very heterogeneous. Not only are some patients unresponsive, others can experience violent side-effects that fundamentally impair their quality of life. A moral dilemma ensues for professionals, uncertain as to whether they should intensify the treatment in the hope of increasing survival time, or suspend it in order to avoid side-effects and improve patient wellbeing.

Individualised medicine aims at addressing this dilemma. Prognostics, diagnostics and therapy will be adapted to specific genetic and physiological characteristics of the patient and the cancer in the hope of avoiding the administration of severe treatment to those who are unlikely to respond effectively. However, what may seem an unquestionably promising strategy raises a number of practical, ethical and social issues that complicate the clinical practice as well as the ethical framework and physician-patient relationship. These new social and ethical discernments need to be explored from the perspective of both patients and researchers so as to be integrated into the complex context of cancer care and treatment.

THE RESEARCH CONTEXT

A German clinical research group at the University Medical Center Göttingen is working to develop novel biomarker tests to assess the probability of patients responding or not responding to therapy for locally progressed colorectal cancer (www.kfo179.de). While it is hoped that they will facilitate a more individualised approach to treatment and improve patient outcomes, the complexity of assessing, integrating and communicating a new level of prognostic information to patients, in a way that they will understand and be comfortable with, needs to be explored before these tests can be integrated into clinical use. There is a danger that their use could impinge on the validity of existing frameworks such as informed consent and shared decision making.

To investigate these issues, a three year sub-project within the wider biomarker test development study is investigating the ethical and social issues related to physician-patient interaction and considering patients' expectations and attitudes towards biomarker tests in the context of individualised oncologic research and therapy. The project is being led by Professor Silke Schicktanz from the Department of Medical Ethics and History of Medicine at the University of Göttingen, and involves her PhD students Sabine Wöhlke and Arndt Heßling as well as Master's student Julia Perry.

A SOCIOEMPIRICAL AND ETHICAL ANALYSIS

The study conducted by Schicktanz and her team was developed over two phases. In the first phase (between 2010-2011), 19 semi-structured interviews were conducted with physicians and researchers of the biomarker test research

INTELLIGENCE

SOCIOEMPIRICAL AND ETHICAL ANALYSIS OF PATIENTS' EXPECTATIONS AND ATTITUDES TOWARDS PROGNOSTIC TESTS BASED ON BIOMARKERS IN RECTAL CANCER THERAPY

OBJECTIVES

To identify and analyse the role of information, values and trust in the decision making processes of patients undergoing individualised rectal cancer treatment. This will be achieved by investigating sociocultural and gender-related factors, and identifying existing uncertainties, conflicts and problems faced by patients, in order to develop an approach that allows shared decision making between doctors and patients

KEY COLLABORATORS

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SILKE SCHICKTANZ has been Full Professor at the Department of Medical Ethics and History of Medicine at the University Medical Center Göttingen since 2010. She studied biology and philosophy at the University of Tübingen and finalised her bioethical PhD on the ethics of xenotransplantation in 2002. Her current research interests include cultural differences in bioethics (particularly individualised medicine, genetic testing, organ donation, ageing and dying) and the normative structure of autonomy, trust, and responsibility. Together with her team, she has published her work in international journals such as *Social Sciences and Medicine*, *Health Care Analysis*, *Medicine and Health Care Philosophy*, and *Journal of Medical Ethics*.



Schicktanz's research group, from left to right: Sabine Wöhlke, Arndt Heßling, Silke Schicktanz and Julia Perry

group. The interviews covered three main topics: attitudes towards individualised medicine by genetic tests; evaluation of the current clinical situation and assessment of implications of a future biomarker for clinical practice; and the significance of a future biomarker test on the physician-patient relationship.

The second phase, currently ongoing, consists of 56 non-participatory direct observations of informed consent procedures between patients and physicians, and 93 interviews with rectal carcinoma patients within the standardised six month cycle of therapy. Questions aim to probe: attitudes and assessment of physician-patient communication; understanding of disease, treatment and side-effects; motivation to take part in biomarker research; attitudes and evaluation towards future biomarkers; experiences of the physician-patient relationship; and assessment of life quality.

Sociocultural factors such as gender, age and educational background were also taken into account. "All interviews were recorded, pseudonymised, transcribed and analysed according to a common sociological methodology," Schicktanz explains.

DIVERGING EXPECTATIONS, CONFLICTING PERSPECTIVES

The study highlighted a number of complex issues but two main areas of conflict were identified. First, the results showed that an increase of available data is not necessarily a positive factor for patients, who sometimes become overwhelmed by the complexity and volume of information. This gives rise to an impression of not being fully involved in a clear decision-making process, resulting in feelings of expectation to agree to the therapy proposed by the doctor who, as an 'expert', is assumed to have a more complete understanding of the facts. Conversely, doctors presume that most patients are happy just to delegate the power to decide and so tend to simplify the information provided because a complete understanding is not necessary. Informed consent becomes a ritualistic procedure and the majority of patients sign the form without reading or understanding it.

The second area of conflict involves the complexity and uncertainty of gene expression analysis. Patients struggle to differentiate between treatment and research and fail to grasp that therapy may be administered to non-responders since, in cases of uncertainty, most physicians prefer overtreatment to be better safe than sorry. It is true, however,

that the introduction of biomarkers may enable patients to understand that decisions are based on scientific evidence instead of a doctor's gut feeling.

Importantly, when a patient learns that their therapy is individualised, their expectations differ. "Patients hope to be treated as an individual. Individualised medicine for them is often associated with being treated as a 'whole' person," Schicktanz points out. Unfortunately, this expectation does not match the perspective of experts, for whom 'individualised' rather means 'stratified'.

Overall, this dynamic leads physicians to experience patients as even more passive and dependent, so that the tendency towards paternalism, already well-established in current physician-patient relationships, remains in place. In fact, asymmetry is increased. Concurrently, patients struggle between a desire for control and self-determination, and a wish to relinquish responsibility and simply be cured by an expert who knows what is best for them.

FUTURE DIRECTIONS

Whether individualised medicine will improve the physician-patient relationship is far from clear. "The implication of our research is that improving patient-doctor communication is an important but insufficient solution to providing patients with the information they want. There is also a need to increase awareness of the underlying ethical and social premises of sharing information," elaborates Schicktanz.

Although the results of this project have provided a valuable insight into patients' attitudes, more research is needed to extend and intensify socioempirical observations of physician-patient communication and carry out further qualitative interviews with patients in later phases of treatment. This increased breadth would allow a more complete understanding of patients with unsuccessful treatment or serious side-effects, as the ethical problem posed by non-responders is particularly challenging.

Despite the difficulties, Schicktanz and her team nurture some cautious hope: "The current situation of decision making can be characterised by a pragmatic trust in doctors and as defensive compliance with paternalistic practice, not as informed and self-determined decision making. We assume that honesty and empathy concerning the outcome and the diagnosis, as opposed to the increase of complex information, will turn this pragmatic trust into real trust," she concludes.

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