European Association of Centres of Medical Ethics (EACME)

ANNUAL CONFERENCE

BOOK OF ABSTRACTS

“PERSONALISED MEDICINE” – MEDICINE FOR THE PERSON? ETHICAL CHALLENGES FOR MEDICAL RESEARCH AND PRACTICE

19 - 21 September 2013, Bochum, Germany

Organised by
Institute for Medical Ethics and History of Medicine, Ruhr University Bochum
Centre for Medical Ethics Bochum

Supported by
Research Ethics Committee of the Medical Faculty, Ruhr University Bochum
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Dear EACME Members,

Dear all Participants,

It is a pleasure and an honor for me to express my warmest greetings to all of you, on the occasion of the annual EACME Conference, which is taking place in Bochum, Germany this year.

First of all, I wish to express my personal heartfelt thanks and in the name of the whole EACME, to the organizers of the event and our hosts, namely the Institute for Medical Ethics and History of Medicine of the Ruhr University Bochum, in cooperation with the interdisciplinary Centre for Medical Ethics Bochum and supported by the Research Ethics Committee of the Medical Faculty of the same University.

Adding a personal word of gratitude to Prof. Dr. Dr. Jochen Vollmann, President of the Conference and PD Dr. Jan Schildmann, Scientific Secretary.

I also would like to express my deep thankfulness to Dr. R. Porz and Prof. C. Gastmans of the EACME Bureau and Mrs. A. Heijnen, executive officier, for all their important work in support of the EACME and collaboration in preparing this event.

The topic of the Conference is interesting and stimulating, and I think it recalls the basic and crucial aims and conceptions, for medical ethics and bioethics.

The expression “personalised medicine” is often meant only as the application of genomic and molecular data towards a specific “personal” diagnosis, therapy and prevention for a single person.

But, it is outstanding, and perhaps provocative to speak of the “Person”, in the sense of a focus on the human being, the person, and not on the disease, and we can understand the dialectic mentioned by the organizers of the Conference between “personalised medicine” and “patient-centred medicine”. We can see the relationship between universal/objective and particular/subjective where in Medicine, the debate on the relationship between Science and Art, between “neutral/standard” elements and “personal/adjusted” elements for the individual, is involved. Important anthropological, philosophical, theological and social topics are present in this debate. The perspective of the Conference of a critical and interdisciplinary approach which includes ethical, medical, socio-cultural, legal and economic aspects is essential to appreciate the challenges of the “personalised medicine”.

In Bochum and in its surrounding area we can see the transformation of mining and a heavy industry in a city and in a cultural, education and services area. And precisely here was born the first interdisciplinary academic institution of medical ethics in Germany. The hope is that Medicine can also find the broadest sense of its being and its acting, through a fruitful dialogue between Science and the Humanistic world, less “heavy technology” for a servicing and care culture, for a “personalised medicine” composed of people/health-care professionals for people/patients.

With this spirit and these aims in mind, I wish to each of you an enjoyable EACME Conference 2013 beginning today, driven by intellectual depth, positive feelings, a constructive dialogue, and appreciation of the city of Bochum.

Prof. Renzo Pegoraro

President of the EACME
Welcome from the President of the Conference

“Personalised medicine” is often understood as the application of genomic and molecular data to improve the diagnosis, therapy and prevention of diseases. Over the last few years, this phrase has become the symbol of medical progress and a label for better healthcare in the future. However, a controversial debate has newly developed whether these promises of better, more personal and more cost-efficient medicine are realistic: “Personalised medicine” – hype or hope?

The EACME Conference 2013 is offering a broad, critical and interdisciplinary approach to so-called “personalised medicine” from an ethical, medical, socio-cultural, legal, and economic perspective. Our scientific programme covers a broad spectrum of topics. We welcome you to this interdisciplinary and international debate! The conference will be organised in cooperation with the interdisciplinary Centre for Medical Ethics Bochum (Zentrum für Medizinische Ethik Bochum), founded in 1986 as the first interdisciplinary academic institution of medical ethics in Germany, and will be supported by the Research Ethics Committee of the Medical Faculty, Ruhr University Bochum.

Our Institute has a strong reputation in national and international research. We coordinate the BMBF Collaborative Research Project “Personalised medicine in oncology: an interdisciplinary study on ethical, medical, economical and legal aspects”. The Institute engages in special programmes for junior researchers and invites international scholars financed by our Visiting Fellowship Programme. Our junior researchers are organising a special network meeting for PhD students and junior scholars as part of the EACME conference.

Bochum, a city formerly determined by coal mining and steel industry, is today an urban centre for education and services. As the centre of the Ruhr Metropolitan Area, Bochum is well-known for its modern culture and industrial heritage and was part of the European Capital of Culture in 2010.

We are doing our best to host an environmentally acceptable conference. Therefore we have encouraged you to eco-friendly travelling by train and ask you to use the public transport within Bochum. Our conference meets ecological standards, so that we offer vegetarian food at the conference primarily. Further we avoid packing, paper and advertisements. Therefore we have asked you in our Email of invitation to this conference to print out from the conference’s homepage the parts of our Book of Abstracts relevant to you. We do not provide hard copies.

On behalf of the organising committee, I welcome you to Ruhr University Bochum and wish all of you an interesting conference with fruitful interdisciplinary discussions, enjoyable encounters and a pleasant stay.

Prof. Dr. Dr. Jochen Vollmann
President of the Conference
# EACME 2013 Committees

**President of the Conference**  
Prof. Dr. Dr. Jochen Vollmann  

**Scientific Secretary**  
Dr. Jan Schildmann, M.A.  

## Organising Committee

Verena Sandow, M.A.  

Caroline Brall, MSc (PhD Programme)  
Dr. Flavio D’Abramo (PhD Programme)  
Britta Menze  
Michaela Prskawetz  
Anne de Vries, B.A.  
Sebastian Wäscher, M.A.  

## Scientific Committee

Prof. Dr. Chris Gastmans  
Prof. Dr. Stefan Huster  
Prof. Dr. Georg Marckmann, MPH  
Prof. Dr. Renzo Pegoraro  
Dr. Rouven Porz, Dipl.-Biol.  
Verena Sandow, M.A.  
Dr. Jan Schildmann, M.A.  
Prof. Dr. Dr. Jochen Vollmann  
Sebastian Wäscher, M.A.  
Prof. Dr. Michael Zenz
Conference theme and sub-themes

“Personalised medicine” – medicine for the person? Ethical challenges for medical research and practice

Theme

The topic of the EACME Conference 2013, “Personalised medicine” – medicine for the person? Ethical challenges for medical research and practice, is offering a critical and interdisciplinary approach to so-called “personalised medicine” from an ethical, medical, socio-cultural, legal, and economic perspective. The scientific programme covers a broad spectrum of topics. We invite you to participate in this interdisciplinary and international debate and to submit contributions on the following conference topics:

Sub-themes

Patient as person in medicine:
- Philosophical and anthropological foundations
- Psychosocial aspects
- “Personalised medicine” versus patient-centred medicine?
- Genetic determinism
- Direct-to-consumer testing

Research in “personalised medicine”:
- Ethical issues of genetic biomarkers and biobanking
- Informed choice and genetic research
- Conflicts of interest in public and private funding

Health-care systems:
- Priority setting, resource allocation and opportunity costs
- Public health genomics
- Policy and regulation of “personalised medicine”
- Global and demographic challenges

Clinical practice:
- Patient-doctor relationship
- Respect for the person and decision-making
- Personalised medicine” in clinical specialities (e.g. oncology, psychiatry, cardiology)
- Concepts of care and “personalised medicine”

The programme of the conference includes plenary sessions as well as parallel sessions.
Information about the Conference & Venue

The Institute for Medical Ethics and History of Medicine, Ruhr University Bochum, Germany, and the European Association of Centres of Medical Ethics (EACME) organises the EACME annual conference in 2013. The conference is organised in cooperation with the Centre for Medical Ethics Bochum (ZME e.V.) and supported by the Research Ethics Committee of the Medical Faculty, Ruhr University Bochum.

The conference will take place at the Conference Centre “Veranstaltungszentrum”. The modern well-equipped conference rooms have a hospitable atmosphere to work with a beautiful view of the Ruhr valley. It is located in the south of the campus, behind the main auditorium and underneath the canteen. Your access to cost-free Wi-Fi will be available at the registration desk. Further information regarding your venue can be found on the conferences’ website: http://www.eacme2013.org/venue/

Social Events

Please see the Conference Programme and, in particular, note:

**Thursday Evening**
18:30 Reception at Conference Centre “Veranstaltungszentrum“

**Friday Evening**
19:00 Conference Dinner at restaurant “Gastronomie im Stadtpark Bochum”, Klinikstraße 41-43, 44791 Bochum, Phone: +49 (0) 234 50709 0

**EACME Prize 2013**

The European Association of Centres of Medical Ethics (EACME) awarded two EACME-prizes (500 Euro each) to

*Ms Caroline Brall* (Bochum) and

*Mr Marco Annoni* (Milano)

for their scientific contribution. There will be a ceremony to award both researchers during the EACME conference by the EACME General Secretary.

**EACME 2013 Poster Prize**

The Institute for Medical Ethics and History of Medicine awards a prize for the best poster presented at the annual conference of the European Association of Centres of Medical Ethics (EACME) 2013. The winner will be selected by the award committee following the poster presentation, which will take place Friday 20 September 12:45h to 13:15h.

The Award Ceremony will take place on Saturday 21 September 9:00h to 9:05h.
PhD Student Meeting

All PhD students are invited to the PhD student meeting as part of the EACME Conference 2013 in Bochum. The event will take place

Thursday 19 September from 17.30-18.30 (Mensa Level 01, “Tagungsraum” 1).

Next to the possibility to get to know PhD students in the field of biomedical ethics and related fields, the meeting will provide a platform to discuss issues relevant to the (post-) doctoral stage.

Two experienced researchers, Prof. Dr. Silke Schicktanz, Department of Medical Ethics and History of Medicine, University Medical Center Goettingen (Germany, Biology/Philosophy) and Dr. Mark Sheehan, The Ethox Centre, Department of Public Health, University of Oxford (UK, Philosophy) have agreed to provide a brief statement on the experiences and perspectives regarding a professional career in biomedical ethics which will be followed by an open discussion involving all participants.
Plenary Speaker Biographies

Plenary 1: Patient as person in medicine

George Browman

Professor George Browman is a medical oncologist and health services researcher. He is Clinical Professor at the School of Population and Public Health at University of British Columbia, and practices oncology at the BC Cancer Agency specializing in head and neck cancer treatment. In the past he has held academic leadership positions as Chair, Department of Clinical Epidemiology & Biostatistics at McMaster University in Hamilton Ontario; and Head of the Department of Oncology at the University of Calgary. He has served as President of the Juravinski Cancer Centre in Hamilton, Ontario and as Director, Tom Baker Cancer Centre in Calgary, Alberta. Since 2007 he has served as Chair of the BC Cancer Agency Research Ethics Board affiliated with the University of British Columbia. His main academic interests are in clinical trials, practice guidelines development methods, and evidence based clinical and policy decision making with recent emphasis on public engagement in policy decisions about public funding of new cancer drugs and other healthcare technologies. He currently serves on the Methods Subcommittee of the Practice Guidelines Committee of the American Society of Clinical Oncology. In 2000 he was awarded the O. Harold Warwick Prize by the National Cancer Institute of Canada for career contributions to cancer control in Canada. His presentation will focus on ethical issues in personalized medicine, for the person with emphasis on the ‘marketing’ of personalized medicine to the public and implications for the patient.

Thomas Wabel

Thomas Wabel is Professor of Protestant Theology (with a focus on Systematic Theology) at the University of Education in Weingarten. Following his studies in Heidelberg, Bonn, and Oxford, and after a research year at Harvard University in 1994, Wabel received his Ph.D. in Systematic Theology from Heidelberg University in 1996. He has taught Systematic Theology at Frankfurt University, Humboldt University of Berlin, Justus-Liebig-University, Gießen, and Hamburg University, and he is a pastor in the Protestant Church of Hessen and Nassau (Germany). In 2008, Wabel held the Ernst Cassirer Fellowship at the Swedish Collegium for Advanced Study (SCAS) in Uppsala (Sweden).

Wabel is author of Sprache als Grenze in Luthers theologischer Hermeneutik und Wittgensteins Sprachphilosophie (Berlin/New York: de Gruyter, 1998) and of Die nahe ferne Kirche. Studien zu einer protestantischen Ekklesiologie in kulturermeneutischer Perspektive, Tübingen: Mohr Siebeck, 2010). Furthermore, his publications include books (both as editor and co-editor) on bioethics and medical ethics (2004; 2007), on neurophysiology, legal responsibility, and the free will (2005), and on commentary as a practice of liberal arts (2011). His articles in journals and books cover such topics as the role of intuition in moral reasoning (2005), religion and aesthetics (2006; 2007), bioethics and medical ethics (2003; 2004; 2012; 2013).
Plenary 2: Research in “personalised medicine”

Barbara Prainsack

Barbara Prainsack is Associate Professor at the Department of Social Science, Health and Medicine at King’s College London. A political scientist by background, she has published widely on the societal, ethical, and regulatory perspectives of DNA testing in medicine and forensics. Barbara chaired the recent Forward Look on ‘Personalised Medicine for the European Citizen’ of the European Science Foundation (ESF), and she is a member of the Austrian National Bioethics Commission advising the federal government in Vienna.

Mark Sheehan

Mark Sheehan is Oxford Biomedical Research Centre (BRC) Ethics Fellow at the Ethox Centre and a Research Fellow at the Uehiro Centre for Practical Ethics, University of Oxford. He received his PhD in Philosophy from The Graduate Center of the City University of New York, where his PhD thesis was on the nature of moral judgements. Prior to coming to Oxford he was a lecturer in the Centre for Professional Ethics at Keele University, Ethics Fellow at the Mt. Sinai Medical School, New York and Adjunct Lecturer in the Philosophy Department at The City College of New York.

He is a National Research Ethics Advisor for the National Research Ethics Service and a member of the Nuffield Council on Bioethics working group of research in children. He was a member of the NHS Advisory Group for National Specialised Services (AGNSS) and vice-chair of the Thames Valley Priorities Forum (MOBBB) for the South Central Strategic Health Authority. He also sits on the University’s Social Sciences and Humanities Inter-Divisional Research Ethics Committee. He Deputy Editor of the Journal of Medical Ethics and is a Senior Research Fellow in Philosophy at St. Benet’s Hall, University of Oxford.

He has more than 15 years’ experience of teaching and research in medical ethics with a special interest in research ethics and resource allocation. As BRC Ethics Fellow, he is involved in Research Ethics and Patient and Public Involvement (PPI) across the Oxford NIHR BRC themes. With colleagues from the Centre for Professional Ethics at Keele University, he has recently completed an EU-funded textbook on research ethics (which can be downloaded from http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1362).
Plenary 3: Health-care systems

Stefan Sauerland

Stefan Sauerland joined IQWiG (Institute for Quality and Efficiency in Healthcare) in January 2010. As Head of the Non-Drug Interventions Department, he is responsible for the scientific evaluation of non-drug therapies (including medical devices), diagnostic tests, and screening procedures. Within the German health care system, IQWiG is responsible for producing evidence-based reports, which inform reimbursement decisions on a national level.

Dr Sauerland has 12 years of experience in surgical research, first at University of Cologne, then at Witten/Herdecke University. His research focus was on clinical studies, clinical guidelines, and meta-analyses. He has published over 200 papers, of which more than 100 are indexed in Medline. In 2005, he was awarded the DKV Cochrane Prize for a Cochrane review on laparoscopic appendectomy. He holds an M.D. from University of Cologne and an M.P.H. from Düsseldorf University.

Jochen Vollmann

Professor Jochen Vollmann is a medical doctor and philosopher.

Since 2005 he is Director of the Institute for Medical Ethics and History of Medicine and President of the Centre for Medical Ethics, Ruhr-University Bochum, Germany.

Currently he coordinates the Collaborative Research Project “Personalized medicine in oncology: an interdisciplinary study on ethical, medical, economical and legal aspects” funded by the German Federal Ministry of Education and Research. This plenary session is part of the final symposium of this collaborative research.

His research interests include beside personalized medicine, informed consent and capacity assessment, ethics and psychiatry, end-of-life decision-making, empirical ethics, clinical ethics committees and clinical ethics consultation.
Plenary 4: Clinical practice

Wolfgang Lieb

Professor Wolfgang Lieb is Director of the Institute for Epidemiology at the Christian-Albrechts-University in Kiel. He received his MD from Rostock University and his MSc in Epidemiology from Boston University. He is a board certified geneticist and epidemiologist. Before joining Kiel University, he was appointed as Professor for Individualized Medicine at Ernst-Moritz-Arndt-University Greifswald. Wolfgang Lieb combines classic population-based epidemiological and genetic research in order to unravel the determinants of common disease conditions, including CVD and related disorders.

Silke Schicktanz

Professor Silke Schicktanz is since 2010 full-professor for Culture and Ethics of Biomedicine at the Department for Medical Ethics and History of Medicine at the University Medical Center Goettingen, Germany. She studied biology and philosophy at the University of Tuebingen and finalised her PhD in the field of ethics of Life Sciences in 2002. During her post-doc, she extended her methodological spectrum. Current research foci are the bioethics of genetics, organ transplantation and ageing medicine, cultural differences in bioethics and biopolitics, the intersection of professional views and patient's perspective and interrelations of ethics and empirical research.

She has established intensive international research collaborations with Ben-Gurion University (Israel), JNU Delhi (India), at CESAGEN Lancaster (UK), Uppsala University (Sweden), and Univ. of California, Berkeley & San Francisco State University (USA).

Most recently, she is leading a research project funded by the Deutsche Forschungsgemeinschaft to investigate patients' views on individualized medicine in rectum cancer treatment.
## Conference Programme Overview

### Thursday 19 September

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1230</td>
<td>Lunch</td>
<td>Conference Centre &quot;Veranstaltungszentrum&quot; (CC): Foyer</td>
</tr>
<tr>
<td>1330</td>
<td><strong>Opening Session</strong>&lt;br&gt;Renzo Pegoraro (President of EACME)&lt;br&gt;Elmar Weiler (Rector, Ruhr University Bochum)&lt;br&gt;Jochen Vollmann (President of the Conference)</td>
<td>CC: Room 2a</td>
</tr>
<tr>
<td>1400</td>
<td><strong>1 Plenary: Patient as person in medicine</strong>&lt;br&gt;George Browman (Vancouver)&lt;br&gt;Thomas Wabel (Weingarten)</td>
<td>CC: Room 2a</td>
</tr>
<tr>
<td>1530</td>
<td>Tea / Coffee Break</td>
<td>CC: Foyer</td>
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<tr>
<td>1600</td>
<td><strong>Parallel Sessions</strong></td>
<td>Please check room for each session</td>
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<tr>
<td>1730</td>
<td><strong>General Assembly</strong></td>
<td>CC: Room 2a</td>
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<tr>
<td>1730</td>
<td><strong>PhD Student Meeting</strong></td>
<td>Level 01, “Tagungsraum 1”</td>
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<tr>
<td>1830</td>
<td>Reception</td>
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### Friday 20 September

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>0900</td>
<td><strong>2 Plenary: Research in “personalised medicine”</strong>&lt;br&gt;Barbara Prainsack (London)&lt;br&gt;Mark Sheehan (Oxford)</td>
<td>CC: Room 2a</td>
</tr>
<tr>
<td>1030</td>
<td>Tea / Coffee Break</td>
<td>CC: Foyer</td>
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<tr>
<td>1100</td>
<td><strong>Parallel Sessions</strong></td>
<td>Please check room for each session</td>
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<tr>
<td>1230</td>
<td>Lunch</td>
<td>CC: Foyer</td>
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<tr>
<td>1245</td>
<td><strong>Poster Session</strong></td>
<td>CC: Foyer</td>
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<tr>
<td>1330</td>
<td><strong>3 Plenary: Health-care systems</strong>&lt;br&gt;Stefan Sauerland/ Jürgen Windeler (Cologne)&lt;br&gt;Jochen Vollmann (Bochum)</td>
<td>CC: Room 2a</td>
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<tr>
<td>1500</td>
<td>Tea / Coffee Break</td>
<td>CC: Foyer</td>
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<tr>
<td>1530</td>
<td><strong>Parallel Sessions</strong></td>
<td>Please check room for each session</td>
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<tr>
<td>1900</td>
<td>Conference Dinner</td>
<td>Restaurant “Gastronomie im Stadtpark”</td>
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### Saturday 21 September

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>0900</td>
<td><strong>Award Ceremony: EACME prizes/Poster prize</strong></td>
<td>CC: Room 2a</td>
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<tr>
<td>0905</td>
<td><strong>4 Plenary: Clinical practice</strong>&lt;br&gt;Wolfgang Lieb (Kiel)&lt;br&gt;Silke Schicketz (Göttingen)</td>
<td>CC: Room 2a</td>
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<tr>
<td>1035</td>
<td>Tea / Coffee Break</td>
<td>CC: Foyer</td>
</tr>
<tr>
<td>1100</td>
<td><strong>Parallel Sessions</strong></td>
<td>Please check room for each session</td>
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<tr>
<td>1230</td>
<td><strong>Farewell Session</strong></td>
<td>CC: Room 2a</td>
</tr>
<tr>
<td>1300</td>
<td>Lunch</td>
<td>CC: Foyer</td>
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</table>
## Plenaries and Parallel Sessions

### Thurs 19 September 1330-1530

<table>
<thead>
<tr>
<th>Time</th>
<th>speaker(s)</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1330-1400</td>
<td>Renzo Pegoraro, Elmar Weiler, Jochen Vollmann</td>
<td>Opening Session</td>
</tr>
<tr>
<td>1400-1445</td>
<td>George Browman</td>
<td>Ethical Implications of Personalized (Genomic) Medicine from the Person Perspective</td>
</tr>
<tr>
<td>1445-1530</td>
<td>Thomas Wabel</td>
<td>Patient as Person in Medicine: Autonomy, Responsibility, and the Body</td>
</tr>
</tbody>
</table>

### Parallel Sessions: Thurs 19 September 1600-1730

#### Patient as person in medicine Level 04 room 2a

<table>
<thead>
<tr>
<th>Time</th>
<th>Speaker(s)</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600-1630</td>
<td>Peter Heusser et al.</td>
<td>Towards integration of &quot;personalised&quot; and &quot;person-centred&quot; medicine</td>
</tr>
<tr>
<td>1630-1700</td>
<td>Roxanna Lynch</td>
<td>Just how ‘personal’ can ‘personal care’ be?</td>
</tr>
<tr>
<td>1700-1730</td>
<td>Marco Annoni, Bettina Schmietow</td>
<td>Integrating Personalized Medicine and Person-Centred Medicine: Lessons and Directions from the Recent Search for Biomarkers of Placebo Response</td>
</tr>
</tbody>
</table>

#### Person and medicine. Philosophical analyses Level 04, room 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Speaker(s)</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600-1630</td>
<td>Rouven Porz</td>
<td>‘beings in time’ – how to integrate the ‘new molecular body knowledge’</td>
</tr>
<tr>
<td>1630-1700</td>
<td>Mathias Wirth</td>
<td>Corporeality and the authority of emotions The New Phenomenology and its relevance for a personalised kind of medicine</td>
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#### Priorities in "personalised medicine" Level 04 room 2b

<table>
<thead>
<tr>
<th>Time</th>
<th>Speaker(s)</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600-1630</td>
<td>Georg Marckmann, Sebastian Schleidgen</td>
<td>Personalized medicine and fair allocation of resources: Do we set the right priorities?</td>
</tr>
<tr>
<td>1630-1700</td>
<td>Franz Hessel</td>
<td>The relevance of the analytic validity of genetic tests in personalized medicine technologies for reimbursement decision making in Germany</td>
</tr>
<tr>
<td>1700-1730</td>
<td>Jean Harrington et al.</td>
<td>A patient-centred approach to biomarkers of (transplant) tolerance</td>
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#### Application of "personalised medicine" and ethical challenges Level 04 room 3

<table>
<thead>
<tr>
<th>Time</th>
<th>Speaker(s)</th>
<th>Topic</th>
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<tbody>
<tr>
<td>1600-1630</td>
<td>Kris Dierickx</td>
<td>The clash between the newest genetic sequencing technologies and old ethical concepts</td>
</tr>
<tr>
<td>1630-1700</td>
<td>Colleen Gallagher</td>
<td>Appropriate Care for the Individual Patient: Using a Decision Tool based on Quality and Justice</td>
</tr>
<tr>
<td>1700-1730</td>
<td>Zuzana Deans et al.</td>
<td>For your interest? The ethical acceptability of using non-invasive prenatal testing to test purely for information</td>
</tr>
<tr>
<td>Parallel Sessions:</td>
<td>Thurs 19 September 1600-1730</td>
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<tr>
<td>Patient as person in medicine</td>
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<td>Chair: Michael Fuchs</td>
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<tr>
<td><strong>5 “Personalised medicine”. History and concept</strong></td>
<td>Level 01 room 2</td>
<td></td>
</tr>
<tr>
<td>1600-1630</td>
<td>Susanne Michl</td>
<td>Individualized Medicine – innovation or remake? From historical pioneer works to modern innovations-nets</td>
</tr>
<tr>
<td>1630-1700</td>
<td>Sebastian Schleidgen et al.</td>
<td>What is Personalized Medicine? Sharpening an Ambiguous Term Based on a Systematic Literature Review</td>
</tr>
<tr>
<td>1700-1730</td>
<td>Christian Lenk</td>
<td>Probabilism and Relevance of Genetic Information in Medical Decision-Making</td>
</tr>
<tr>
<td><strong>6 Persons in medicine and care</strong></td>
<td>Level 04 room 82</td>
<td></td>
</tr>
<tr>
<td>1600-1630</td>
<td>Şerife Karagözoglu et al.</td>
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<td>Voice Recorded Messages from Significant Others as an Adjunct Therapy to Increase The Level of Consciousness of Patients With Reversible Coma</td>
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#### 2 Plenary: Research in “personalised medicine”
Level 04 room 2a  
Chair: Guy Widdershoven

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### Parallel Sessions: Research in “personalised medicine”  
Fri 20 September 1100-1230

#### 7 Minors and relatives in “personalised medicine”
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<td>The caregiver steals from the elderly, but it's not our job to do anything…Moral Case Deliberation at The Dutch Health Care Inspectorate - A Pilot Study -</td>
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#### 8 Healthcare professionals perspectives
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#### 10 “Personalised medicine” and consent
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Chair: Mark Sheehan

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Chair: Kris Dierickx

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**Fri 20 September 1100-1230**

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Speakers & Abstracts
Patient as person in medicine

Thursday 19 September

1400-1530

Speakers:

George Browman
Thomas Wabel
Ethical Implications of Personalized (Genomic) Medicine from the Person Perspective

George P. Browman MD, MSc, FRCPC
British Columbia Cancer Agency and the University of British Columbia, Canada

Advances in genomics hold promise for the use of genetic information across a spectrum of applications in healthcare. “Proofs of concept” have already led to advances fuelling enthusiasm among scientists. But others express valid reasons for caution. Opinions about the true promise and real world readiness of genomics are split between enthusiasts and sceptics because interventions are associated with intended and unforeseen consequences. Concerns revolve around ethical challenges – legal, social, and personal that are dominated by issues of privacy and confidentiality; the utility and potential (mis)use of genomic information; uncertainty about its interpretation given current knowledge gaps; and the unique nature and reach of genomic information across families and generations. Ethical frameworks for addressing these challenges will differ depending on the healthcare context (medical/treatment; public health/prevention); who requests such information (the healthcare provider or the consumer); where and by whom testing is done; and who is really in control of test ordering and follow-up counselling. These concerns are compounded by imperfectly aligned motives – health benefit to the individual, commercial benefit and purely research benefits. The genomic era is also blurring the distinction between medical and research ethics, for which new analytical frameworks and guidance may be required. This presentation will address some of these issues and their implications.
Patient as Person in Medicine. Autonomy, Responsibility, and the Body

Prof. Thomas Wabel (Weingarten)

Current debates on personalised medicine bring many of the underlying assumptions to the fore that shape our understanding of persons as patients. Among these, respect of autonomy, including full information for the patient and the patient’s opportunity and ability to make a responsible choice, range high. However, recent interview studies indicate that the sheer amount of information to be conveyed, the complexity of the treatment, and high expectations on the patients’ side make it hard to arrive at an informed consent in the full sense. Having the choice to make use therapeutic and preventive means, it seems, can also be a burden for the patient.

In this paper, I am arguing that a concept of autonomy as freedom from external constraint and as decision-making capacity is too narrow to describe and understand the patients’ decision concerning their own body. Alternatively, I am suggesting to understand autonomy essentially as embodied autonomy. The paper discusses some of the implications of this concept.
Parallel Sessions 1

*Patient as person in medicine*

Thursday 19 September

1600-1730
Title:
Towards integration of “personalised” and “person-centred” medicine

Authors:
P. Heusser¹, E. Neugebauer², B. Berger¹, E.G. Hahn³

Affiliation:
¹Universität Witten/Herdecke, Gerhard Kienle Lehrstuhl für Medizintheorie, Integrative und
Anthroposophische Medizin, Institut für Integrative Medizin, Fakultät für Gesundheit, Herdecke,
Germany
²Universität Witten/Herdecke, Lehrstuhl für Chirurgische Forschung, Institut für Forschung in der
Operativen Medizin IFOM, Campus Köln-Merheim, Fakultät für Gesundheit, Herdecke, Germany
³Universität Oldenburg , Gründungsdekan, European Medical School Oldenburg-Groningen,
Oldenburg, Germany
peter.heusser@uni-wh.de

Abstract text:
The term “personalised” or “individualised medicine” is increasingly applied to designate the use of
individual genetic and molecular markers for diagnostic, therapeutic and preventive purposes in
medicine. Tremendous amounts of financial resources and research capacities are invested to
improve risk prevention, diagnostic accuracy and treatment outcomes by developing more individually
tailored biological problem solutions in medicine. However, this almost exclusively molecular and
biological concept of “personalisation” leads to a strong connotation - if not to a de facto identification -
of “person” with the molecular set-up of an individual’s physical body.

This is a pitfall which ought to be avoided. Evidence shows that patients do not identify themselves
with their bodies alone, and that there is an increasing dissatisfaction among patients with one-sided
physical and technical forms of medicine. This is one of the reasons why they turn to holistic forms of
complementary or alternative medicine. Also, in the lay public, the term “personalised medicine” is
usually associated with more holistic concepts of “person”, including not only physical, but also
psychological, social, existential and contextual aspects of human individuals. In this sense, patients
seek more humanistic or “person-centred” forms of health care that include a more compassionate
and empathetic approach of practitioners to patients, with responsiveness to psycho-social issues,
individual needs, preferences and values of patients. Likewise, according to more classical concepts
of “person” or “individuality” in philosophical and medical anthropology, a human being or “person”
cannot be understood on the basis of molecular and biological variants alone, but as an individual in
the wider context of its biological, psychological, mental, social, economic, cultural and spiritual
dimensions. Thus, “person- or “patient-centredness” entails an integrative view on the differentiated
facets of a human individual, in diagnosis, treatment and prevention.

One can reasonably and ethically argue that within their limits “personalisation” and “person-
centredness” are equally meaningful and justified and should be combined in the attempt to establish
more encompassing and individualized, and possibly more effective forms of health care. However,
this would necessitate a corresponding adjustment of research projects as well as funding. Therefore,
the Faculty of Health of Witten/Herdecke University has established a common research focus on the
topic of “Integrative and Personalised Health Care”. In this context the term “integrative” includes a
comprehensive perception of the patient, an emphasis of the practitioner-patient relationship, and the
integration and inter-professional cooperation of different disciplines of health care according to the
perspectives covered. The term “personalisation” is used in its humanistic extension, including the
account for molecular and biological markers such as in “personalised medicine”, but also the wider
context of individual’s biological, psychological, mental, social, economic, cultural and spiritual
dimensions such as in “person-centred” care. The term “health care” refers to the areas of health
promotion, prevention, diagnosis, treatment, rehabilitation, and palliative care, but also the functionality of health systems.

From an ethical, societal and economic perspective, the present distribution of resource allocation would have to be reconsidered, if “personalised” and “person-centred” forms of medicine were to be harmonised according to patient needs.
Patient as person in medicine

Thurs 19 September 2013

1 Patient centred medicine – “personalised medicine”

Title:
Just how ‘personal’ can ‘personal care’ be?

Authors:
R. Lynch

Affiliation:
Swansea University, College of Human and Health Sciences, Swansea, United Kingdom
roxannajesselynch@gmail.com

Abstract text:
This paper focuses on the problems associated with trying to provide care that is ‘personalised’ (i.e. suitably in accordance with the cared-for’s own conception of what constitutes his/her flourishing) in an institutional setting where care givers may be reasonably assumed to be bound by the codes of conduct of their profession. I define care as the successful promotion of the flourishing of the cared for, for the cared for’s own sake (where flourishing is conceived as both objective and individualised).

In the film ‘The Princess and the Warrior’ (‘Der Krieger und die Kaiserin’) there is a scene in which the heroine, a psychiatric nurse named Sissi, in response to a clear request from one of her patients (who is presented as being intermittently lucid, and whom Sissi has both known and cared for for many years), performs a sex act on that patient. In the context of the film, the act comes across primarily as one of care. Sissi’s willingness to attend to the sexual needs of her patients exemplifies not only her dedication to them, but also their total reliance on, and vulnerability to, her.

In reality, though, Sissi’s act would typically be classed as an instance of abuse, or at least misconduct. So the question is, was Sissi right to act as she did?

As an employee, and as a nurse instructed to care for vulnerable patients, Sissi will have assented to certain codes of conduct and accepted various role responsibilities (of which refraining from having sexual relations with patients was likely to be one). So as an employee, Sissi should not have done what she did: institutions that exist to protect and care for vulnerable adults apparently have a clear reason to prohibit sexual relations between staff and patients (e.g. to minimise the chances of abuse to either party).

However, Sissi is simultaneously an employee and a human being. The strongly felt sexual needs of a patient if left unattended to could, arguably, cause great suffering in terms of feelings of isolation and frustration. As human beings, it is our emotional response to such needs of others and their suffering that typically causes us to care at all. So as a human, and as a care giver, it is not so clear that Sissi acted wrongly: in satisfying the sexual needs of a patient (needs that are arguably as objective as they are individual), Sissi succeeded in promoting the flourishing of someone in her care for that person’s own sake and responded appropriately to the dictates of her conscience.

So Sissi appears to have acted both wrongly and rightly.

I shall argue for the conclusion that if we want institutional care to be personal, and if we want to avoid what I shall call ‘Sissi’s dilemma’, we must subordinate the rules of institutions to the primacy of the caring relation and trust that our definition of care is adequately robust to protect the vulnerable from malevolence and/or incompetence.
Patient as person in medicine

Thurs 19 September 2013

1 Patient centred medicine – “personalised medicine”

Title:
Integrating Personalized Medicine and Person-Centred Medicine: Lessons and Directions from the Recent Search for Biomarkers of Placebo Response

Authors:
M. Annoni1,2, B. Schmietow1,2

Affiliation:
1European Institute of Oncology, Department of Experimental Oncology, MILANO, Italy
2University of Milan, Health Sciences, Milan, Italy
marco.annoni@ieo.eu

Abstract text:
In recent years debate has spurred over the potential conflict between two emerging paradigms in biomedicine: Personalized Medicine (P-Med) and Person-Centered Medicine (PCM). Though both P-Med and PCM aim at tailoring therapies to the individual level, they do so by resorting to different conceptual frameworks and techniques. The promise of P-Med is that of using new technologies such as genetic screening to develop therapies targeted to the molecular level. The core idea of PCM, instead, is that of promoting health and recovery by considering the patient’s individual beliefs, values, past experiences, and narratives as an integral part of the healing process. PCM thus takes a holistic approach to healing and care, while P-Med is driven by a combination of evidence-based techniques and a mechanistic understanding of the molecular pathophysiology. Accordingly, they are often presented in contrasting terms, with the former accused of lacking an adequate empirical basis, and the latter of disregarding the patient’s agency. Against this dichotomous perspective, in this talk we put forward our view that P-Med and PCM should not be understood as two competing or mutually exclusive approaches, but rather as two sets of diverse strategies that can and eventually ought to be integrated to maximize the patient’s benefit. In order to illustrate our position, we analyze the theoretical and ethical implications of a recent study on the genetic predictability of placebo responders in patients suffering from Irritable Bowel Syndrome (IBS). This study tested the hypothesis that the COMT functional val158met polymorphism was a predictor of placebo effects (Hall et al. 2012). The study build upon a previously reported randomized controlled trial in people with IBS that showed how a different quality of the patient-physician interaction (none, limited, or augmented) correlated with a significant difference in the modulation of IBS symptoms, most likely through the eliciting of placebo effects based on expectations and the reward system (Kaptchuck 2010). These studies suggest that patients homozygous for the COMT val158met methionine allele (met/met) are more susceptible to placebo effects elicited by expectations, and thus they are the ones that would profit the most from receiving an “enhanced” therapeutic relation, while the reverse is true for homozygous valine (val/val) patients. By combining an epistemic strategy typical of P-Med - i.e. screening for a specific genetic polymorphism - with a clinical protocol typical of PCM - i.e. enhancing the physician-patient relationship -, these studies provide a first proof of principle that an effective integration between PCM and P-Med approaches is not only theoretically desirable but also practically feasible. This case study, we conclude, represents a timely contribution to rethink the future of clinical care in the age of personalized genomics.
Title:
“beings in time” - how to integrate the ‘new molecular body knowledge’

Authors:
R. Porz

Affiliation:
Unit for Clinical Ethics, Bern, Switzerland
rouven.porz@insel.ch

Abstract text:
An increasing number of genetic tests represent a new and fast growing field of molecular biomedicine. This field gives rise to new forms of decision-making situations for the individual patient involved. These situations might also trigger difficult personal phases of “coming to terms” with the new molecular body knowledge.

Both the decision-making situations and the ”new genetic knowledge” about the body may present existential Grenzsituationen to the ones affected (using the concept of Karl Jaspers). These situations may also be perceived, either consciously or unconsciously, as existentially ”absurd” (in which it is used by the French philosopher Albert Camus). For example, questions about the meaning of one’s own existence and the fatedness of the illness may be raised. The new genetic knowledge may force those affected to restructure their own identity over time. As we are humans beings in time, these situations might also be interpreted as molecularly triggered reflection marks in our “Dasein zum Tode” (following Martin Heidegger).

In this paper I will make use of some core concepts of these existential/hermeneutical thinkers to broaden the concepts of “personalized medicine” from a philosophical point of view. I will focus on genetic testing issues as both the process of making the decision (for or against a genetic test) and the subsequent integration of the new information takes place over a timespan that varies from patient to patient and that might offer existential challenges for the one affected. On an ontological level, especially the temporal implications raise difficult questions for the affected persons who must place themselves in relation to their own lifetimes.

Finally, I will stress that a patient-directed description of my illustration may lead to the identification of new ethical implications in terms of patients` autonomy, informed consent and genetic counselling.
Title:
Corporeality and the authority of emotions
The New Phenomenology and its relevance for a personalised kind of medicine

Authors:
M. Wirth

Affiliation:
University Medical Center Hamburg-Eppendorf, Department of History and Ethics of Medicine, Hamburg, Germany
m.wirth@uke.de

Abstract text:
Question:
Illness gains authority through the result of the element of suffering. On the base of this authority medicine follows the obligation to heal the source of a given illness. A number of developments being observed in the field of medicine allow for a medicine that is more and more personalised. The focus on the individual physiology and pathology has so far only concentrated on the somatic side, although the term personalised medicine has been applied. In order to do justice to the authority of suffering and its concrete shape, a more comprehensive appreciation of the place of suffering within a given illness is required. Medical ethics could help taking advantage of the ever-growing importance of a personalised medicine that gives the complete physical dimensions of a given illness. With regard to the illness, it is not the tumour that suffers, but the actual person who is by definition corporeal (leiblich). The dualistic view, that is widely approved of, classifies the physical, the measurable as core suffering. As opposed to this, there is the mental side, hopelessly private, that concerns the individual and no-one else.

Results/Conclusion:
Yet, there is a third dimension, the corporeality (Leiblichkeit), a dimension that is the particular focus of the philosopher Hermann Schmitz in his New Phenomenology. Unlike the body, corporeality cannot be measured empirically, yet it is the actual place where such emotions as shame, lust, fear, and pain are located, a place where a person is “real”. To the patient, a respectful appreciation of his corporeality counts much more than the details of his diagnosis, the prognoses or his therapy regime. The authority of illness includes the relevance of “emotions” and “atmospheres” that have been strongly emphasized by Schmitz. In a clinic that ignores the corporal needs for tranquillity, security, attention, best care, and, above all, respect, the term personalised medicine does not apply.

Methods:
As a first step, this study will show an ethical criticism of the claims that an all-encompassing focus on a person within the personalised medicine cannot exist within a common dualistic perspective upon what a person is. In the next step, the view of Schmitz’ New Phenomenology will be presented, his position relates to the criticism of a too narrow perception of personalised medicine by referring to the “involuntary life experience”. The next step will be to focus on the central topics of the corporeality (pain as the corporal reaction, cruelty etc..), emotions (emotions as „semi-objects“, corporeality and the authority of emotions etc.), atmospheres (atmospheres as emotions that affect others, fear as a boundless atmosphere etc.) that cast a light on the individual experience of illness through a dialogue with Schmitz’s approach. The last step will consist in drawing the necessary medical ethical ramifications and how they can be realigned to a new conclusion in cooperation with Schmitz question: What precisely is the personal with regard to illness and medicine.
Title:
Personalized medicine and fair allocation of resources: Do we set the right priorities?

Authors:
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Abstract text:
Background: Personalized medicine (PM) has become a high priority not only in the pharmaceutical industry, but also in public research programs. First PM applications have made their way into clinical practice, often providing a small incremental benefit for the patient at high costs. Given the limited resources available both for research (in the private and public sector alike) and medical care and the high opportunity cost of PM, the question arises whether the high investment follows the right priorities.

Methods: We analyzed the ethical issues that arise with resource allocation on different levels in the context of PM. In addition, we conducted a qualitative interview study with stakeholders in the German health care system. Our purposive sample included 17 representatives of basic research, health economics, regulatory authorities, reimbursement institutions, pharmaceutical industry, patient organizations as well as clinicians and legal experts involved in PM developments or policy making.

Results: Based on the analytical investigation and the qualitative interview study, we identified four levels of resource allocation in the context of PM: (1) Allocation of resources into personalized medicine, (2) allocation of resources within the field of PM, (3) Distribution of / access to PM, (4) Indirect consequence (e.g. discrimination due to diagnostic / prognostic information from PM). The ethical issues arising on these four levels are elaborated. We then propose ethical criteria that should guide allocation decisions on the different levels. Finally, we present policy options to make ethically justified decisions on the four levels. These include explicit priority setting (level 1), incentives for pharmaceutical companies to invest in "orphan populations" and more public research funding (level 2), improved benefit assessment and cost-benefit assessment (level 3) and regulatory measures to prevent discrimination of patient subgroups (level 4).

Conclusion: Despite the ethical challenges involved on the four allocation levels, a complete rejection of PM cannot be justified. Rather, appropriate policies - some of which we discuss in this presentation - should be implemented to ensure a development and application of PM that contributes to an overall fair allocation of resources.
Title:
The relevance of the analytic validity of genetic tests in personalized medicine technologies for reimbursement decision making in Germany

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Abstract text:
The German reimbursement body Federal Joint Committee (G-BA) is commissioned by the German social law to base its reimbursement decisions on the extent of the additional medical benefit in comparison to the existing standard treatment (if there is any). Based on the G-BA’s recommendation the head association of statutory sickness funds (GKV-SV) and the drug manufacturer negotiate the price of the new drug.

The G-BA has evaluated the first genetically stratifying drugs entering the market for treating patients with oncological diseases. The crucial criterion for the G-BA is the extent of the additional medical benefit of a test-drug-combination derived from the scientific evidence on clinical efficacy of the drug in the target population given by the indication according the regulatory approval. The clinical validity of the test, meaning whether a positive test result is connected to having the disease and a negative test result means that the disease is not present, is implicitly expressed by the clinical trial. But the analytic validity of the test, defined as the analytic sensitivity and specificity, is not included in the evaluations. The analytic specificity is the degree to which a test will return a negative result for persons who do not have the mutation. On the other hand side the analytic sensitivity is the degree to which a test will provide a true positive result such that a person tested positive in fact has the mutation for which she is being tested.

According to the first evaluations the G-BA assumes that all tests for a specific genetic marker show a given, identical analytic validity, although the accuracy of genetic tests to detect alterations varies depending the technical approach, on the condition being tested for, and whether or not an alteration has been previously detected.

Therefore the choice of the test method and other circumstances which might vary in routine care use show a significant influence on the number of correctly stratified individuals. Furthermore routine care observation studies showed a great variation of the methods used for genetic tests e.g. for HER2, KRAS and BRAF mutations, also driven by economic reasons.

In the consequence a lack of analytic accuracy leads to unnecessary adverse events in non-responders and to untreated patients who could have benefit from the treatment.

Therefore the necessity of international quality standards, the recommendation of a fixed combination of a specific test methodology, possibly a specific manufacturer, and the inclusion of the analytical accuracy of the genetic biomarker test in the evaluation of the drug by reimbursement bodies such as the G-BA is regarded a necessary for patients’ safety, ethical and potentially economic reasons.
Title:
A patient-centred approach to biomarkers of (transplant) tolerance

Authors:
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Abstract text:
Research is underway to develop a biomarker test that will identify kidney transplant patients who may be tolerant to their graft and therefore require little or no immunosuppressant (anti-rejection) medication. Biomarkers that define the immunological fingerprint of tolerance in kidney transplant patients have the potential to benefit both individual patients and society as a whole. For example, patients accurately identified as tolerant would benefit from a better quality of life, the avoidance of late graft loss (due to chronic rejection) and longer term survival. Society would benefit from maximising the use of donated kidneys, currently in scarce supply. However, biomarker tests are not 100% accurate and the benefits of minimizing immunosuppressant medication must be weighed against the risk of precipitating acute graft rejection.

This paper describes and discusses recent work by a multi-disciplinary team to incorporate 'patient-preference' into the formulation and categorisation of biomarkers of tolerance. A mixed method study involving 100 kidney transplant patients is in progress with the aim of producing a novel method by which the risk associated with ‘biomarker-led care’ can be adjusted to individual patient’s circumstances. The research uses a modified Standard Gamble task to assess the level of risk that patients may be prepared to take, accompanied by an adjusted self-assessed quality-of-life and symptom burden Questionnaire to educe whether attitude to risk is associated with low quality of life and high symptom burden. This quantitative approach is augmented by a qualitative approach where 30 of the 100 participants are interviewed to elicit their attitude to risk and uncertainty and the range of influences that may affect their decision-making and choice in relation to biomarker tests of tolerance and biomarker led care.

Early findings indicate that although patient preference for biomarker-led care and acceptance of risk may be associated with low quality-of-life and high symptom burden scores, individual patient choice will vary depending on singular and contextual criteria. Despite recognised advances in the treatment of kidney disease brought about by ‘personalised medicine’, analysis of these findings indicates that further benefit would be achieved by integrating a patient-centred approach into research at an early stage; incorporating a ‘sensitive’ rather than ‘blunt’ comprehension of patient choice. This in turn would facilitate the translation of biomarkers of tolerance into the clinic and into practice.
Title:
The clash between the newest genetic sequencing technologies and old ethical concepts

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Abstract text:
The newest genetic sequencing technologies, such as whole genome sequencing, have the potential to deliver an enormous amount of often unsought for genetic information of widely varying significance. As new genetic sequencing technologies become cheaper and more widely available in ordinary clinical care, the ethical challenges they raise become relevant for everyone. The sheer amount and wide variety of information produced form a specific challenge to three rights of the subjects of genetic tests: their right to be fully informed about what can be expected from the tests; the right to choose to know or not know the various results of the tests; and the right to autonomously choose about further action. There is much discussion in current ethical literature about how protecting the rights of the subjects of new genetic tests might conflict with the responsibilities of medical professionals towards these subjects. The same tension is apparent in the guidelines available on the return of information resulting from new genetic tests. In contrast, empirical research on the return of information resulting from new genetic tests places far more emphasis on the principle of beneficence as it applies to the subject.

In this paper we examine this tension between rights and responsibilities as presented in the ethical literature and guidelines, and critique it with the principle of beneficence as introduced in the empirical literature. The themes of rights, responsibilities, and beneficence, are all old themes in the field of ethics. We argue firstly that all three themes take on a new spin in the context of new genetic sequencing technologies. None of the three can be defined in an absolute way by only party, because the implications of the masses of information produced are too great to be handled by any one party. There must be a process of defining these old ethical concepts that involves all relevant parties: medical professionals, subjects, and to an extent their families and the wider society. We argue secondly that the best way forward is for medical professionals to take up their responsibility and accept that it is impossible for subjects to be fully informed about their options. The wellbeing of subjects, their families and the wider society should be the most important concern of medical professionals, and more energy should be poured into meeting this concern than in searching for new ways to protect the rights of subjects in the new genetic era.
Title:
Appropriate Care for the Individual Patient: Using a Decision Tool based on Quality and Justice

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Abstract text:
There are several ethical principles that apply to healthcare. The four most acknowledged are beneficence, non-maleficence, self-determination, and justice. Of these, justice is most complex in that it not only applies to the individual but is also defined by societal rules and decisions. We propose that justice in healthcare for the individual be defined as the most appropriate care for that individual. In this paper, we will review the meaning of the term “appropriate care” and propose a tool for ethical review of “appropriate care” in individual cases.

To examine what might be the determinants for appropriate care for an individual, one can look at the six aims for improvement or key dimensions of healthcare, which are stressed in the 2001 report by the Institute of Medicine as essential for appropriate or just healthcare. These dimensions are safety, timeliness, equitability, effectiveness, efficiency, and patient-centered focus of the care.

We propose a grid module which could be applied to an assessment of appropriateness of care for an individual patient. A specific treatment decision or care plan for a specific patient with a particular condition would be measured along the six dimensions of quality. Each dimension would be examined as to whether it has been met or unmet by that decision. The overall score would be used to stratify the quality for the decision. A second analysis could also be conducted with focus on the dual dimensions of healthcare, that is, the tension between the individual needs and evidence, as well as the individual and/or societal benefit.
Title:
For your interest? The ethical acceptability of using non-invasive prenatal testing to test purely for information

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Abstract text:
Non-invasive prenatal testing (NIPT) is a form of prenatal genetic testing which allows women and couples to obtain highly predictive information about the health of a fetus via a blood test during pregnancy. As with standard prenatal diagnosis, NIPT can be used to make a decision about continuing the pregnancy, to plan contingencies for birth or to prepare to raise a child with a genetic condition. Prenatal testing could also be used by women and couples to test purely ‘for information’. In this kind of testing, no particular action is envisaged following the test; it is instead entirely motivated by an interest in the result.

The fact that NIPT can be performed without posing a risk to the pregnancy, coupled with the fact that using this technology for whole genome sequencing is now technically feasible, could give rise to an increase in requests for comprehensive NIPT for ‘information only’. In this paper, we examine the ethical aspects of this particular potential application of NIPT, questioning the justifications for seeking personalised information in this context. We discuss the competing interests of the prospective parents and the future child and the acceptability of testing for ‘frivolous’ reasons. We claim that the arguments about testing children for genetic conditions are applicable to the question of whether NIPT should be used for information only. In addition, we raise concerns for the potential for objectification of the child. We conclude that, in most cases, testing for adult-onset conditions would be unacceptable and that, in some circumstances, it may be appropriate to counsel against or even deny a woman access to information about her fetus, judged on the impact testing is likely to have on the future child.
Title: Individualized Medicine - innovation or remake?
From historical pioneer works to modern innovations-networks

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Abstract text:
Individualized Medicine is considered as a fairly new field of research. Nevertheless, in historical perspective this seemingly new approach could certainly be inscribed in a process of advancements in medical research and technology, particularly in the field of molecular biology and pharmacogenetics starting in the 1950s. Besides this technical approach, Individualized Medicine is also deeply rooted in broader societal developments in the period considered: the endeavor to extract more and more socio-biological health information from populations in order to detect risk factors and to get a valid data base to conceptualize efficient curative and preventive interventions on an individual and a population-based level.

In the first part of the contribution I will retrace this process, by analyzing the early stages when in 1956 the biochemist Roger J. Williams stated that "the interest in variation and individuality [...] has not gained the respectability that it deserved".[1] Thus, it will raise the question how this medicine for the person has become a field of research worth investigating and being promoted by public funding. Personalized Medicine must therefore be contextualized by considering the emergence of the widely epidemiological studies like the Framingham Heart Study in 1946, the impacts on preventive discourse and its broader societal and ethical impacts until today. In this data-driven research, the notion of "person", "individuality", its specific use, the reference and reminiscence to older conceptions of a medicine for the person is crucial for the understanding of the dynamic developments in the 20th and 21st centuries.

The second part of the contribution raises the more theoretical question if Individualized Medicine could be considered not so much as a paradigm shift in the history of medicine, but rather as an innovation which has the potential to change the doctor-patient-relationship, to alter the rules in the health sector and to have an ethical impact on societal values relating to the notions of health and illness. In this respect, considering the innovative character of Individualized Medicine does not only mean the recognition of technological advancements but also the interplay between different stakeholders, experts and non-specialists, adopting and supporting this new technology, and not least a broader public acceptance. I will therefore refer to different sociological approaches to the notion of innovation from the analysis of the "heroic" individual researcher or engineer triggering the innovation process to broader conceptions of innovation-networks. The contribution will then analyze the conditions, potentials and the impediments of these innovation networks by seizing the case of Individualized Medicine and its implementation into clinical research and practice. Furthermore, Individualized Medicine could be considered as a Leitbild, a mission statement for further innovations. This new approach to medicine is indeed in the process of entering the public debate. Since action-oriented mission statements are designing what is desirable and what is feasible, they have stabilizing and destabilizing effects in the coordination and communication between experts and society.
Title:
What is Personalized Medicine? Sharpening an Ambiguous Term Based on a Systematic Literature Review

Authors:
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Abstract text:
Background: In recent years, individualized or personalized medicine (IM/PM) has become a buzz word in the academic as well as public debate surrounding health care. However, PM lacks a clear definition and is open to interpretation. This conceptual ambiguity unduly complicates public discourse on chances, risks and limits of PM. Furthermore, stakeholders might use it to further their respective interests and preferences. Additionally, PM's underspecification can lead to unwarranted fears of patients as well as unfounded hopes that will necessarily be disappointed. For these reasons it is extremely important to have a shared understanding of PM. In our talk, we present a sufficiently precise and widely acceptable definition of PM analytically derived from a systematic literature review.

Methods: PubMed was searched using the keywords “individualized medicine”, “individualised medicine”, “personalized medicine” and “personalised medicine” connected by the Boolean operator OR. A data extraction tabloid was developed which puts forward a means/ends-division. Full-texts of articles containing the search terms in title or abstract were screened for definitions. Definitions were extracted; according to the means/ends distinction their elements were assigned to the corresponding category. To reduce complexity of the resulting list, summary categories were developed inductively from the data using thematic analysis. In a second step, we applied six well-known criteria for good definitions to these categories to derive a so-called precising definition which builds on the current usage of the term PM, while sharpening it.

Results: We identified 2457 articles containing the terms IM/PM in title or abstract. Of those 683 contained a definition of PM and were thus included in our review. 1459 ends and 1025 means were found in the definitions. From these we derived the precise definition: PM seeks to improve stratification and timing of health care by utilizing biological information and biomarkers on the level of molecular disease pathways, genetics, proteomics as well as metabolomics.

Conclusion: Our definition includes the aspects that are specific for developments labeled as PM while, on the other hand, recognizing the limits of these developments. Furthermore, it is supported by the quantitative analysis of PM definitions in the literature, which suggests that it probably finds general consensus and has the potential to avoid the above mentioned issues.
Title: Probabilism and Relevance of Genetic Information in Medical Decision-Making

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Abstract text:
In the last thirty years, the biomedical sciences experienced a strong shift towards the so-called information society. Especially in medical genetics, technological innovation and new research approaches like biobanks and genome-wide association studies led to an explosive increase of medical data. However, the mere availability of genetic data does not necessarily lead to a better information of medicine in general and concerned patients and families in particular.

The decisive point concerning the distinction of useless and valuable information in medical decision-making is described by the concept of relevance. The information society produces and stores enormous masses of information, but only a very small fraction of this knowledge is relevant for the appropriate answer to a detailed medical question. The relevance of an information is described by the degree of usefulness of this information to solve a defined problem. When I am in a hurry and have to travel from Ulm to Munich, the information about a delay of this particular train is highly relevant for me. In other cases, the punctuality or delay of this train is absolutely useless and has no influence concerning my behavior. It follows, that such detailed information has normally no value as such, but only in the context of a previously defined question or problem.

Genetic knowledge as well as other medical knowledge, for example concerning possible risks or side effects of a drug or a medical intervention, is nowadays normally expressed in the form of probabilities. This is a major difference to the traditional form of medical diagnosis where the outcome is clearly defined, for example that a person has a specific disease or not. Probabilities can have different functions in medical decision-making. Firstly, probabilities have a descriptive function, for example that a health-related event will occur in a patient group with a specific prevalence. The patient will then learn that he has for example a probability of 15% to suffer a myocardial infarction. In many medical situations, such knowledge is very useful. However, as such, the value of mere probabilities is also limited, because it is not clear what follows from them in practical terms.

This leads us to the second function of probabilistic knowledge, i.e. the comparative function. When two equivalent medical interventions exist with a different probability to experience certain side effects, the patient should usually decide to choose the intervention with the more acceptable risk profile. Equally, when research shows that a person group has (in comparison to the rest of the population) an increased genetic risk to develop a certain disease, preventive measurements are of special relevance for this group. In the planned conference contribution, different types of medical and genetic information and situations will be discussed and interpreted in regard of their relevance for medical decision-making.
Title:
Validity and Reliability of the Turkish Version of the Moral Distress Scale Revised (ICU MDS_R) in Intensive Care Units

Authors:
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Abstract text:
Background: Moral distress is an ethical problem affecting the quality, quantity and cost of the care and treatment. Moral distress is the stress suffered by a professional, when he/she cannot achieve the right action due to obstacles although he/she knows what the right action to take is. In several studies, it has been reported that nurses working in intensive care settings suffer moral distress more.

Among the factors that cause moral distress are that nurses directly witness patients suffering and distress with the technological advances and changes in health care, that the patient, family, members of the health team and health service managers have difficulty in the decision-making process because care and treatment services which have complex and flexible structure can be affected by political and economic processes, that nurses spend more time with the patient in the intensive care units, that person-specific systematic care cannot be planned and thus cannot be provided. Among the other factors that cause moral distress are the effects of paternalistic health care system, lack of effective communication and team collaboration, lack of a clear task descriptions related to the treatment and care in these areas and inadequate staff and increased workloads. Another factor that significantly causes moral distress is that nurses are not the professionals taking part in the decision-making but they just put the already made decisions into practice. In her study (2005), Gutierrez reports that nurses suffer moral distress because they cannot display assertive behaviors in the team, the communication between the nurse, patient and physician is not effective enough, or the time needed is limited.

Several studies report that moral distress causes anger, frustration and emotional distress among nurses, discourages nurses from providing care for patients, reduces the quality of the care, causes inability in coping, and causes nurses to quit their present job or even their profession. Whereas some studies on the issue indicated that nurses suffered medium level of moral distress, some other studies revealed that they suffered high level of moral distress.

Due to the frequent occurrence of moral distress among nurses and various effects of moral distress on them, for the sake of the health care system and nursing, it is important to understand and appropriately evaluate moral distress, to identify stressors and to develop strategies to avoid these stressors.

The validity and reliability studies of different versions of the moral distress scale have been performed in different countries. However, in Turkey, there is neither a measurement tool used to assess moral distress suffered by nurses nor a study conducted on the issue.
**Objective**: The present study aims to prepare the Turkish version of the Moral Distress Scale (MDS-R/The scale was revised by Hamric et al. in 2012) to be used in intensive care units and to examine the validity and reliability of the Turkish version of the scale.

**Methods**: The sample of this methodological study comprises 200 nurses working in the intensive care units of internal diseases and surgery departments of 4 hospitals located in three provinces in Turkey. The data were collected with the socio-demographic characteristics questionnaire and The Turkish Version of the Moral Distress Scale-Revised (ICU MDS-R). Data were evaluated with SPSS 14 software package, factor analysis, Cronbach's alpha, test-retest reliability, item-total score correlations, content validity and construct validity. The total score to be obtained from the 21-item ICU MDS-R varies between 0 and 336 and higher scores indicate higher levels of moral distress.

**Results**: The mean age of the nurses participating in the study was 27.19±5.11. Of them, 73.5% were female, 59.0% were single and 70.0% had a bachelor's degree in nursing. Nurses' total length of service was determined as 5.01±4.81. It was also determined that 24.0% of the nurses considered resigning due to moral distress but did not whereas 16.0% of them considered quitting his/her job. Prior to the analysis, the results of Kaiser-Meyer-Olkin (KMO) and Bartlett's test of Sphericity were determined as (0.810) and (X2=1184.937) respectively and considered statistically significant (p=0.001). It was also determined that item-total correlations of the scale ranged between 0.84 and 0.85 (p<0.001), the mean value of item-total correlations was 0.845 and Cronbach's alpha value of the total scale was 0.85. In parallel with the original scale, ICU MDS-R consists of 21 items, and shows a one-factor structure.

It was determined that the nurses who participated in this study suffered lower levels of moral distress in general, but higher levels of moral distress regarding the scale items such as inadequate communication within the team, working with professionals they considered as incompetent and futile care.

**Conclusion**: In conclusion, ICU MDS-R, can be used as a reliable and valid measurement tool for the evaluation of moral distress experienced by nurses working in intensive care units in Turkey. With its use in intensive care unit, this measurement tool can help to figure out the level of moral distress nurses suffer, to make institutional arrangements to reduce moral distress and to increase nurses’ levels of personal and professional well-being.
Title:
Personalized Medicine and Psychosocial Interventions in Cancer Patients

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Abstract text:
Over the last decade dramatic advances in molecular biology and genetics have identified multiple potential targets for the treatment of cancer and targeted drugs have become established in oncology. While initially marketed as cancer specific agents with lower toxicity than conventional chemotherapy, it has become increasingly apparent that these drugs have numerous serious adverse effects and treatment-related complications represent a major cause of morbidity and mortality in patients receiving cancer targeted therapy. In order to transform cancer treatment into a personalized therapeutic intervention - i.e. minimize toxicity in patients unlikely to benefit targeted therapy and maximize the cost-effectiveness ratio in those likely to benefit, a great research effort is done to find new biomarkers to predict patient’s response. High-throughput approaches coupled with bioinformatics are accelerating the pace of biomarker research, but the high phenotypic heterogeneity of cells in cancer tissues jeopardizes this research and too often the subset of responding patients are not identified. Due to the big pressure on finding a cure for metastatic cancer, in many cases targeted drugs have been approved with an accelerated procedure, using Progression Free Survival as the main endpoint. This end point, beyond not translating into the gold standard end point Overall Survival, it opens big dilemmas in the assessment of treatment value such as the benefit of patients’ Quality of Life (QoL). In these talk we focus on angiogenesis inhibitors targeting Vascular Endothelial Growth factor, a class of targeted drugs, which have no specific biomarkers of response. They disrupt the established abnormal vasculature that feeds tumours but their action is counterbalanced by a severe induction of hypertension. In patients with advanced breast cancer the administration of angiogenesis inhibitors increases disease free interval but does not lengthen their life. In the last two decades a parallel interest on psychological therapies for cancer patients has developed, mainly prompted by the finding of a striking survival difference in metastatic breast cancer patients receiving this kind of support. However, in subsequent studies the survival increase was limited to patients with specific cancer receptors. Psychological intervention did not show a clear impact on survival for metastatic cancer patients. However, psychological therapy has a better clinical value when different, more important, end points are evaluated in the clinical setting of metastatic cancer patients. Emotionally supportive context, behavioural and cognitive coping strategies, relaxation training are the effective end points to be considered. In fact, multiple studies in metastatic cancer patients have provided conceptual and empirical replications of their effectiveness. These end points are the components of QoL measurements, which resulted in favourable outcome. QoL broadens the parameters of benefit beyond the conventional ones of disease free intervals and survival. We show how in the literature, increasingly QoL and its overall components constitute good prognostic indicators.
Title:
Voice Recorded Messages from Significant Others as an Adjunct Therapy to Increase The Level of Consciousness of Patients With Reversible Coma

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Abstract text:
Introduction: Hearing is the last sense that deteriorates when a person becomes unconscious. Meaningful auditory stimuli provide emotional arousal that brings about an increase in the level of consciousness.

Methodology: This study aims to determine the effects of the voice recorded messages from significant others as an adjunct therapy to increase the level of consciousness of patients with reversible coma. Using purposive sampling technique, 15 subjects were chosen with the following criteria: (1) in a reversible comatose state, (2) receptive to stimuli, (3) not in comatose state for more than 1 month, (4) no left-sided brain affectation, (5) admitted in the stroke unit or medical ward of East Avenue Medical Center, (6) accompanied by relatives, (7) 18 years old and above, (8) relatives able to sign the informed consent. The message lasts for 3-7 minutes and repeated 4 times daily for two weeks. The FOUR Score, GCS and Vital Signs of the patient will be assessed before and after the intervention.

Results and Discussions: Assessments were as follows: FOUR score scale (p=0.004), GCS (p=0.000), pulse rate (p=0.000), respiratory rate (p=0.000), temperature (p=0.655), systolic blood pressure (p=0.196), diastolic blood pressure (p=0.745). P-value lesser than 0.05, showed a significant result.

Analysis and Conclusion: Voice recorded messages from significant others as an adjunct therapy showed improvement in the level of consciousness and vital signs of patients with reversible coma as evidenced by significant differences found in FOUR score, GCS, RR, PR and some behavioral responses observed such as jerking, groaning, crying, and having the patient's first movements of the day as verbalized by relatives.

Keywords: reversible coma, level of consciousness, voice-recorded messages, auditory stimulation
Plenary 2

Research in “personalised medicine”

Friday 20 September

0900-1030

Speakers:

Barbara Prainsack
Mark Sheehan
“Thanks a lot for taking part in our revolution!” - Personalised Medicine and the participatory turn in health

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A decade ago, Personalised Medicine was largely synonymous with the matching of drug therapies to the genomes of individual patients. Today, it has become a much more inclusive term. ‘Personalised Medicine’ as well as related terms, such as stratification medicine, or precision medicine, all revolve around the idea that the consideration of individual characteristics - molecular and otherwise - can improving the practice of medicine, at every stage from prevention, diagnosis, and therapy to monitoring.

The current popularity of the idea of personalisation can be fully understood only against the backdrop of data-rich medicine. The large datasets generated during and in the aftermath of the Human Genome Project have been disappointing in terms of clinical utility. One way of rendering them meaningful for clinical use is by analysing and interpreting them in connection with other clinical as well as non-clinical datasets. One of the less discussed aspects of Personalised Medicine so far has been the expectation that patients and healthy citizens will contribute such data, both for the purpose of their own health care, as well as for research. In my talk I will take a closer look at the practices of personalisation in medicine and health that citizens are increasingly willing and expected to engage in.
How broad is too broad? Justifying models of consent to research

Dr Mark Sheehan
Oxford BRC Ethics Fellow
The Ethox Centre, University of Oxford

There has been a good deal of ethical consideration given to the acceptability of various models of consent to participate in research, particularly in the context of biobanks. Elsewhere I have argued that broad consent is a valid form of informed consent and so, in appropriate situations, is an acceptable means of enrolling subjects into research.

In this paper I consider other models of consent and the arguments in support of their use (either as required or as permissible forms of consent to research). More particularly, I consider the distinction between broad consent and open consent and focus on circumstances under which broad consent is ethically preferable to open consent. In the final part of the paper I consider the ethical status of forms of consent that may be grouped under the heading ‘interactive models of consent’, in which participants are able continually to modify elements of their consent to participate in research.
Parallel Sessions 2

*Research in “personalised medicine”*

Fri 20 September

1100-1230
Title:
Living Kidney Donation by Minors: An Overview and Analysis of the Proposed Ethical Standards

Authors:
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Abstract text:
Living-donor kidney transplantation is the optimal treatment for children in need for kidney replacement therapy. Compared to deceased-donor transplantation, living donation leads to significantly better clinical outcomes and reduces the risk for potentially life-threatening morbidity and inferior quality of life as a consequence of long-term dialysis. Although parental donation is most common in the pediatric recipient group, also minors have been considered as suitable donors.

In a previous study, we have shown that most guidelines advocate a prohibition of living kidney donation by minors under the age of 18. By contrast, some guidelines exceptionally allow living kidney donation by minors with sufficient decision-making capacity, provided that an independent body determines that the donation would serve the best interests of the prospective minor donor. In light of this lack of clear guidance, a more profound analysis of the ethical aspects in living kidney donation by minors is necessary. Therefore, we aim to analyze and compare the ethical principles that have been proposed in the academic literature in order to guide the decision-making on living kidney donation by minors. For each principle, we will also evaluate its applicability to the context of living kidney donation by minors.

Five different principles will be discussed. First, the principle of autonomy focuses on the cognitive and psychosocial capacity of the minor to provide informed consent to living kidney donation. Second, the principle of best interests focuses on the balance between short- and long-term risks and the anticipated benefits for the prospective minor donor. Third, the principle of ‘clear benefit’ combines the best interests standard with a standard of substituted judgment. Fourth, the intrafamilial principle focuses on the right of parents to make decisions that will benefit the family as a unit, by make trade-offs between the wellbeing of individual family members. Fifth, the intimate attachment principle focuses on the degree of emotional attachment between the potential minor donor and the recipient.

Insight into the strengths and weaknesses of these standards may be useful to support clinicians and donor advocacy teams in decision-making on living kidney donation, in case when they find themselves in a situation in which a minor may be the most suitable or only available living donor. Moreover, this analysis may enable us to develop a more critical and integral approach toward living kidney donation by minors.
Title:
Patient-centered medicine and the interests of the patients’ relatives

Authors:
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Abstract text:
It is a cornerstone of patient-centered medicine that the treatment of patients has to be justified by its conduciveness to the patient’s wellbeing and by his or her informed consent. Treatment that is not in the interest of the patient is usually regarded to be futile and thus not justified. There are some specific interventions that may not entail a benefit to the patient from an objective point of view, but the fact that patients want it or voluntarily consent to it at least suggests that they may associate it with some form of benefit from a subjective perspective. Examples for such interventions are participation in non-beneficial research or living-organ donation (usually for close relatives in need of an organ). Treatment, however, that is performed with the sole purpose and consequence to benefit relatives without the patient’s consent is usually regarded as not being justified. Yet, there is abundant empirical evidence that such treatment is frequently being performed, especially if the patients themselves are incapable to give their consent. Life-sustaining treatment on intensive care units is sometimes continued only to reduce the anxiety of relatives. Artificial nutrition and hydration may be administered during the dying process although it may harm the patient, just because it apparently eases the relatives’ fears and concerns. In this presentation I will analyze whether and under which circumstances it may be ethically permissible to perform treatment that is only in the (presumed) interest of relatives, without having the informed consent of the patient. I will first show that the purely utilitarian and impartial view that would give equal weight to the benefit for patients and relatives is not sustainable in the medical context. The health care professionals’ special obligation towards the patient not only results from the size of benefit, but also from the gravity of the patient’s health care needs. In addition, purely instrumentalizing the patient for the sake of a relative contradicts the Kantian categorical imperative. Such treatment could only be ethically justifiable if three conditions are met: 1) the patient’s presumed consent to the non-beneficial treatment can be reliably demonstrated, 2) the benefit for the relative must be significant and probable, and 3) the relationship between the relative and the patient must be close so that the wellbeing of both partly depend on each other. I will use different paradigm cases to illustrate this position and show how it can be applied to clinical decision making.
Title:
The caregiver steals from the elderly, but it's not our job to do anything…
Moral Case Deliberation at The Dutch Health Care Inspectorate
- A Pilot Study -

Authors:
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Abstract text:
Background: In The Netherlands, the Dutch Health Care Inspectorate (IGZ) regulates public health through enforcement of the quality of health services, prevention measures and medical products. It advises the responsible Ministry of Health, Welfare and Sport (VWS) and applies various measures, including advice; encouragement, pressure and coercion, to ensure that health care providers offer ‘responsible’ care. The IGZ investigates and assesses, independent of party politics and unaffected by the current care system. To regulate, the IGZ uses the following methods of detection: enforcement measures (to ensure compliance with legislation, (professional) standards and guidelines), phased regulation (to ensure efficient and effective enforcement of the legislation for which it is responsible), investigation and monitoring of incidents (investigation of incidents, unsatisfactory situations and ongoing shortcomings in care) and monitoring based on themes (specific issues in health care, sometimes asked for by VWS or parliament).

Introduction: The IGZ pursues an appropriate balance between trust in care providers on the one hand, and regulation on the other. Creating this balance raises ethically important questions. For example, an inspector determines during a visit in a nursing home that one of the caregivers is stealing from the elderly when he washes them. Stealing is not the responsibility of the IGZ and they will hand the case over to the police and the caregiver gets punished. However, it is very likely that this caregiver is going to continue to work in elderly care and thus shall keep on stealing. The inspector wonders: ‘what should I do?’. These ethical questions also raise questions about the profession: what is good regulation? When is it applied in the correct manner? What is a good inspector? What does an inspector need to properly deal with moral dilemmas and normative questions regarding regulation?

In order to identify ethical questions in relation with regulation and to support employees in dealing with these questions, we started a research pilot in which we focus on concrete experiences of primary process employees (senior inspectors and reporting center employees). The ethical questions are systematically discussed by means of Moral Case Deliberation (MCD). In MCD participants systematically reflect on one of their moral questions within a concrete clinical case from their daily practice. The overall objective of this study is to support employees of IGZ in managing ethically difficult situations in everyday practice.

Research questions: In our presentation, we will mainly present the preliminary outcomes of this pilot study. This analysis will contain: 1) identification and analysis of difficult ethical situations in health care regulation (what issues are occurring?), 2) evaluation of MCD as a reflection method for health care regulation and 3) what do participants learn from MCD?

Methods and analysis: Participants will participate in eight MCDs (from December 2012 to July 2013). We will investigate the research questions in several ways. First, participants fill in several
questionnaires (moral competence, coping, normative statements and perspective taking): before the MCDs start (baseline; T0), after 4 MCDs (T1) and after the MCDs (follow-up; T2). Furthermore we will organize two (pre- and post) focus groups; a group interview with all MCD participants from IGZ who will respond to some fixed themes and questions. The pre-focus group interview (to identify ethical difficult situations, current coping with these situations and their expectations of MCD) and a post-focus group interview to identify experiences with the MCD, current coping, (experienced) outcomes and future use of MCD) with 10 senior inspectors and reporting center employees. We will also conduct 5 interviews with IGZ stakeholders on ethical issues and their perspective on dealing with ethical issues. And finally we will analyse the case presentations from the MCDs and the evaluation questionnaires (filled in after each MCD by the participants).

**Results and discussion:** In our presentation we will discuss and reflect upon the main results of this study. Furthermore we will discuss the specific moral themes (on regulation) and the specific context (governmental body instead of health care institution). Finally, we will pay attention to changes in responses to the baseline questionnaire.
Title:
Nurses’ Attitudes towards Futile Treatment and Practices: A Scale Development Study

Authors:
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Abstract text:
Introduction: Unsteady structures of the intensive care environments, the vagueness of the dividing line between life and death and the use of high technology in the field of health often bring the applications of futility onto the agenda. While making the decision of treatment and care to be provided for a terminally ill patient, nurses may face ethical dilemmas due to their caregiver and patient advocacy roles when they manage the care of patients. Although there are many studies in the international literature about futility, there is no scale to measure nurses’ attitudes towards futility. The concept of futility is quite new in our country and thus there is neither a study nor a measurement tool aiming to measure nurses’ attitudes towards futility in the Turkish literature.

Objective: The aim of this study is to develop the first specific measurement instrument to measure nurses’ attitudes towards futile treatment and practices, and to perform its validity and reliability studies.

Methods: The sample of this methodological study comprises 315 nurses working in the adult intensive care units of 6 university and teaching hospitals located in the central region of Turkey. The possible total score to be obtained from the scale ranges between 18 and 90. Lower scores indicate that the participant evaluates futile interventions negatively (in other words, the participant does not approve the implementation of futile interventions), higher scores indicate that the participant evaluates futile interventions positively (in other words, the participant approves futile interventions if they are implemented in accordance with established procedures and principles). Data were evaluated with SPSS 14 software package, Cronbach's alpha, test-retest reliability, item-total score correlations, factor analysis, content validity and construct validity.

Results: The mean age of the nurses was 29.60 ± 5.69. Of the nurses, 81.9% were female, 45.0% were married, and 56.2% had a bachelor degree in nursing. Nurses’ total service time and service time in intensive care units were determined as 8.08 ± 6.00 and 4.46 ± 4.41 respectively. The item-total score correlations and the total Cronbach’s alpha value of the scale were found to be 0.92 and 0.72 respectively. Prior to analysis, the Kaiser-Meyer-Olkin (KMO) value was 0.779 and the Bartlett Test of Sphericity (X² = 1609,801) was found statistically significant (p = 0.001). The scale consists of 18 items and has a four-factor structure.

Conclusion: The Nurses’ Perception of Futile Treatment Scale (NPFTS), can be used as a reliable and valid measurement tool for the evaluation of nurses’ attitudes towards futile treatment and practices in Turkey. The scores obtained by the nurses participating in our study from the Perception of Futile Treatment Scale were above the average. This finding suggests that nurses evaluated futile interventions performed in intensive care units positively and agreed that futile interventions can be
maintained until the end of life provided that they are implemented in accordance with established
procedures and principles.
It is recommended that the validity and reliability of the scale should be tested when it is implemented
in different cultures and populations.
Title:
Decision-making of respiratory treatment in advanced COPD: The perspective of physicians and nurses in pulmonary ward and ICU

Authors:
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Abstract text:
Background: COPD is one of the fastest growing chronic illnesses worldwide. In the advanced stages of COPD the patients’ lung functions are deprived and patients usually develop a wide range of health problems and burdens. When the illness is exacerbated, patients frequently need ventilation support. However, it has, in recent years become more common to use non-invasive ventilation support (NIV), research highlights that 20-30% of patients with COPD need respirator treatment once or more. However deciding whether the elderly patients with advanced COPD will benefit on respirator treatment or time has come for palliative treatment are complex decisions. Recent research from Norwegians ICUs elucidated that physicians and nurses experienced a growing ethical dilemma of multi-morbid, very old and fragile patients with marginal benefits from ICU treatment, i.a. some patients with advanced COPD, were given advanced ICU treatment at the end of life. The same research elucidated moral dilemmas with regard to rarely knowing the patients preferences and values, since there seldom was communicated to the patients about these issues, in times when their condition accepted it. It is imperative to gain knowledge on how physicians and nurses communicate with patients with severe COPD about their preferences according to advanced ventilation treatment. In addition there is a need of this knowledge from the perspective of patients.

Aim: The aim of this paper is to elucidate considerations according to decision-making of respiratory and NIV treatment in advanced COPD from the perspective of nurses and physicians in pulmonary wards and ICUs. Further it is to shed light on the health care personnel's reasons for not communicating about vulnerable and complex issues according to the patients preferences of withholding advanced ventilation support.

Method: This paper is part of a larger project «Elderly with advanced COPD: Care and clinical priorities» within the qualitative research paradigm. The aim is to gain knowledge of the preferences and values of elderly patients, suffering from advanced COPD according to advanced ventilation support. Further it is to reveal a deeper meaning of the actions and choices taken by nurses and physicians in ICU and pulmonary wards in their clinical decision-making about respiratory and NIV treatment in advanced COPD. Patients are interviewed individually when not being hospitalized. Nurses and physicians from pulmonary wards and ICUs are being interviewed through focus group interviews. The results will be analysed through qualitative content analysis and interpreted in a perspective of care ethics and other relevant theories.

Preliminary results: The preliminary results indicates that there are gaps in the insight of the nurses and physicians according to the preferences of patients and that communicating with patients about this complex and sensitive issues rarely happens. Further it seems like it is a divergence associated to the reasons the nurses and physicians are giving for not talking to the patients about their illness and the consequences of the deterioration of their illness.
Title:
Evaluation of the Behavior of Health Workers, Who Have a Chronic Disease on Themselves or on Their Relatives, while Providing a Healthcare Service to Patients Having the Same Disease

Authors:
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Abstract text:
Objective: In this research our aim was to investigate and evaluate the behavior and attitude of health workers when they have a chronic disease on themselves or their relative, while providing a healthcare service to patients having the same disease.

Material and Method: This study was performed on November 2012 in Inonu University Turgut Ozal Health Center located in Malatya which is a provincial city in Turkey and total of 1178, lecturers (physicians), research assistants (physician assistants) and nurses providing a health service in this center consisted the universe of this study. For the purpose of this research, a survey was conducted with the help of lecturers, research assistants and nurses providing the healthcare service in Inonu University Turgut Ozal Health Center. The answers to this survey were evaluated in SPSS 15.0 program Pearson Chi-Square, Yates Corrected Chi-Square and Fisher's Exact Test and results such as P<0.05 were accepted as reasonable.

Conclusions: According to our research we made, we found that the most important factors affecting attentiveness to patient with a chronic disease were respectively found as; gender (OR=2.35; 95% CI=1.06-5.17), working years (OR=0.53; 95% CI=0.32-0.88), and profession. (OR=0.22; 95% CI=0.075-0.667) As can be understood from this analysis, factors like gender, working years and profession are related with “being more attentitive” on to their patient with a chronic disease.
Title:
A Code of Conduct as institutional answer to the specific ethical challenges that come with biobank-based whole genome sequencing

Authors:
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Abstract text:
Questions: Breakthrough discoveries in genomics allow the sequencing of the human genome within a couple of days at a reasonable price. In translational cancer research, whole genome sequencing helps to identify the molecular lesions that drive tumour growth in individual tumours thereby guiding the development and clinical testing of targeted therapies. However, genomic research also raises specific ethical questions. The EURAT Project in Heidelberg addresses these normative questions. It aims at further developing an ethically and legally informed practice for genomics-based stratified oncology in Heidelberg.

Arguments: This paper identifies two key ethical challenges that come with whole genome sequencing and the scientific interest in sharing sequencing data as unrestricted as possible: (1) since the genome is inherently self-identifying, measures of data protection like anonymization and pseudonymization can be circumvented as soon as only a short sequence of the one’s DNA is somewhere connected to accessible personal data. Therefore, the scientific value of easily accessible data needs to be balanced against the right to privacy. (2) In contrast to other advances in research or clinical diagnostics where occasionally findings outside the research or diagnostic field of interest are registered (incidental findings), whole genome sequencing produces findings beyond the research question with a high likelihood (additional findings). Therefore, the handling of additional findings and potential preferences for re-contacting the patient or donor need to be addressed.

Results: This paper drafts answers to the ethical and practical challenges with regard to the handling of incidental findings, confidentiality and sharing of genetic data and the informed consent process. It also presents a Code of conduct as an institutional ethics response to the question, how research institutions can foster the responsible handling of genetic information in genomics-based translational research throughout the institution.

Conclusion: The code of conduct should inform the conduct of all employees concerned with the handling of sensible genetic data. However, a well-balanced equilibrium between scientific interest and protection of privacy in international research requires coordinated measures and standards that allow for sharing of genomic data from whole genome sequencing while protecting access to complete genomic datasets.

Funded by the Marsilius Kolleg, Heidelberg and the NCT- Precision Oncology Program
Title: Who owns biological specimens taken for research?

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Abstract text: The question in the title has only become pertinent in light of the recognition of the economic value of human tissue. The law has never dealt with the ownership of human tissue. A number of legal cases have drawn attention to the matter of ownership relating to human tissue:

*Washington University v. Catalona (2006)*: The Court ruled that individuals who make an informed, voluntary decision to contribute their biological materials to a particular research institution for the purpose of medical research do not retain ownership of those materials. The controversy around the *Henrietta Lacks case* is discussed, where the HeLa cell line (which originated from her biological samples) has generated significant financial gains from bio-medical research which her family have not benefited from.

*Moore v Regents of UCLA*: In this case the court concluded that Moore retained neither a possessory nor an ownership interest in his cells after they were removed.

The ownership of one’s body cannot be equated to the “ownership” of one’s spouse, children or dog amongst others. Veldman identified four elements are necessary to establish ownership:

i. Use - that is morally and legally sanctioned;

ii. Possession: - right to bodily integrity;

iii. Exclusion - the right to exclude access; and

iv. Disposition - the ability to dispose of property.

Van Niekerk adds a fifth element namely, that of individual ‘will’ to maintain control over one’s body.

The conclusion is that the body is not simply a thing among other things and thus not merely an object for commercial transactions or a commodity. As human beings we possess certain rights in terms of what happens with our body parts. It is thus problematic that huge profits are made out of medical research especially as the original “owners” who donate body parts appear to “give up” ownership.
Title:
Ethics in biobank governance
Interdisciplinary approach to ethical issues in biobanking for genomic research

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Abstract text:
The creation and operation of population-based research biobanks involve several ethical, social and health policy issues, such as: questions of informed consent, confidentiality and data protection, non-discrimination, commodification and intellectual property rights, and feedback of individual findings to participants. More recently, governance has become another topic of concern in the public discourse and in academic literature on biobanking. In fact, governance frameworks affect both the functioning and the priorities of biobanks, and shape interactions between the biobank and the society of which it is part.

Ethical, social and policy issues related to governance are particularly relevant to population-based biobanks for genomics research. This type of biobanks requires continuous collection of data and information over extended periods of time, and presupposes long-term participation and commitment by participants. Moreover, large-scale population biobanks raise several concerns of broad public interest, such as issues related to benefit sharing, involvement of private actors in the exploitation of the biobank, and the setting of research priorities. In this context, governance models cannot be solely understood as top-down management structures aimed to ensure that the biobank achieves outcomes such as quality of collection and storage, or security and integrity in access to samples and data, within the relevant system of regulation. Rather, biobank governance should be considered as an issue to be discussed and negotiated within the public arena. Governance frameworks should be developed by taking into account interests and perspectives of the various stakeholders concerned in biobanking (e.g.: patients, research participants, citizens, researchers, health professionals, policymakers), since their engagement is the key to promote public trust and potential social value of biobanks.

We would like to discuss our interdisciplinary approach to ethical issues in biobank governance in the context of institutional biobank initiatives for genomics research. In particular, we want to address questions related to public engagement and benefit sharing in prospective biobanking, critical issues of interdisciplinary work in practical ethics, and more general questions about the role of ethics in biobank governance.
Title:
Biobank and consent: an analysis of German consent documents for biobank research

Authors:
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Abstract text:
Background: In biomedical research the significance of bio(material)banks has been growing. Biobanks are collections of human samples and related health information. They are used among others for basic research, research in personalized / stratified medicine (biomarkers) or on widespread diseases. This development also has implications in ethical, legal and social aspects, for instance regarding data protection and consent of the donors. An informed and voluntary consent is an established concept to protect patients’ rights and autonomy. As acquired for clinical procedures, the patient’s / donor’s consent is an ethical and legal precondition for the collection of samples and clinical data in a biobank. Crucial points are the scope and content, especially considering future research projects (broad / general consent vs. specific consent). Up to now there has been no systematically developed “best practice” model of consent available for biobank research. Several ethical guidances exist for biomedical research (e.g. CIOMS 2002, Declaration of Helsinki 2008). Nevertheless, there is not a specific guidance for biobank research and consent procedures serving per se as an assessment tool for consent documents.

Methods: We performed a survey on presently used consent documents in German biobanks. Within our sample we considered all biobanks registered in the “National Register of Biobanks” (July 2012). First we developed an assessment matrix that presents issues that might be addressed in consent templates regarding biobank research. We referred to prominent policies and guidances dealing with general recommendation for consent procedures in biomedical research (clinical studies) and / or biobank research. Second we assessed the extent to which each individual consent template of our sample mentioned the issues presented in our matrix.

Results: Our assessment matrix on consent issues in biobanks comprises 41 items, subsumed within the categories „General information“ (e.g. item “Research explanation and purpose”), „Conditions of participation“ (e.g. item “Right to withdraw or alter consent / without disadvantage “), „Consequences of participation“ (e.g. item “Feedback on findings or incidental findings “) and “Dealing with data” (e.g. item “Confidentiality of records and data / extent and limits of confidentiality“).

We included 31 consent documents of German biobanks in our analysis. The distribution of the detected assessment items was very heterogeneous. The number of items addressed in the consent documents ranged from 6 to 28. The item „Dealing with data and material after participants die or become incapacitated “, was not mentioned in any document. At the conference I will present the assessment matrix, its development process, and the consideration of the items in our sample.

Discussion: The results of our survey on informed or broad consent documents in German biobanks speak in favour of the improvement and harmonisation of such documents. The results shall contribute to a systematic and transparent development of a „best practice“ model of consent for biobank research. Further steps should include the discussion of a consent template with stakeholders (e.g.
researchers, research ethics committees, patients’ representatives, and ethicists), a user testing with (potential) biobank donors and the further evaluation of the model, once applied in practice.
Title: Consent in genomic research. A review of socio-empirical research and ethical analysis

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Abstract text:

**Background:** New technologies such as genome wide association studies and related biobank research challenge concepts and practices of informed consent for research participants. In this paper we present data of socio-empirical studies on the perceptions and views of research participants regarding consent in the context of biobank research and provide an account on how such data can inform the debate about normative aspects of appropriate consent.

**Method:** A literature search was performed in PubMed to identify socio-empirical studies on research participants' perceptions and views regarding consent in biobanking published before 23rd October 2012. The data of empirical research are analysed against the background of key issues discussed in the ethico-legal debate on consent in biobank research.

**Results:** The search in PubMed generated 244 abstracts. 64 articles fulfilled the inclusion criteria. Main results of the review of socio-empirical literature comprise the limited understanding of research participants with regards to biobank research, preferences of participants regarding characteristics of the informed consent procedures and concerns for privacy and data sharing. Moreover the review indicates that factors such as country specific and institutional aspects (e.g. owner of biobank) or the model of consent used in research practice, as well as socio-demographic characteristics on side of the research participants, may influence perceptions, views and choices regarding biobank research.

**Discussion:** The review of the socio-empirical literature provides a starting point for critical reflections on information in biobank research. While much of the normative analysis focuses on the problems associated with lack of information in biobank research, the data of empirical literature indicate that even in cases of available information research participants have limited understanding of the matter to which they consent. Furthermore the reviewed empirical research indicates that there are a number of context factors (e.g. owner of biobank, culture and country specific issues) which seem relevant for a morally appropriate practice of consent but which are little discussed in the normative debate. Taking the aforementioned and other supplementary examples we will show how further interdisciplinary empirical-ethical research can inform and contribute to the development of consent models for biobank research.
Title:
Patient and physician Perspective on informed Consent
Ethical requirements and information needs of patients donating tissue for biobank-based genomic cancer research

Authors:
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Abstract text:
Background: The German ethics council explicitly asks to develop and validate workflows that ensure the right of self-determination of biobank donors. Biobank-based genomic research is one of the cornerstones of current cancer research since it allows for sequencing of larger samples of the same tumor entity. In cancer research, whole genome sequencing helps to identify the molecular lesions that drive tumour growth and thereby provide the basis for the development of targeted therapies. However, biobank-based genomic research also raises specific ethical questions concerning the content and process of informed consent. So far there is no common practice, or quality standards for the informed consent process and only scarce data about the information needs of patients before they consent to donating their tissue for cancer research. The aim of this project is the development of an informed consent process that supports patients in their decision-making about donating tissue for research projects using genome sequencing. It is part of the Precision Oncology Program as well as the EURAT Project (Ethische und Rechtliche Aspekte der Totalgenomsequenzierung) that aims at developing an ethically and legally informed practice for biobank-based genomic research in Heidelberg.

Method: This project will use the qualitative research method of focus groups, consisting of physicians, scientists and patients of the National Center for Tumor Diseases, to answer the following questions: How much and what information and support is required by patients to decide for or against the donation of material for genome sequencing. And how can the process be tailored to the needs of individual patients and at the same time be integrated in the workflow of patient care in daily clinical life?

Results: We hypothesize that important aspects are privacy protection measures, data sharing protocols and dealing with incidental findings. By the time of the conference we will present the results a literature review about the information needs of patients and donors for biobank-based genomic research and the first data analysis from the focus groups, that we are planning for June 2013.

Conclusion: In this paper we will give an overview about the ethical aspects and information needs of patients before they consent to donating their tissue for biobank-based genomic cancer research.

Funded by the NCT Precision Oncology Program
Title:
Alarming symptoms of a paradigm shift? An approach to bridge the gap between hypothetical ethics and the current status of IM-research

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Abstract text:
The analysis of the ethical discourse on Individualized Medicine (IM) shows that the most extensively studied areas are (still) relatively far away from a practical implementation. The discussion of the IM as an engine of a "dictatorship of prevention", in which IM is placed in the context of the ethical acceptability of mandatory screening tests or the rejection of the principle of solidarity under the banner of personal health responsibility, can be understood as a prime example.

However, such discussions are situated within the range of a purely "hypothetical ethics", since the extensive medical knowledge and applications they are based on merely exist in the anticipation of potential successes, rather than the outcome of the real research context of individualized medicine, which - particularly in the area of complex diseases - does not go far beyond the level of rather trivial recommendations for a fundamentally healthy lifestyle. On the other hand, if one focuses on the reality in the field of IM research, it becomes evident that there are promising approaches mainly in two areas, both of which are not very promising for „hypothetical ethics“: The fields of biomarker-based prediction of the course of a disease (e.g. in oncology) and the biomarker-based prediction of the success of drug and non-drug interventions.

The progress in research in Germany's largest joint project for IM, GANI_MED - Greifswald Approach to Individualized Medicine - exactly points in that direction: The promising studies within GANI_MED refer to limited and clearly defined questions. The endocrinologically-based prediction of the course of a metabolic syndrome and the use of biomarkers for the prediction of treatment response for immunoadsorption in dilated cardiomyopathy are to be named here as respective examples.

Obviously, both tendencies can be understood as examples for the ethical problems of marginal utility, but they certainly give no reason for an alarmist self-promotion of bioethics. Even if one concedes that the alarm calls of bioethics have been provoked through excessive promise of healing and output (etc. "IM as a paradigm shift from curative to preventive medicine") of IM-propagators and stakeholders in medicine and human biology, it has to be noted that the current status of research raises a very differentiated and, in parts decidedly, clear-cut record: The biomarker-based IM is - according to the thesis of the authors - certainly not the new paradigm of medicine, but a research approach, which may contribute progress in very limited areas in medical care.
Title:
Personalised medicine and the ethics of Radiology

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Abstract text:
Whilst much of the debate surrounding personalised medicine has focussed on genomics and the pharmaceutical industry, the emergence of some of the newer radiologic technologies has the potential to raise yet more complex ethical issues in this area.

Techniques such as 3D ultrasound, functional MRI and PET scanning all have the potential to reveal structures and functions of the human body that could have implications for the patient’s future healthcare needs and this paper would like to argue that the revelation of this information may not always be in the patient’s best interest.

The issues raised by these new technologies are mainly polarised around the issue of informed consent, and whilst many patients undergo these procedures so their symptoms can be explained, we are now facing a scenario whereby technology can reveal conditions that would have otherwise have gone undetected. Once these conditions are detected, however, concerns around disclosure and inability to provide a cure begin to emerge.

This situation is further compounded by the fact that traditionally radiologic tests were used to diagnose patients presenting with specific symptoms but public health issues are now promoting the screening of the asymptomatic “worried well” who may opt to self refer and take advantage of what has been termed “retail radiology”\(^1\) Members of the public can then pay for a CT scan from a commercial company which promises early detection of heart disease, lung cancer, colon cancer, aneurysms and osteoporosis. This provision has the potential to increase patient choice but sometimes at the cost of raised anxiety due to the potential for the increase of false positives and over diagnosis\(^2\).

Whilst self referral practices have been widely criticised\(^3\) there is no escaping the fact that predictive radiology has major implications for the future. Advances in PET and MRI have produced studies that identify a predisposition to life changing diseases such as depression\(^4\) and psychopathic tendencies\(^5\) and this has obvious issues relating to disclosure and patient welfare.

So whilst a future where we can detect and treat most diseases in their infancy has great appeal we need to question the ethicacy of early detection without realistic cure and debate the issues that evolve from the development of ever more accurate and sensitive radiologic procedures.

References:
Final Symposium of BMBF-Collaborative Research Project
“Personalised medicine in oncology – ethical, medical, health economical and legal aspects”

Coordination: Prof. Dr. Dr. Jochen Vollmann

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Jan Schildmann et al.
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1120-1140
Matthias Port et al.
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Franz Hessel et al.
Developing personalized medicine drugs – Incentives for pharmaceutical companies

1200-1220
Sina Gottwald, Stefan Huster
Personalised medicine and Orphan drugs. A legal analysis

1220-1230
Discussion
Title:
Information and consent in "personalised medicine". Findings from interdisciplinary research on normative and practical aspects

Authors:
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BMBF-Collaborative Research Project “Personalised medicine in oncology – ethical, medical, health economical and legal aspects”
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Abstract text:
Normative and practical aspects of information and consent in the context of biobank research are at the centre of the debate on ethical issues related to individualised medicine. In light of the limited possibility to inform research participants about the future use of genetic and clinical data at the time of eliciting consent different models of consent have been suggested to handle this challenge. Next to normative characteristics of the various models of consent (e.g. informed consent, broad trusted consent, blanket consent) there are also a number of descriptive presuppositions associated with the different approaches to information and consent. Furthermore, application of the different models of consent in research practice poses distinct challenges for the involved researchers, research participants and the society.

In this presentation we summarise findings from interdisciplinary research within the BMBF-Collaborative Research Project “Personalised medicine in oncology – ethical, medical, health economical and legal aspects” on the topic of information and consent within the context of biobank research. The focus will be firstly on the findings of a literature review regarding socio-empirical research on perceptions and views of (potential) participants in biobank research regarding information and consent. Secondly, we will report characteristics of a dynamic-dialogical model on information and consent which has been developed following an interdisciplinary analysis of current practice of biobank research with cancer patients.
Title:
Cost-of-illness study in patients with cytogenetically normal acute myeloid leukemia

Authors:
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Abstract text:
Introduction: Modern treatment of acute myeloid leukemia (AML) is more and more based on the genetic profile of the disease. Standard treatment consists of induction followed by consolidation chemotherapy. Allogeneic Hematopoietic stem cell transplantation (allo-HSCT) is the treatment of choice for patients with high risk of recurrence in first clinical remission. AML with normal karyotype (CN-AML) is considered to be intermediate risk. Nevertheless an increasing number of mutations have been identified in the last years which have an enormous prognostic but even more important a predictive impact in whom to proceed to allo-HSCT in first complete remission (CR1) and in whom not. Due to molecular classification the German–Austrian Acute Myeloid Leukemia Study Group (AMLSG) has changed the allocation of allo-HSCT in CN-AML in CR1 from a related donor in all patients if available to molecular based risk classification and allo-HSCT from matched related and unrelated donors in all patients with a high risk profile. Aim of this study is to assess the costs of illness for CN-AML.

Methods: Hospital data and charts have been evaluated with regard to Diagnosis Related Groups (DRG) and uniform evaluation matrix (EBM) to evaluate cost data. Relevant items of costs identified to be addressed were diagnostic procedures prior to therapy, donor search in case of allo-HSCT, induction- as well as consolidation therapy, conditioning, allo-HSCT, salvage-therapy and complications based on inpatient data. For outpatient costs relevant items are for instance consultations, technical examinations, drugs or laboratory analysis.

Results: 52 Patients could be evaluated for cost data. Costs for molecular profiling in CN-AML are about 1,000 €. Inpatients costs were for instance about 24,000 € for induction therapy and around 100,000 € for SCT. Direct costs and follow-up costs after treatment completion are much higher when allo-HSCT is performed. Costs for outpatient performances are still in evaluation due to extensive and complex data.

Discussion: Treatment recommendations based on the molecular profile in CN-AML have extensive impact on costs. Possible cure has to be weighed against prolonged treatment duration in patients receiving allo-HSCT and to end up finally with a cost-benefit ratio. This Cost-of-illness study generates data to be used for a consecutive cost-effectiveness study.

Perspective: After integration of clinical data and costs of in- and outpatient-treatments into a Markov-Model the results could help to understand the effect of new treatment schedules and allocation of resources necessary for modern biology based therapy in CN-AML.
Title:
Developing personalized medicine drugs – Incentives for pharmaceutical companies

Authors:
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Abstract text:
Objectives: Stratification of oncology drug therapy by genetic marker diagnostics can reveal additional patient benefit but also might influence the development process of drug manufacturers. The objective of this study is to identify and describe the most important incentives for pharmaceutical companies to develop personalized medicine drugs.

Methods: To describe the main factors influencing the decision-making process in the development of personalized medicine drugs we designed a qualitative systemdynamic-model. The main factors influencing the process and their priority ranking were determined by systematic literature search, structured expert interviews with pharmaceutical companies, test manufacturers and other key stakeholders such as regulatory bodies, reimbursement decision makers and payers. The model was build with the Consideo iModeler software package.

Results: In contrast to small companies big international companies constantly look for suitable companion diagnostic tests to select subgroups of high responder. The most important key factor for market success is the extent of clinical efficacy in comparison with competitors respectively the current treatment standard. Stratification of patient populations according to treatment response or frequency of adverse events using biomarker is regarded to increase clinical efficacy of the target indication. The test performance is important due to unsolved safety issues although not regarded as crucial for the success of the drug. In contrast to other stakeholders pharmaceutical companies did not consider personalized medicine to relevantly decrease development costs or marketing efforts respectively to increase the price potential for new drugs. A low prevalence of the remaining patient population after testing is not irrelevant but it is not seen as a factor which might lead to a stop of the development of a new drug by pharmaceutical companies.

Conclusions: Genetic stratification is seen as a breakthrough in cancer therapy by pharmaceutical companies and physicians. Due to the current need for improvement of approval and reimbursement processes for personalized medicine approaches in oncology especially in Europe future sales are more difficult to predict.
Title: Personalised medicine and Orphan drugs. A legal analysis

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Abstract text: The development of Personalised Medicine is currently a popular topic. Particularly the personalised pharmacotherapy is a matter of relative importance due to pharmacological and molecular-genetical development. For this reason it is required to examine the implications of personalised pharmacotherapy to German statutory health insurance and health care of patients. In this context the question of orphanization arises: If medical drugs of personalised medicine could be regularly indicated as orphan drugs, i. e. as drugs to medicate orphan disease, it would not be necessary according to the Arzneimittelneuordnungsgesetz (AMNOG) to prove an auxiliary value within the assessment of the Gemeinsamer Bundesausschuss (GBA). Crucial to the drug's indication as an orphan drug is among other things the rate of prevalence of the patient group, whose disease should be medicated with the drug. In this connection there is attached importance to the stratification of patient groups within Personalised Medicine. An orphanization causes consequences in terms of prices to the statutory health insurance because the lack of knowledge about an auxiliary value. The implications to the patients must regard more differentiated.
Poster Session

Friday 20 September

1245-1315
Title:
Elderly Person as a Patient: Psychological, Ethical and Educational Aspects

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Abstract text:

Abstract: Geriatric care in Bulgaria is facing many challenges. A level of professionalism is needed for the implementation of quality health and social care for the ever-growing number of adults and elderly people who need its support. This study attempted to draw up specific problems of occupational health professionals when providing medical care for elderly people and specified educational needs in the field of person centered care for elderly. The carried out study establishes and analyses the specific difficulties of the occupational health professionals in providing medical assistance for old people and specifies the educational needs in the field of of person centered care for elderly and personalised medicine. To achieve this, the following methods of research were used: critical analysis and synthesis of scientific literature on the research problem; documentary method - national and European documents were examined, inquiry method - direct inquiry. Respondents are 1875 people in 10 cities across Bulgaria. Results: Determined are the main reasons for the difficulties of health professionals in taking person centered care for elderly patients. Educational needs of 940 respondents - professionals in health care are in the following areas: specific manifestations of disease in adult patients, age changes in mentality and behavior, communication skills for working with adult patients and dying elderly, patient-health professionals relationship, training in health care for chronically ill and their families, aging prophylaxis. According to 2/3 of the 935 adult patients respondents, communication skills, patience and responsiveness are the mostly needed qualities that health professionals have to possess besides their professional competence for implementation of treatment and care. Conclusions: Based on the survey data, recommendations for improving the healthcare for elderly and adapting the educational training of health professionals were prepared in order to realize the requirements for competent person centered care for elderly in Bulgaria and personalised medicine. Adequate education and training of such professionals is a necessary first step toward a more compassionate, humanistic, and dignified care of the elderly. To meet the greater challenges facing health related to demographic aging in the coming years and provide for aging senior citizens, requires international cooperation on all levels.

Key words: person centered care for elderly, health professionals, educational needs, psychological aspects, ethical aspects, patient-health professionals relationship

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Application of ethical matrix in case of consumption of genomics goods for the purpose of enhancement

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Abstract text:
The last decade showed an increasing international interest in the area of consumption of genomics goods and in the same time ethical concerns. The genomics goods like targeted drugs and genetic tests are used for prevention, treatment as well as enhancement and certainly the industry governs the evolution of such products and makes difficult a real estimation of the benefits from societal and individual prospective. Generally speaking the enhancement as such is beneficial for society and is in the interest of society to use it (Harris, 2007) but by exploring the ethical dimension of consumption of genomics goods by individuals and by society for enhancement purpose due attention should be paid to global market trends and to public health policy.

In this context the article investigates whether the ethical principles such as autonomy, solidarity and justice could be used in evaluating the premises for decision making process in case of consumption of genomics goods, of investigating whether the decision to support the costs of such enhancement products by public health system is ethically justified. The methodology is based on ethical matrix elaborated by Mepham (Mepham et al. 2006) initially used to facilitate ethical deliberation. The method use a set of principles applied to a set of very well defined interest groups.

The interest groups for our case are represented by: companies/industry producing genomics goods, consumers/citizens, society, future generation, health insurance companies, policy makers.

The research investigates which of these three principles offer a better coverage of the citizens and society interests and whether the combination of two out of three principles is useful for ethical evaluation of the consumption of genomics goods by society for enhancement purpose.

References:

Title: Challenges for the Personalized Medicine in Bulgaria

Authors: L. Chakarova, P. Balkanska, S. Mladenova

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Abstract text: Personalized medicine is the next stage of the medical science development. It represents another step further of the evidence-based medicine. Neither of the stages through which medical science passed in its development could overcome the moment “trial-error” in the treatment of the ill, which patient today understand and cannot always justify, especially from the moral point of view. The personalized medicine will contribute mostly to medicine as a field of human knowledge to be again “science and art”, but to be nearer to the exact science and to rely less on the intuition and the morality of the individual physician. The perfect diagnostic technology, what is personalized medicine, is on the way to realize the great dream of people - to live as healthy persons as longer as possible. At the same time mankind has the task to cope with the diseases, which are genetically grounded and for which medical decisions are necessary which surpass the contemporary boundaries of science. The idea of personalized medicine represents at the same time a real challenge, if not a revolution to the health systems of the separate states. It is extremely innovative, but expensive and requires a new approach, standards and computer systems. And in spite of that we are on the threshold of this jump in the development of medical science, which is at the same time inevitable. That is why we carried out an investigation among medical professionals - doctors and medical nurses specializing at the Faculty of Public health in the Medical University- Sofia with the purpose to examine their opinion about the introduction of personalized medicine in Bulgaria and their vision of the ethical problems which it states.

The method of examination is anonymous sociological questionnaire. Inquired were 85 medics totally. Data have been put to statistical processing and interpretation.

Results show, that the idea of personalized medicine is as a whole not quite clear, its concrete realization is estimated as impossible in the near years and even decades, having in mind the price of only one gene identification. As a conclusion we can formulate that participants understand that personalized medicine will enter into practice in the future because it is a logical and unavoidable stage in medical science development but it will take a long time and the scope of application will be limited.

Key words: personalized medicine, medical specialists, gene identification

References:


Title:
Advance Directives: an improvement tool for the quality of care

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Abstract text:
In Spain, Advance Directives allow people to manifest their wishes concerning health care treatment in advance. It is possible to include the expression of the end-of-life decision making, always within the legal frame.

The aim of this abstract is to show the importance of Advance Directives within the palliative care. This document eases the health care professionals’ decisions concerning patients that are not able to decide.

Ten years ago, the Law 41/2002 that regulates the patient’s autonomy and rights and obligations of information according clinical documentation; introduced the Advance Directives in the Spanish legal frame. With Advance Directives a person of legal age, competent and free, manifests his/her will in advance. This way, the will is enforceable in the moment he/she will be unable to express the health care treatment he/she would like to receive. The future patient can also express in this document the fate of his/her organs or his/her body after dying. The patient may also designate in the same document a representative who will act as a speaker between the patient and the doctor or the health care team; in the case it would be necessary. In Spain, this is a formal document that is legally binding, either for the health care professionals or patient’s relatives and caregivers.

However, it is not possible to include any wish in this document. Advance directives must not be against the legal system or the lex artis. It is not possible to enforce advance directives related to different medical cases than the ones expressed in the patient’s will.

Palliative care professionals have a difficult task within the health care whether a person’s life should be sustained, or whether it can be permissibly be ended, will depend on the doctor’s view of the goals of medicine. But even more so, it will depend on the patient’s interest and values. The Advance Directives constitutes a useful tool to protect the patients’ autonomy and enforce the end-of-life decision making previously expressed. This way it will be easier to improve the quality of care, according patient’s wishes.
Title: Beneficence and Autonomy reappraised: a new model of relationship between doctor and patient

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Abstract text: Over the last 50 years, the patient’s freedom has become the hallmark of the patient-physician relationship, while beneficence has moved away from the central point it has held until now. In the era of bioethics, autonomy is considered to be one of the master principles of bioethics, and it should not be long before it takes the lead within the medical setting. Unfortunately, some scholars believe that the principle of beneficence is strictly tied with paternalism characterized by maximum physician discretion while autonomy emphasizes the patient involvement. The misunderstanding about beneficence and autonomy relies on the fact that they are considered as separated principles, as in the Beauchamp and Childress theory, or even contrasting, as in the Engelhardt theory. This may be troublesome in some ways. In fact, the profound “raison d’être” of the importance of autonomy is tied to the principle of beneficence. Everyone seeks happiness (beneficence), but no-one can reach it unless given the opportunity to choose freely, that is, consciously and without constriction. Therefore, the good of the patient cannot be achieved without promoting his or her right to autonomous choice. Enlightened by these considerations, we started to consider autonomy as a means to achieve the good of the patient and not a principle beside or even contrasting with beneficence. Consequently, the so-called informed consent becomes an indisputable means of support to autonomy through which to attain beneficence. These considerations have persuaded us that we need a new model of consent process where the attention must be put on awareness rather than on information. The new model of consent must avoid extreme circumstances: the unilateral decision of the physician with total disregard for the role of the patient, the unilateral decision of the patient where the physician is deprived of authority, an excess of information or a complete lack of information. Furthermore, we strived to avoid a simply formal and aseptic interpretation of consent totally lacking an appropriate hierarchy of values and priorities. But if the fundamental duty of the physician is to make sure that he or she is aware of, and has genuinely understood, the risks and benefits of the proposed treatment and of alternative procedures and treatments, then the concept of informed consent doesn’t work anymore. For these reasons, our reflection led us to shift from the concept of “informed consent” to a more explanatory term of “conscious consent”.


Title:
Quality of life and clinical ethics - the way to the patient

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Abstract text:
Background: Progress and introduction of modern diagnostic and medical technologies into the medical practice, standardization of diagnostics and treatments from positions of demonstrative medicine led to paradox in modern medicine, expelling of the major principle of doctoring «to treat not illness, but patient». These are accompanied by deterioration of treatment effectiveness and dehumanization of medicine. Possible break of deadlock in medicine today is recognition of the patient's autonomy, studying of his/her quality of a life (QOL) which is an integral stage to make the decision in clinical medicine, and clinical ethics. QOL has been found to be impaired both in patients with Asthma and in patients with Diabetes Mellitus, but the relative burden of these diseases has not been investigated.

Method: 102 patient with Asthma and 78 patients with severe course of Diabetes Mellitus (DM) participated in the study. The patients completed a Ukrainian version of short Form Health Survey - 36 (SF - 36) questionnaire. Asthma was not controlled in 45% patients, controlled in 55% patients. 38% of diabetic patients had compensated DM and 68 % - subcompensated DM. Socio-demographics and clinical parameter characteristics (the diagnosis, treatment management, sex, age, body mass index, and blood pressure) were indicated.

Results: Total parameters: physical (PCS), mental (MCS) health, and separate indexes of these scales was appeared significantly decreased in patients of both groups. Essential distinctions of parameters of QOL at DM are revealed: gender distinctions of physical health at DM isn’t revealed, and women’s mental health was lower than men one. Another result was obtained during examination of patients with Asthma: lower PCS was established in women in comparison with men; MCS decreases at men. At the patients, suffering from DM, parameters QOL was increased at young patients (till 30 years), was lowered in patients with obesity (BMI > 30 kg/m²). The lowest levels of QOL were found in patients with DM type 2. The lowest parameters of QOL at asthma patients were detected in young patients, even at the easy form of disease, an elder patients’ adaptation for disease were better. PCS was lowered, MCS was raised in patients with overweight (BMI >24< 30). Both parameter decreases at BMI> 30 kg/m². The arterial hypertension was the universal factor worsening QOL at diabetes and asthma.

Conclusion: The SF-36 Health Survey is the most widely used self-report measure of functional health. It has a primary advantage of ease of administration which allows estimating a disease by the patient himself, to reveal «critical factors», influencing on QOL in each individual case, to establish the possible reasons for a low assessment the patient of the physical, mental, social possibilities. In addition, it provides a vehicle for quickly screening patients for readiness and specific treatment-related concerns. By consideration of the ethical problems arising at dialogue of the patient and the doctor, it is necessary to consider results of its research QOL.
Title: “Dr Paparazzi- What's The Worst That Could Happen?” - Ensuring patient confidentiality in the modern age of mobile technology

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Abstract text:
Objective: When the United States Department of Health and Human Services (HHS) issued their latest guidance on the production and storage of clinical images in December 2012, questions were raised about the plans to use social media in patient education by the department and guidance on medical imaging may have been overlooked in recent years. Especially where almost all clinical staff are in possession of a powerful and portable camera as part of their smartphone.

Method: In this review the current National Health Service (NHS) policies on digital imaging will be examined, with a focus on hardware which is not owned and regulated by the NHS Trust. In the United States clinicians have already been challenged medicolegally for the misuse of digital images of patients. By reviewing the outcomes of these lawsuits, the UK policies and data protection act, European Human Rights Act and the latest American HHS guidance, important lessons can be learned to prevent clinicians failing their duty to patients.

Results: The regulation of these devices in the clinical setting is fraught with difficulties.

Where medical staff in senior and training grades are encouraged to present and publish their experiences and work, the access to medical images is important to capture interest in their work when it comes to visual presentation and also to improve their memory of the event for write up.

The distinction is made between therapeutic and non therapeutic medical photography in the literature. Both play an important role in modern healthcare and as is well defined in policy the consent procedure which accompanies the capture, storage and use of such images. Now Medical Illustrators are registered professionals in the United Kingdom and provide excellent skill and advice. To allow clinicians to function properly these allied professionals require their skills recognised and utilise to maintain standards in medical photography.

More interesting is the use of off the record photography on mobile telephones in the clinic and operating theater. While many national health trusts have policies prohibiting the use of non trust photography, many do not. It is reported that only one third of UK emergency departments have relevant policies governing medical imaging, of these just 5% have a written policy concerning consent for clinical and educational photography.

Trainees and clinical staff need to be trained in the appropriate use of medical imaging, the consent process and their local and national policies. This review will explore what has led us to the current position and where it would be most beneficial to go given the world wide experience of medical imaging abuse. Clinical images are very important to display a patients condition, monitor progress and in research and training.
**Conclusion:** To properly care for our patients we must all be aware of the law. Legal proceedings are currently taking place due to the inappropriate production, storage and distribution of patient and medical images in the United States. In 2010, 46 of the 60 The National Council State Boards of Nursing (NCSBN) in the United States were surveyed. 33 boards reported receiving complaints about nurses posting photographs or information about patients on line, 26 boards took further disciplinary action against those involved.

Since the upsurge of social media, medical teaching institutions have become aware of the implications of their students and higher trainees posting inappropriate personal information. Trainees are now more experienced in the use of social media than their trainers, however, they still require the overarching principles of professionalism to be taught in such a way that they can apply them to the decisions they make when posting online.

There needs to be a better understanding of social media within medicine, how we, as clinicians, can harness it as publicity for our own institutions but also how we can prevent our colleagues, trainees and staff from failing in their duty to maintain both patient confidence and confidentiality.
Title:
End of life Decision Making: philosophical and legal issues in Italy

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Abstract text:
During the 20-th century there was an increase in medical discoveries that led to the reconsideration of end of life’s issues. Renowned Italian philosophers and jurists started to converse if humans have or not the right to die.

Nowadays, dying has become a process of steps that involves the duty of care and the patient’s autonomy. This involves the relation between technology and beneficence that patient get from them. Therefore, it is really important to find the right proportion among duty of care and treatment’s result.

The main concern is if life-sustaining treatments should or should not be removed in case of an autonomous request from the patient that has to be personal, authentic, real, actual and informed. For that reason, it is important to define if artificial nutrition and hydration are considered as normal care or as medical treatment.

In 1990, the Decree of the Prime Minister established the National Bioethics Committee, as an advisory body to the Government composed of expert in the medical, ethical and legal field. Therefore, from 1990s, philosophers started to discuss about the concept of “quality of life”.

Concerning the right to die, philosophers are divided in two main groups. In the first group, philosophers representatives of the Catholic doctrine, the neo-Kantianism and the neo-Classicism, believe that humans do not have a right to die. They base their reasoning on the concept of sanctity of life, natural life and in the argument of slippery slope. In contrast with the first group, the majority of philosophers support the complete autonomy of humans. They think that all the humans have the right to die, but, this does not entail that the physicians have the duty to kill. Doctors can always abstain from that by using the conscientious objector. This is based even in the Medical Ethics Code that reject any kind of futility.

In Italy, physician-assisted suicide (PAS) and euthanasia are considered as criminal offense. In concrete, although in case of PAS patient has always the control of the situation, PAS is considered as assisted-suicide (article 580 P.C.). On the contrary, euthanasia is considered as intentional homicide (article 575 P.C.), in case of non-voluntary active euthanasia, or homicide of the consenting person (article 579 P.C.) in case of voluntary active euthanasia. But, indirect euthanasia is legal. Based on the doctrine of double effect, the doctor’s intention is to alleviate pain and not to kill the patient, even if death is a foresee effect.

However, it should be noted that withdraw treatment is legal because article 32 of the Italian Constitution recognizes the right to health which grants patients the right to consent to and even withhold or withdraw from medical treatment. This article should not be interpreted as “equal treatment” but as “treatment as equal” and therefore human dignity has to be pondered. The right to health has been accepted even in cases of non-conscious patients if it is proven that dying is the
patient’s best interest and his/her will has been constructed through the substitute judgement which take into account the “advance directives”. It should be empathised that article 9 of the European Convention of Human Rights and Biomedicine of 1997, which is approved but not ratified in Italy, considers “advance directives” as statements of intent and not as declaration of intent. In case of withdraw treatment there is not injection of lethal drugs; therefore there is no space to qualify it as euthanasia. All the physician does is to stop an unwanted invasion of the body of the patient, at the patient’s request and administrations of sedatives and pain-killing. This means that the Italian judges have not recognized a right to die, but a right to physical integrity.

Due the facts that I presented in this paper, we can say that philosophers and lawyers do not have the same idea about end-of-life decision making. The majority of philosophers believe that patients have the right to die and recognize to the doctors the consciousness objection. But, the Italian judges recognize to the patients only the right to physical integrity as a specification of right to health. The grey area between right to life, right to physical integrity and duty of care can be clear only with the intervention of the Italian legislator.

**figure 1**
Title:
Journeying With the Terminally Ill: Decision-Making Issues and Challenges

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Abstract text:
Facing terminal illness could be compared to an endurance test for some. For an individual patient, his or her reality is colored by the illness experience. Hence, one’s judgment at any particular time would also be informed by the illness experience. However, for care givers and family members who may also be involved in the patient’s care decision making, the struggle may be in understanding what appears to them as “erratic” or “uncoordinated” decisions by the patient. Besides, they may either want to take over decision from the patient or have nothing to do with the process.

This paper intends to present a patient’s illness experience, which reflects an inner struggle within the self. The apparent inconsistencies in the patient’s care decisions from time to time could actually be as a result of the inner unresolved struggle. Those closest to the patient on a daily basis, such as care givers and family members could become easily disenchanted, and may think the patient is being difficult, uncooperative or simply refusing care.

I will hereby highlight some issues of ethical importance that this paper intends to address. First, there is the individual struggle by the patient in accepting a terminal diagnosis. While the patient may have an intellectual understanding of a diagnosis, spiritually, the patient needs the support of others in accepting the reality of a terminal condition. Second, there has to be an acknowledgment of the patient’s individuality by family and also by care givers. Third, respect for patient’s autonomy of will. Patient’s autonomous decision making right has to be respected even when the exercise of that right appears to contradict the preference of family and care givers.

I will argue that the principle of respect for persons essentially recognizes the autonomy of each individual as a decision maker over his/her life. This has to be recognized with every individual, especially the most vulnerable, the terminally ill. When an individual is not able to actively exercise the decision making power, he/she can still exercise it passively in another, by virtue of a surrogate decision maker or through an advance directive.

Keywords: Terminal illness, Respect for Persons, Autonomy of Will, Decision-making
Title:
Preimplantation Genetic Diagnosis with HLA-typing: balancing the healing of a sick sibling and the well-being and autonomy of the saviourbaby/donor child

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Abstract text:
Preimplantation genetic diagnosis for HLA-typing (PGD/HLA) is a method using in vitro fertilisation (IVF) for conceiving a tissue matched child that can serve as a haematopoietic stem cell donor to save its sick sibling in need of a stem cell transplant.

Since PGD and PGD/HLA raises a lot of ethical questions, families asking for this procedure are psychologically and ethically screened at the intake. Parents wishing a 'saviourbaby' are only allowed when the newborn is not only a mere 'instrument' to save a sick sibling but a child wished and loved for him or herself. Advocates of PGD / HLA believe that the discomforts and risks to a donor of HCS cells are minimal. On this basis, they posit that the risks to the donor outweigh the benefits of the sick child whose life it could be saved.

We argue that the well-being of the future saviourbaby is strongly linked to the outcome of the bone marrow transplantation of the sick sibling.

In the literature, the opinions on the welfare of the saviourbaby point in different directions. We distinguish three scenarios depending on the outcome of the transplantation.

(a) A succesfull bone marrow transplantation has a positive impact on the way the donor perceives the world: he/she values life more conscious and can easier relativize. The donation of cord blood and bone marrow can contribute to the psychological well-being of the donor child.

(b) Even with a successful bone marrow transplantation, the sibling, depending on the disease and the stage of the illness, can relapse and need additional bone marrow transplantations. The consequence is that the saviourbaby has a lifelong risk to be addressed as the ideal donor. Since the life of the saviourbaby is being mortgaged by decisions made before his or her conception, will he or she be able to make an autonomous choice? Walsh and Ahles study children who are bone marrow donors and conclude that 55% of the donors don't experience their donation of stemcells as autonomous but as a 'forced no choice'.

(c) In the worst case, the sick sibling dies and the donor child can not possibly succeed in the expectations. Research on child-donors points that it's very difficult for the donors not to feel responsible. The donors experience feelings of regret, guilt and sorrow. These feelings are stronger when they feel not enough involved in the decision to donate or not (informed consent).

For the well-being of the donor, certainly when the outcome of the transplantation is less positive, the feeling of donating freely and without pressure is important for the well being of the donor.
We conclude that in an ethical debate about the appropriateness for allowing parents to have a saviourbaby with PGD/HLA, not only arguments about possible degrees of instrumentalization and the assumption that the risks for the donor do not outweigh the benefit of the sick child should be the main points of considerations. We advocate an ethical assessment case by case where the scenarios of the possible outcomes of the transplantation are considered. This way the well-being and respect for the autonomy of the saviourbaby/donorchild are included in greater extent.

References:


Title:
Complex decision-making concerning Alzheimer Disease patients in a home-care setting. An institutional ethics research project supporting participants

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Abstract text:
Learning objective: Develop a methodological approach that is between a case studies based (sociological) approach and clinical ethics reasoning. Help patients, caregivers (proxies), and professional stakeholders work together more effectively when managing complex situations in the home setting.

Background: At the crossroads of recent work in political and moral philosophy, sociology, and psychology, the idea of social participation seeks to link together the concepts of autonomy, recognition, or social support and individuals' life project as much as their quality of life. The concept of social participation is therefore an invitation to extend the movement to expand care to the social aspects of the illness. However, it is a particularly complex objective that centres on several major uncertainties surrounding patient care.

Aim: Come to a better understanding of how to create a well-thought-out care community through collective support that respects the subject of care.

Method: Research in four steps

First step
Collect data from cases with professionals who work in a home-care setting.

Second step
Interview the stakeholders in these cases: professionals, in-home caregivers, patients, or family.

Third step
Revisit the cases with the caregivers.

Fourth step
Carry out clinical ethics reasoning crossed with a group analysis method that brings together those involved in the cases analysed.
Title:
Personalised and Patient Centred Care from the Perspective of Nursing

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Abstract text:
The difference between personalised and patient centred care we can see in the way in which the patient’s perspective is incorporated in the process of decision making. In personalised medicine the patient and his needs is assessed by somebody else - by DNA analysis in genomics, by a physician in medicine, by a nurse in nursing. Patient centred care accepts patient’s perspective as a key element in the assessment of his situation. The two modes of health care are not contradictory; we can understand them as complementary.

The meaning of such differentiation we can show in nursing care. Nursing ethics is based on care ethics. On the contrary to Kantian and utilitarian ethics care ethics is rooted in the relationship of actors. Relational ethics recognizes the other as an infinite being (e.g. according to E. Levinas). From this reason the interest in the other and in the other’s perspective is crucial.

There are several theoretical concepts in Nursing. For our purpose we shall introduce two of them. The first could be considered an example of personalised care, the second patient centred care.

In the NANDA International (North American Nursing Diagnosis Association) diagnostic system the nurse makes diagnosis of unmet needs after profound examination of the patient. Then she makes decisions about her actions. She decides which unmet needs and in what way she will help the patient to fulfil. Patient is more or less the object of assessment and care.

Dorothea Orem’s self-care theory recognizes the fact that every human being takes care for himself to maintain bodily health as well as to keep psychic and social balance. The care of nurse starts by understanding patient’s self-care. In the second step she looks for possible changes in patient’s self-care, which could better serve to restoration or maintenance of health.
Health-care systems

Fri 20 September
1330-1500

Speakers:
Stefan Sauerland/Jürgen Windeler
Jochen Vollmann
Personalized medicine in health-care systems - methodologic requirements

Prof. Jürgen Windeler (Cologne)
Speaker: Dr. Stefan Sauerland (Cologne)

Medicine has been „personalized“ from its very beginning. Its primary intention is to promote or restitute health according to individual burden and individual aims. So called “personalized medicine” does not address either of these aims. Instead it describes therapeutic (merely drug-based) strategies which are controlled or stratified by (new) biomarkers. Many indications for such strategies are oncologic. At the moment, apart from a few impressive examples the possibilities of such approaches are more or less speculative. In some cases therapeutic effects are marginal, biological models seem to be incomplete, knowledge about the molecular basis is insufficient. As the hype of the last few years seems to be fading away already, it has to be stressed even more that all such interventions have to undergo an adequate evidence-based assessment before they can be integrated into a health care system and compete for the limited resources.
More personal, better and cheaper? A critical analysis of “personalised medicine”

Prof. Jochen Vollmann

Problem “Personalised medicine” currently gains considerable attention and evokes a multitude of hopes in modern medicine. The identification of genetic markers enables more precise diagnoses, targeted therapy and more specific statements about the personal prognosis. Often used as synonym for future medicine, “personalised medicine” promises to be more personal, better and cheaper than current medicine.

Arguments (1) However, big achievements in basic genetic research do not mean necessarily better personal treatment for the majority of patients in clinical medicine. It is more likely that future clinical success in targeted therapies will be limited to subgroups of patients. In contrast, a considerable part of patients will have no personal benefit at all. (2) “Personalised medicine” is genetic biomarker based targeted diagnostic and therapy. It does not focus on a more personal patient-doctor relationship, like patient-centred or person-centred medical care provides. (3) In fact so called “personalised medicine” is a research and economy driven adventure governed by global stake holder, e. g. pharmaceutical and biotechnology companies. Since economically independent and publically funded research is missing widely, these private interest groups are setting the research agenda following their commercial interests. In this context and with the record of current cost development of new cancer drugs in targeted therapies the promise of cost saving and of cheaper health care lacks any evidence. (4) Furthermore “personalised medicine” is associated with ethical problems like priority setting and opportunity costs in solidarity based public health care systems. “Personalised medicine” provides modern, highly specific and expensive diagnostics and treatments, which will serve subgroups of patients only. At the same time research in other fields of clinical medicine, which could serve more than some subgroups of patients, remain underfunded. A public debate on priority setting in medical research and treatment and about how societies and public health systems can influence the development of the research agenda regarding the priorities for future health care is needed.

Conclusion Genetic biomarker based “personalised medicine” does not contribute to a more personal treatment of single patients, like in patient- or person-centred medical care provide. Subgroups of patients, e. g. in oncology, have medical advantages from the present progress in “personalised medicine”, but not the overall majority of patients. Any empirical evidence is lacking for the promise of a cheaper health care through “personalised medicine.” However, due to past experiences an increase of costs is more likely.
Parallel Sessions 3

*Health-care systems*

Fri 20 September

1530-1700
Title:
Which value judgments should guide priority setting decision making in genetic testing? Experiences with a discrete choice experiment

Authors:
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Abstract text:
Background: As our understanding of genetics has increased, so has the number of genetic tests that have become available clinically and have entered clinical practice. Whilst the laboratory costs of genetic tests are steadily decreasing, overall, health care costs of genetic services are likely to increase. Given this situation the question of how to prioritize genetic tests fairly in the face of budget constraints has become of emerging concern within the genetic community. In order to work towards an accountable use of limited health care resources the aim of this study was to assess the value judgements that stakeholders believe should guide resource allocation decision making.

Methods: Within this study we use the discrete choice experiments (DCE) methodology to elicit respondents’ perspectives regarding resource allocation decisions in genetics. In the DCE individuals choose between two hypothetical scenarios that differ in certain predefined attributes. Attributes considered included severity of the disease, risk for the disease, aim of the test, medical benefit of the test, and costs of the test. The results were presented to a group of stakeholders and implications for priority setting were discussed.

Results: Responses from about 600 participants (including clinical geneticists, laboratory scientists, academic researchers, and patient representatives) were analysed. The most valued attribute levels were a proven medical benefit of the test, high risk for having the disease, and low costs of the test. All attributes levels were significant except of the middle level for costs of the test and aim of the test. Some preferences differed between clinicians, patients, and other genetic experts. While clinicians attached greater value on attribute levels referring to risk high risk for having the disease and costs of the test, patients had increased preferences for testing highly severe conditions. The stakeholders showed high academic interest in the study results but hesitated to use a DCE-based algorithm for prioritizing genetic tests at this point in time, e.g. because there is a lack of evidence regarding the attribute levels.

Discussion: Priority weights determined by scientific methods may help to improve the consistency of priority setting in genetics. However, further work is needed until such DCE-based frameworks can be used for prioritization practice.
Title:
Personalised Medicine and Public Health: An ethical account on the basis of Public Health Ethics Frameworks

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Abstract text:
‘Personalised medicine’ has been hailed as a strategy which provides the right person with the right care in a more cost-effective way than conventional approaches. Yet, the implications ‘personalised medicine’ have on the ‘state-of-the-art’ of public health in terms of organisation of health care and prevention measures are rather unclear. Moreover and relevant from an ethical perspective there may be tensions between the focus of ‘personalised medicine’ which is on the individual and of public health inheriting a ‘population-focused’ view.

In this paper the ethical dimensions of “personalised medicine” and possible implications for a public funded healthcare system will be explored against the background of public health ethics frameworks. Our preliminary analysis, which is based on a literature review as well as on qualitative interviews with stakeholders relevant to decisions about funding of public healthcare, indicates that prominent ethical values and principles within public health are challenged by ‘personalised medicine strategies’. One example in this respect is the principle of equal access and the problem to define on which grounds certain groups may receive ‘personalised treatment’ and how to solve issues concerning reimbursement and priority-setting. Also concerns with regard to privacy and genetic information have to be discussed anew since genetic information about individuals are valuable for scientific advances and might be used for public health interventions such as cancer prevention through screening. Therein tensions arise between autonomy - precisely the respect for the will of every single person - on the one hand and solidarity on the other hand. Furthermore our analysis indicates that the public presentation of ‘personalised medicine’ might lead to misleading expectations among the public which can result in violations of keeping promises and commitments.

We will conclude with suggestions on how the implementation of ‘personalised medicine’ in research and clinical practice which is funded, at least in parts by a public health system, may be reconciled with key public health ethics principles.
How can “knowing more” lead to “knowing less”? - Maybe by using biomarkers to individualize the decision on chemotherapy after surgery in breast cancer?

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Abstract text:
Background: We will address a currently relevant and much debated field of what many may call a prime example of “individualized” or “personalized” medicine: The usefulness, the need or at least helpfulness of (biomarker based) tests in deciding for an (adjuvant chemo-)therapy after breast cancer surgery with substantial negative impact on health and wellbeing, that never the less is expected to prolong survival - or against it, if one could be reasonably certain of not suffering premature death.

Methods: Currently available results on the therapies and tests in question are researched and presented, bases on number of recent published (systematic) reviews, technology assessments and decision guidance documents. They will be critically reviewed regarding underlying the scientific (un-)certainty these results and recommendations convey.

Results: On the one hand, the expectation of better survival “for all” when doing the therapy is well founded in terms of its evidence base. It consists in a considerable number of randomized controlled trials - we are “knowing more” about this then on many other health interventions. We are currently “knowing less”, on the other hand, about what the consequence of using of these tests will be. Also there are at the moment quite a number of competing tests available, owing to the comparative ease with which “new” test might be designed from e.g. genetic material.

Discussion: When deciding on the use of a test, the effects of “more or less” knowledge should be reflected, as the use of a test does not necessarily lead to better or “more” knowledge. By the availability of more tests than just one, the question of more or less knowledge comes up again. Do we “know more” by more tests or “know less” as we do not know which test to choose? It may also be asked, why a situation where I know quite well the likely fate as a member of the group I am in, but with a quite high uncertainty as to my individual fate, should supposed to be inferior to a situation where the knowledge of the future of the “individualized” group is less certain, but more likely to be similar to my own?
Title: The Ethics of Rarity in Healthcare Resource Allocation

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Abstract text:
Do treatments for rare or very rare conditions need special consideration in the allocation of healthcare resources?

I take as my starting point the idea that patients in a healthcare system should be treated equally, fairly and consistently. This means that both outcomes and opportunity matter. On the one hand, a healthcare system is required to use the resources it has in the best way. On this, equality of outcome approach, two treatments that have the same outcome ought to be resourced to the same extent. If treatment A has a better outcome than treatment B then (other things being equal) A should be prioritised over B. On the other hand, a healthcare system should ensure that people are given an equal opportunity at the best health possible for them. On this, equality of opportunity approach, each person, rather than their ability to be made healthy, is to be treated equally alongside other people. This means giving each person an equal opportunity at the best health possible for them.

Both equality of outcome and equality of opportunity are important in the fair allocation of healthcare resources. However, on a single system of resource allocation (be it local, regional or national), those who suffer from conditions that are rare or very rare are systematically disadvantaged because they are deprived of an equal opportunity at a healthy life. This is because such a system cannot deal with the extreme range of cost and evidence related issues that the treatment of rare or very rare conditions raise.

I argue in this presentation that a separate process of resource allocation for the treatment of rare or very rare conditions and which has a settled, ring-fenced budget would be well placed to ensure that equality of opportunity at health is provided for this group in a way that is consistent with the other principles of fair healthcare resource allocation.
Title: Is there a place for personalised medicine in todays health care system and its prioritisation debate?

Authors: B. Vanderhaegen

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Abstract text:
Prioritisation in healthcare is an issue of growing importance, especially in the Western world. Prioritisation has always existed - it has always been an extremely important issue in developing countries - and will always be necessary in the healthcare sector on various levels and in a variety of ways. However, in a democracy people want, and should have the right, to know and to have a chance to influence the grounds on which health priorities are decided. One way of achieving this is to reveal the decision makers’ views concerning prioritisation. Both politicians and physicians are important decision makers with regard to prioritisation and resource allocation and their views concerning how increasing healthcare costs should be financed are highly relevant and should be taken into account. But the debate about prioritisation should also be held on a more basic level. Not the politicians and physicians but the general public should be made aware and eventually choose which principles should be used by the policy makers to make decisions concerning prioritisation. The reason for this is very simple. Various European systems are financed through taxation and are governed by political decisions made in democratically chosen bodies.

In this paper I want to propose three basic ethical principles which should guide the public in the prioritisation process and have to be known and accepted by the public.

These ethical principles seem to be very reasonable and fair. The first principle is the principle of human dignity - meaning that human dignity should not be dependent on people’s personal qualities or functions within the community, such as their ability, social status, income, etc., but is a part of their very existence. The second principle is the principle of need and solidarity - meaning that most of the care resources should be given to those who are most in need, with special consideration being given, for example, to children, patients who have dementia or are not conscious, and others who have difficulty in communicating with those around them. The third principle is the cost-efficiency principle - meaning that the aim should be a reasonable costs/effect relationship, measured in terms of improved health and enhanced quality of life.

Some would like to add a fourth principal which is much more controversial. It is the principle of personal responsibility for one’s own health. The implication is that one is personally responsible for both the prevention of ill-health and for choosing a healthy lifestyle. Along with that there is also suggested too that individuals should take a certain amount of financial responsibility for public healthcare.

In this paper we deal with the question concerning which principles should guide prioritisation and at the same time with the question if the emerging field of personalised medicine can have its place in health care systems with scarce resources.
Today, many medicines do not work effectively for a large number of the patients they are supposed to treat. Personalised medicine aims to improve this situation by providing the right diagnosis leading to prevention or to treatment at the right dose to the right patient at the right time.

Personalised medicine starts with the patient. However, rather than having a unique treatment for each individual person, patients can be sub-divided into groups based on their individual biological genetic and genomic characteristics. By this stratification of patients, medical interventions can be tailored to be more effective and have fewer undesirable side effects for this particular group, than the currently dominating "one size fits all" medical approach. The move towards personalised medicine can be seen as an evolutionary rather than revolutionary process. Although some personalised medicine approaches have already been introduced into practice in Europe, we are at an early stage of its implementation. Significant paradigm shifts will need to take place in major fields of medical research and health care for this innovative area to be fully exploited. But should these paradigm shifts take place? The question is not if personalised medicine is a bad thing but can the health care system afford to introduce personalised medicine in times when resources are scarce?

In this paper we will defend the position that from an ethical point of view personalised medicine can only be introduced if all the above mentioned principles are respected. If society can’t guarantee this, personalised medicine should not be introduced into the health care system and research regarding personalised medicine should not be funded.
Title:
Points to consider for prioritizing genetic tests. Experiences with a European consensus process oriented at the principles of Accountability for Reasonableness

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Abstract text:
Context: Given the need of many health care systems to contain costs, criteria are needed which genetic tests to fund from public health care budgets if not all can be covered. To ensure high priority services for personalizing medicine are available equitably across Europe, a shared set of criteria would be desirable. Procedural fairness can support the legitimacy of decisions about such criteria.

Methods: A decision process oriented at the frequently cited framework of accountability for reasonableness was established in collaboration with the European Society of Human Genetics to work towards shared criteria for prioritizing genetic tests on a regional and local decision level across Europe.

Results: The involved participants agreed that prioritization does take place and that there is a need for prioritization criteria. Intermediate results are that prioritization should be based on considerations of evidence of benefit (medical benefit for the individual being tested, benefit for live decision making, benefit for other persons apart from the testee), patient-specific likelihood of the condition tested for, severity of the condition, purpose and timing of the test as well as costs and budget impact of the test. Further discussion and better evidence regarding these criteria is needed before clearly defined recommendations for prioritizing genetic tests can be made. Overall, the A4R-framework provided a valuable orientation for designing a decision process, but also practical limitations of the approach became apparent like difficulties with involving patient representatives.

Conclusions: This is the first time a clinical society started a decision process on the prioritization of health care resources on a European level, oriented at criteria for procedural fairness. Overall, this process can serve as an orientation for future similar exercises for prioritizing personalized interventions but a couple of pitfalls should be considered which are discussed.
Title:
Challenges of Patient-Centred Care: Advance Directives in the Context of Limited Resources for Healthcare

Authors:
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Abstract text:
Health and social care systems in the developed world are facing increasing concerns about the medicalisation of dying. There are concerns not only that the costs of end-of-life medical care may become unsustainable but also that unbridled application of medical technology which is not patient-centred may lead to inappropriate end-of-life care. Older people in particular have an increased risk of dying in highly technical medical surroundings. Since the mid-1990s, the question has been raised whether the use of advance directives to refuse treatments might help to reduce the costs of care.

Advance directives have the purpose of sustaining patient autonomy in cases where patients are no longer competent, particularly so as to prevent unwanted treatment or overtreatment. Would it then be ethically justifiable to promote them as instruments for cutting the costs of care or reallocating resources from acute to long-term care settings? Or would such a use of advance directives be tantamount to an abuse of patient self-determination and patient-centred care?

Our paper first provides an account of the cost-control and medical technology context, as well as the increasing difficulties of public health systems in sustaining appropriate levels of end-of-life care. We then review studies of the impact of advance directives on the costs of such care. Finally, we discuss the ethical acceptability of the use of advance directives in the context of cost control and equitable allocation of resources.

Important questions can be raised as to whether advance directives are valid instruments to express the patient’s genuine will in a specific situation. It is difficult for many patients to anticipate future events and specific preferences, and advance directives are not always known about or taken into account by physicians. Therefore, we argue that the writing of advance directives should not be left to the patient alone but be generated through an open doctor-patient communication. Ultimately, a patient-centred approach is a necessary condition for any advance directive in relation with end-of-life care and the use of advance directives for cost-cutting (if it really cuts costs) is only acceptable on that condition.
Title:
Personalised and Econometric Approaches to Healthcare Allocation, and their Relation to the Assisted Dying Debate

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Abstract text:
Econometric measures, such as the QALY, DALY and cost effectiveness ratio, play an important role in informing public policy decisions about the allocation of care at the end of life. They provide an apparently 'value neutral' way to distribute care fairly and effectively, among a demographic for whom the burden of disease and disability is unevenly distributed. 'Personalised' medical thinking can be seen as making a valuable critique of these econometric measures, providing a useful dialectical framework in the context of healthcare allocation. Personalised healthcare challenges economic reductionism, and encourages the consideration of individual concerns that might be missed by the aggregating tools of healthcare economics. It is, however, not at all clear that QALYs, and other econometric measures on the one hand, and 'personalised' considerations on the other, are helpful in the debate on assisted dying and euthanasia. There is an equivocation over the meaning of 0 QALYs that fails to distinguish between death, dying, being dead and being killed. The dialectic of best value for money versus personalised decision making avoids the debate over both the social impact of legislation and the nature of 'best interests' that are prevalent in the debate over euthanasia and assisted suicide.

This paper analyses these concepts to show that while cost effectiveness is necessary, and personalisation ought to be taken into account in healthcare allocation contexts, the assisted dying debate is of a categorically different kind. If features and tools of healthcare allocation on the one hand, and arguments for public policy on assisted dying on the other are not separated, one might think that a concern for econometric or personalised healthcare favours the legalisation of assisted dying. A focus on QALY's and 'personalised' healthcare hinders rather than helps the debate over euthanasia and assisted suicide.
Assessing Individualized Medicine - the Example of Immunoadsorption

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Question: Heart failure is a widespread disease and common in the elderly. Thus the corresponding economic burden will increase during the process of double aging and pose a serious challenge for public health. Dilated Cardiomyopathy (DCM) is one the most important varieties of heart failure. Recent research has shown that biomarkers can be adapted to DCM, for making adequate therapeutic decisions. This paper aims to evaluate the application of Individualized Medicine (IM) in the case of immunoadsorption (IA) for treating DCM patients.

Methods: Costs both of gene analysis (homogenization, RNA-isolation, array analysis and evaluation) as a prerequisite for decision making concerning the reasonability of IA and for IA (personnel and materials) were calculated. Therefore costing data from the hospital information system of the Greifswald University Hospital were used. Additionally, data were collected by conducting a time study. Relevant activities were identified and the costs of each activity were assigned with resources (such as general material, filter system, IA-Kit, laboratory, drugs and immunglobuline) and services (e.g., by medical doctors, health care staff and ward round) according to the actual consumption by each. Fixed, variable and overhead costs were identified. The effectiveness of IA was ascertained by the use of the Minnesota Living With Heart Failure Questionnaire (LHFQ), a commonly used measure of health-related quality of life in persons with heart failure. Patients were interviewed several times before and after performing IA therapy. Based on costs and effectiveness, cost-effectiveness was calculated.

Results: Total costs of gene analysis are highly sensitive to sample size due to high fixed costs. Increasing the number of samples from n = 18 to n = 100 results in decreasing total costs per sample from EUR 4,015 to EUR 1,197, on average. Further cost savings can be realized by e.g., changes in organizational arrangements or higher discounts. Currently endomyocardial biopsies are used as material for conducting gene analysis. Switching to blood plasma can both decrease costs and the patients’ burden. The total costs of IA therapy were calculated as EUR 19,351. They were dominated by costs with regard to the filter system (59%). Attributable staff costs are only accountable for about 1.5% of total costs. Because IA is highly expensive, the adoption of this novel therapeutic approach as a standard therapy in Germany will probably face resistance. The acceptability can rise, if IA turns out to be effective of high degree. There is some experience that IA can accomplish that. Society and the responsible decision makers have to determine, whether the resulting cost-effectiveness-ratio is high enough for supporting this technology.

Conclusions: The case of DCM and IA therapy demonstrates that IM should not be reduced to applications in pharmacogenomics and oncology. IM may also be adapted to widespread and highly complex diseases. Based on reliable methods of health economic evaluation cost-effectiveness-ratio can be used as guiding criterion for decision makers to decide if that technology is appropriate for inclusion within the package of the statutory health insurance. Beyond that it is the task and challenge of researchers to improve cost-effectiveness to make IM possible for everyone.
Title:
Knowledgeability of Bulgarian medical specialists about the possibilities and perspectives of personalized medicine

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Abstract text:
The rapid enter of new inventions and technologies in medical science states many ethical problems to medical specialists. The mastering and the application of the newest and contemporary methods of the personalized medicine is a challenge not only in the practical sense. It requires also the successful solving of a variety of emerging moral dilemmas caused by this innovation.

The purpose of the study is to investigate the knowledge of medical specialists about the possibilities and the perspectives of personalized medicine and the moral problems caused by its application.

Material and methods: We carried out an inquiry of 61 medical specialists studying the specialties "Management of health care" and "Public health and health management" at the Faculty of Public Health, Medical University - Sofia.

Results show, that the medical specialists have a certain idea only about a small part of the great potentials which personalized medicine opens to the whole human society. The received answers show that they are not clear about the application of the personalized medicine in their specialty field and the new ethical problems will probably hamper their relationships with the patients.

As a conclusion we can sum up that in order medical specialists to have an adequate and ethical behavior in the process of applying personalized medicine they need more specialized information and new knowledge. It is necessary to give them rational and practical approaches, based on the ethical principles and rules.

Key words: personalized medicine, medical specialists, gene identification.

References:
Title:
'Personalised medicine' in oncology. - Physicians’ perspectives on contribution to and challenges for clinical practice

Authors:
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Abstract text:
Background: Public discussions about ‘personalised medicine’ indicate that this approach is often associated with high expectations regarding its contribution to clinical practice. However, little is known about physicians’ perspectives on the impact of ‘personalised medicine’ on current and future clinical practice. This qualitative interview study aims to provide insight into physicians’ perceptions and views regarding the impact of ‘personalised medicine’ on their daily work and challenges associated with this approach for clinical practice.

Methods: We conducted qualitative in-depth interviews with physicians working (mostly specialised) in haematology and oncology. A qualitative analysis within the framework of grounded theory was performed.

Results: Eleven interviews were conducted. Physicians in our sample view ‘personalised medicine’ as a progress within medicine but do not see a major departure from long-standing practices nor do they identify ‘personalised medicine’ as a ‘paradigm shift’ within medicine. All interviewed physicians see themselves confronted with several challenges, which can be directly or indirectly connected with the rise of information about genetic or molecular aspects. As a major problem physicians identified handling the amount of information and to integrate it into diagnosis and treatment. Strategies to handle the increasing information such as the development of more expertise and/or more therapy guidelines emerged as a further topic from the qualitative analysis.

Discussion: Compared with the public and in parts also scientific debate the physicians interviewed in our study seem to have more ‘down-to-earth’ expectations regarding ‘personalised medicine’ technologies and their contribution to clinical practice. Taking into account physicians’ reflections on the increasing information and the associated challenges one may ask whether ‘personalised medicine’ runs a risk to reach the opposite of what its name connotes - a more patient centred medicine. The strategies for handling the enlarged information, pointed out above, raise novel challenges which stay in contrast to the ideas of a patient centred medicine. Instead of taking the patient as a complex person into account, forms of standardisation and expertise focus on the disease and split the patient into parts of body functions. Furthermore, a holistic patient-doctor-relationship may be replaced by several patient-expert-relationships. In the end this might lead to a phenomenon that could be called ‘fragmentation of the patient’.
Title:
Systematic review and meta-analysis to evaluate the prognostic significance of nucleophosmin 1, FLT3 internal tandem duplication and CEBPA gene mutations for acute myeloid leukemia patients with normal karyotype and younger than 65 years

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Abstract text:
Introduction: Diagnosis and classification of acute myeloid leukemia (AML) are based on cytological criteria and cytogenetic alterations. An increasing number of mutations have been found to have a prognostic impact to assess the prognosis and treatment strategy in patients with otherwise classical intermediate-risk AML with normal karyotype (CN-AML). In this systematic review we examined the prognostic significance of three frequent mutations in CN-AML: mutated nucleophosmin (NPM1), mutations of fms-related tyrosine kinase 3 (FLT3-ITD) and mutations of the CEBPA gene.

Methods: A systematic literature search regarding the three markers in patients with AML, normal karyotype and younger than 65 years in the databases Embase, Pubmed, Healthstar, BIOSIS, ISI Web of Knowledge and Cochrane from year 2000 up to March 2012 was conducted. A quality assessment of the included publications was performed and relevant information was extracted into tables. A qualitative and quantitative synthesis of information - in terms of a meta-analysis - was done.

Results: Nineteen studies were included in the qualitative analysis. Two to four studies entered the meta-analysis incorporating 1378 to 1942 patients with CN-AML. The meta-analysis for overall survival (OS) and relapse/disease free survival (RFS/DFS) of FLT3-ITD showed a statistically significant worse prognosis with a hazard ratio (HR) of 1.86 and 1.75. The HR of 0.56 and 0.56 for NPM1 mutation and 0.37 and 0.42 for CEBPA mutation demonstrates a prognostic advantage of mutated NPM1 and CEBPA over wildtype genes. A request for unpublished data of the study groups included in the qualitative analysis is currently under evaluation.

Conclusions: FLT3-ITD is associated with worse prognosis whereas mutations of NPM1 and CEBPA are associated with a significantly better prognosis as compared to the wildtype status.
Title: Individualised medicine as a strategy to reduce cancer treatment. A medical-ethical analysis

Authors: J. Schildmann

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Abstract text: Individualised medicine is mainly understood as an approach according to which patients with a specific genetic or other biological marker receive the respective targeted treatment. However, a variant of individualised medicine often applied in current clinical research and practice is the use of markers as prognostic indicator which informs treatment decisions. A concrete example is the treatment of acute myeloid leukaemia, a form of blood cancer. Patients with genetic marker which indicate a bad prognosis are recommended to undergo early an intensive chemotherapy and bone marrow transplantation while patients with a better prognosis receive conventional chemotherapy.

In this presentation I will focus on the possible application of individualised medicine strategies to identify those patients who do not benefit from aggressive treatment. In my interdisciplinary analysis I will present challenges associated with such application of individualised medicine from a medical as well as ethical perspective. For the purpose of this presentation I will use examples from medical oncology as a field in which on one hand individualised medicine has been implemented as part of diagnosis and treatment of many diseases and in which on the other hand the decision for treatment is often associated with considerable burdens and risks.

In a first step I will review data from empirical research which indicates that cancer treatment is given frequently also in situations for which there is little evidence with regards to the benefits (i.e. improvement of quality of life and/or extension of life). In a second step I will point out methodical challenges of medical research which aims to identify patients who may not benefit from further cancer specific treatment. In this context I will summarise parts of the methodical critique of current research in individualised medicine which is directed to the validity and other quality criteria of markers as well as the design of clinical study (i.e. prospective controlled intervention studies) which is needed to be able to stratify patient. In a second step I will analyse ethical challenges associated with research which aims to identify patient subgroups which may not benefit from (aggressive) cancer treatment. Here I will discuss the challenges associated with the normativity built into clinical outcome measures according to which the success of studies which aim to identify patients who do not benefit from cancer specific treatment could be measured. Furthermore I will explore ethical issues relevant to information and eliciting consent of patients who may be eligible for such clinical trial. Finally and relevant from the perspective of social ethics I will analyse the priorities with regards to research funding and further incentives which need to be set to support research which aims to identify patients who do not profit from aggressive cancer treatment.

In my conclusion I will argue that for now there are sufficient empirical data and ethical arguments which warrant further interdisciplinary research with regards to the potential use of individualised medicine strategies to identify patient groups which may rather benefit from best supportive care than from another trial of cancer directed treatment.
Potential ethical trade-offs in the context of ‘personalized medicine’: Dealing with ‘non-responders’ in oncological treatment

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Abstract text:  
Background: ‘Personalized medicine’ is one of the most important approaches in current medical research. The information obtained should be used to provide patients with a stratified therapy with fewer side effects. Future patients should, on the basis of molecular-genetic information, be classified into groups of ‘responders’ and ‘non-responders’ with regard to standard therapy.

Central ethical problem: Apart from the issue of test accuracy, direct and indirect implications of stratified medicine for different patient groups have to be extensively discussed from an ethical perspective. Especially the further dealing with so-called “non-responders”, i.e. patients who would, due to the planned test procedure, have to be informed that standard therapy will be hopeless or would only provide the patient with low chances of recovery, may contain ethical and practical conflict potential.

Research question: How do physicians and patients assess the potential ethical trade-offs connected to such tests with regard to a classification of ‘responders’ and ‘non-responders’?

Methods: Apart from an evaluation of current social-empirical literature, we will analyze our empirical-ethical data. It consists of a) semi-structured interviews with physicians and researchers (n=19) who are involved with the further development of a stratified classification in rectal carcinoma treatment, and b) semi-structured interviews with patients (n=71) who were diagnosed with locally advanced rectal carcinoma.

Results: The analysis of the data shows that researchers see relevant conflict potential especially regarding correct classification and dealing with uncertainties. Independent of the therapy regime for different cancer treatments, researchers very rarely expect a stigmatization by classifying ‘non-responders’. Patients, however, do not per se see the advantage of stratification. Patients rather tend to want that something is done about their “cancer”. Loss of trust and lack of understanding on the part of the patients are possible consequences of non-treatment. These results, according to our interpretation, imply new challenges not only regarding communication of this new pre-selection of therapy but also regarding the communication options.
Clinical practice

Sat 21 September

0905-1035
Please note: From 0900 to 0905 the Award Ceremony will take place.

Speakers:

Wolfgang Lieb
Silke Schicktanz
Personalized medicine – from basic science to clinical applications

Prof. Wolfgang Lieb (Kiel)

Recent progress in the understanding of the human genome, paralleled by the development of high throughput technologies to measure genetic variation, metabolites and proteins in hundreds of thousands of individuals, fueled the hope for more personalized approaches in the prediction and treatment of diseases. While the development of these high throughput technologies led to an improved understanding of the pathophysiology of several common conditions, including cancer and cardiovascular disease, the clinical implementation of more personalized medicine is still at the very beginning. The talk will present current concepts of personalized medicine, describe important drivers of personalized medicine, reflect on the scientific background, and will discuss different approaches to implement personalized medicine in the clinical workflow of major hospitals. The talk will close by describing future issues and challenges related to the clinical implementation of personalized medicine.
Professionals hopes and patients pragmatics: Empirical-ethical issues in the context of research for more personalized approaches of cancer treatment

Prof. Silke Schicktanz (Göttingen)

Personalized medicine promises better diagnostics and treatment, e.g. by stratifying patients into groups who react differently to treatment. The aim, among others, is to reduce side-effects and have 'tailored' treatments. Especially in cancer treatment where serious side effects or low treatment efficacy are often a challenge, this seems very promising and timely.

However, 'personalized' medicine is rather a long-term goal than already established practice. In my talk I like to highlight some aspirations and expectations made by the expert community as well as on experiences made by patients, both involved in a large research project to personalize treatment of colorectal cancer. I am drawing here on interviews with both groups and non-participatory observations of doctor-patient-communication our research team conducted in 2012-2013. This project is part of an interdisciplinary German research consortium on personalized cancer treatment of colorectal cancer, including oncology, surgery, genetics, molecular biology, pharmacology, data mining and data handling, and ethics.

I will highlight some conflicting lines of argumentation and collidating expectations between professionals and patients. By this, we hope to contribute to an empirically informed discussion of the ethics of personalized medicine, including the recent research conditions.
Parallel Sessions 4

Clinical practice

Sat 21 September

1100-1230
Title:
The philosophical and anthropological conception of the terminally ill within the Brazilian Health System - a plea for a broader concept of person under end-of-life care

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Abstract text:
After the Federal Constitution of 1988 and the development of the jurisprudence of the so called right to health, which interprets the universality of the public health care system in Brazil as an unlimited right to extremely costly treatments in end-of-life care even when no medical evidence is given, a not only unsustainable situation from the financial point of view, but also unethical situation has emerged for the majority of people who die in medical facilities (percentage that goes from a general 74% up to 82% when we consider oncological causes). In the country, a new perspective for bioethical discussions regarding individual rights of terminally ill patients is urgent and should lead to the plenitude of the protection of the legal rights of the ill, especially at the late stages of the disease, when hipermedicalization of the dying process asserts itself as the major source of the various damages caused to individual rights. To recover the centrality of the human person as the single and only end to which Law and Medicine should serve, we present a path of the concept of personhood in its juridical and philosophical development to affirm that every human being is an individual (ubi homo sapiens, ibi persona), even if he/she doesn’t have legal capacity and, therewith, demonstrate the impossibility of belonging to a class of non-persons independently of circumstances or the bio-psychic development. We also argue that treating and caring of seriously ill and terminal patients should be related to the person in its dignity and fullness, in a biomedical, philosophical and metaphysical conception of existence, irreducible to mere obstinacy in prognosis and treatment, as a result of a reductionist perspective which relates treating a disease to a futile investment of a sterile extension of human life. In this sense, we present a innovative ethical juridical perspective to illness and the experience of this condition in Brazil, from the point of view of terminally ill patients, caregivers and health care teams in light of Emmanuel Lévinas’s thought and the centrality that he grants to the figure of the Other, which illuminates our interpretation of individual rights. We conclude that a change in the extant paradigm of the end-of-life care in Brazil is imperative also in the legal realm, with the acceptance, in the therapeutic choice, of the natural course of death at the end of our existence: from the search for cure, to care; from quantity to quality of the life remaining. An ethos centered in palliative care should allow a new approach in previous court decisions in Brazil, as well as a change in the current health policy with more investments in hospices and palliative care facilities inspired by a new concept of the person and its needs.
Title:
Activating patients - a way to go in the Slovak health care system

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Abstract text:
Question: Prevention has always espoused a strong position in the medical practice. Its role has become even more significant in the contemporary scheme of the health care which is presented as a patient-orientated. Prevention helps patients to understand their own abilities to set their standards of life and activate them to protect and guarantee the desired quality of their life. The goal of this paper will be then to abandon the traditional naturalistic concept of health as not only a value-neutral concept but also as a patient-absent concept. Therefore, it is necessary to understand the health care with the respect paid to the holistic understanding of health and its active, vital and normative aspects.

Methods: For this purpose, I present a form of the holistic theory of health, originally formulated by Lennart Nordenfelt, reflected through the consequential ethical theory of ethics of social consequences. The importance of the agency, activity, and the ability to set one’s own goals in her/his life are highlighted in both of these theories.

In the second part of the paper, I would like to reflect on the status of preventive medicine and the patient as a moral agent in the health care system in Slovakia (in relation to economical aspects, social aspects, and educational aspects).

Results: Firstly, Slovak codes of conduct of health care professionals (namely the code of conduct of physicians and the code of conduct of nurses) react to the shift to the patient-orientated model of health care. They propose to understand the medical decision making process as the two side model in which the patient (as an autonomous, independent being) is an active participant and his/her needs, emotional states and personal preferences are taken into an account and are fully respected by the health care professionals.

On the other hand, the role of preventive medicine and its status in health care in Slovakia is still not formulated in these documents. The tendency to highlight the role and function of prevention in Slovak health care might be detected in several manifestos of political parties in Slovak election campaigns (summer 2010) but they are rather partial, not complexly delimited and, in practice, still ineffective.

Conclusions: There might be done two main conclusions in this paper. Firstly, the absence of the concept of preventive medicine is significant in Slovak legal and normative formulation of health care and health care system. This can be seen at the level and the tendency of reflecting this problem by politicians and political parties (e.g. election campaign in Slovakia, summer 2010) or in professional codes of conduct of health care professionals in Slovakia. On the other hand, the importance of understanding health as patient’s own goal and activity has been recently distinguished.
Title:
Quality of care at the end of life: sharing and communication between patients and clinicians

Authors:
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Abstract text:
End of life care is a serious challenge for healthcare settings, in particular for countries dealing with an increase population aging and financial curtail to the healthcare system. These conditions could affect patients with life-limiting diseases in terms of quality of care. The issue of end of life care is perceived as a determinant one in many official documents, international charts and recommendations, while scientific literature is recently driving more attention on these topics[1]. Several protocols[2] and assessment tools[3] have been implemented in healthcare institutions to assure a good quality care during the end of life, but most of them systematically provide only the perspective of clinicians neglecting the point of view of patients and their families[4]. In accordance with the principles by which C. Saunders reshaped the end-of-life-care[5], we believe that collecting information from patients and their families on the situation they are living will give a major contribution to a better understanding of the needs of the terminally ill and useful information on the quality of the relationship with physicians. We started with a research based in Sardinia that has revealed very interesting dynamics among people involved in the care pathway. Using and adapting an American questionnaire on the quality of end of life care to our Italian context, we gathered information from a significant number of patients, their family members and nurses, living in Sardinia, on the competence of physicians in the context of providing care for terminally ill patients. An analysis of data detected some levels of sharing in communication and aspects referring to the multidimensionality of each subject that need to be better analyzed and understood. In particular, we observed the most relevant aspect during the very first step of the study was the firm rejection of topics related to death right from the patients approaching their death as they considered not concerning the condition they were living. It emerged that health professionals tend to avoid some delicate topics, giving the necessary information mainly on the disease and leaving less room for issues of death, while patients and families wish to be more informed on the true condition they live. Some differences emerged from this study between an Italian and an American approach to the issue of death, especially due to the quality and quantity of communication and other relevant differences in the healthcare systems and services providing end of life care. From these first findings we observed how analyzing quality of care by a patient and family centered tool of investigation emphasized the quality of communication and the quantity of information clinicians share with their patients and families giving a valid support in bridging the gap between professional caregivers and care-seekers. We have drawn a path walking the which we think that a more detailed perspective of the problems will help healthcare providers to meet the expectations of patients and their caregivers.


Title:
The inclusion of children in decision-making at the end-of-life

Authors:
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Abstract text:
Background: Making end-of-life decisions for children and adolescents is difficult. The question whether the minor himself/herself should take part in them is highly debated because children's and adolescents' ability to make end-of-life decisions is disputed. As such, competency has emerged as a central theme and guides the discussion around minor’s participation in this process. Despite long-standing research tradition on minors in end-of-life situations, no clear recommendations are available on their involvement. To understand this issue, we closely examined the distribution of articles on end-of-life decision-making featuring the three parties mainly involved in that process: healthcare professional, parents, and the minor patient. Furthermore, those articles including minor patients were searched for accounts of children's and adolescents' competency.

Methods: A literature review using five databases (PubMed, Medline, PsycInfo, CINHAL, and Sociological Abstract) captured original research on end-of-life decision making in pediatrics.

Results: This search resulted in 69 articles fulfilling the inclusion criteria. A majority of these articles included parents' and/or healthcare professionals' perspectives. Only 19% involved minor patients' views. Very few papers discussed the competency of their participants to make end-of-life decisions.

Conclusions: Given the diversity of opinions ranging from paternalism to requests to respect children's autonomy, the lack of empirical research on children and adolescents' participation in end-of-life decision making is disturbing. As a consequence, no sound and evidence based framework exists for answering the question if and how minors should be involved in such decisions. Appealing models, such as shared decision making, though offering practically sensible solutions to this clinical dilemma, should not be further developed without considering the inclusion of minor’s view. In addition, guidelines urging for more flexible frameworks of promoting their autonomy need to be synchronized with clinicians' views and parents' attitudes. Future research placing greater focus on the relational aspects of decision making and including children's perspectives should be the driving force behind such guidelines. Only when all the perspectives of those affected by the decision are taken into consideration, can the course of action in a concrete situation ever be tailored to the needs of the individuals involved.
Title:
Attempting Suicide and Refusing Treatment: Respect Autonomy or Protect Life?

Authors:
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Abstract text:
The obligation to respect persons, whilst undeniably laudable, can generate considerable ethical conflicts for professionals, patients and their loved ones. In this paper, I consider some of the tensions by reflecting on an increasing international phenomenon, in which individuals who have attempted suicide also seek to refuse life-saving medical intervention. Two scenarios arise: in the proximate scenario, the refusal of treatment appears closely related (in timing, motivation and intention) to the suicide attempt; in the remote scenario, meanwhile, the refusal of treatment was set out in an advance directive, maybe even years before the suicide attempt.

Respect for persons would seem to insist that life should be protected - but the obligation is also frequently described in terms of respecting the patient's autonomous wishes. How should the balance be struck in these cases and are there pertinent differences between the proximate and remote situations? Moreover, what obligations are owed by the individual who encounters the suicidal person, be they a loved one, a paramedic, or a health care professional on the emergency ward?

I begin by considering the obligation to respect autonomy, which - in many legal systems - seemingly underpins not only the entitlement to commit suicide, but also the right to refuse unwanted treatment, whether now or in advance of incapacity. Indeed, in English law for example, the right to refuse life-saving treatment extends to patients with a mental disorder. On this view, the suicidal person should be free to die, not least in the remote scenario, if a legally-binding advance directive has been prepared.

However, as I explain, the right to refuse treatment is often limited, with patients found to be lacking the requisite capacity and many advance directives being deemed invalid or inapplicable. Furthermore, and particularly in the proximate case, the professional may use mental health laws to assess, detain and treat the suicidal patient. The obligation to protect and preserve life becomes even more pronounced for the loved one: rulings from England show that they might even be found guilty of a homicide crime (such as assisted suicide by omission) if they elect not to call the paramedics and instead, in accordance with that person's wishes, they sit with their loved one as he or she dies.

It is, therefore, not entirely clear what the obligation to respect persons requires of bystanders in these difficult cases. Ultimately, I suggest, the proximate and remote cases might not be so different in (ethical) principle, since they each engage with the same conflict between life and choice. I conclude by outlining a possible solution, which seeks to achieve a compromise of the competing values: according to this approach, life initially assumes priority, unless the validity of the autonomous choice for death can be established. This is a compromise since it involves rather more intervention than defenders of autonomy might endorse, whilst also allowing refusals of treatment to stand rather more often than defenders of the intrinsic value of life might permit. Although my analysis draws on widely-publicised cases from the UK (like that of Kerrie Wooltorton), such cases are not confined to this jurisdiction, and the issues will be relevant in any country which seeks simultaneously to respect autonomous choices and protect the lives of the vulnerable.
Title:
What do patients need to know to participate in medical decisions?

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Abstract text:
Contemporary Western medical ethics takes patient autonomy as its central tenet. Yet clinical practice may fail to implement that tenet widely. To explore the status of patient autonomy in clinical practice, I searched the American and Canadian literatures for inpatient surveys addressing two questions: Do patients prefer to participate in decisions about their care? and Do patients perceive that they actually participate in such decisions? I found seven studies about preferences and four about perceptions. Large majorities of patients in six preference studies (range, 62-74%) and a near-majority in the seventh (47%) preferred to participate in decisions about their care. But only minorities of patients in all four perception studies (range, 35-48%) perceived that they had actually done so.

One possible explanation for patient nonparticipation in decisions is the specialized reasoning methods of clinicians, which may unintentionally exclude patients from the decision-making process. I, therefore, conducted a second literature search to identify and characterize those methods. I found four:

- **Clinical hypotheses based on a clinically meaningful problem** involve categorizing the patient’s complaint under a clinically meaningful problem, listing all possible diagnoses for that problem, collecting clinical data to confirm or refute each diagnostic possibility, and treating the most likely or most dangerous ones. Chronic cough, for example, might suggest asthma and require pulmonary functions tests to confirm or refute it and to guide inhaler treatment.

- **Bayesian analysis** uses clinical tests to revise upwards or downwards a “pretest probability” for each diagnosis considered, thereby creating a “posttest probability.” When that posttest probability surpasses a certain threshold, the clinician treats for the diagnosis. For example, the possibility of angina might prompt a clinician to order cardiac stress testing for a patient with chest pain. If the results are “positive enough,” the clinician might order catheterization and treat with antianginal medications.

- **Pathophysiologic reasoning** deduces a diagnosis from knowledge of basic medical sciences such as physiology or anatomy. For example, abnormal bony configurations might suggest either a fracture or osteoarthritis and treatment by reduction or analgesics, respectively.

- **Pattern recognition** draws on extensive clinical experience to compare the symptoms and signs of an undiagnosed new patient with those of similar, diagnosed past patients. The closest match suggests the diagnosis and treatment. Clinicians often diagnose skin rashes in this way.

Experienced clinicians likely use all four reasoning methods, sometimes several simultaneously. But, on their own, patients probably cannot understand these reasoning methods well enough to participate actively in the decision-making process. Realizing the patient autonomy ideal, therefore, may require clinicians to identify the reasoning methods they are using for a particular problem at a particular time and to explain those methods clearly to patients.
Title:
Ethical challenges of decision-making in oncology - research design and results of a multiperspective empirical-ethical study

Authors:
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Abstract text:
Decision-making in oncology poses intricate ethical questions, not only due to the severity of disease and its partially fatal course but also because of the complexity of cancer treatments and the need for strong interdisciplinary cooperation. Not least, the question has to be raised how oncological care can transgress the borders of disciplinary thinking and account for the patient as a person.

In this contribution, we will present the results of a qualitative study which identifies ethical challenges in the clinical practice of an oncological department in Germany. The study is the first stage of a bigger project aiming at the development of an empirical-ethical intervention to support decision-making in patients with advanced cancer.

Using non-participating observation as an open methodological approach, three different settings of oncological decision-making are explored, namely a) the outpatient clinic, b) the ward round, and c) the interdisciplinary tumor board meeting. The observation focuses on decisions made in respective settings as well as on reasons given and implicit factors underlying the decisions. Furthermore, ethical challenges as experienced by the stakeholders are identified and characterized. The qualitative data analysis of observation protocols proceeds in three different steps including open coding and selective coding with focuses on the decision-making as well as on the ethical relevance of the identified categories.

Main results emerging from this exploratory research comprise the distribution of responsibilities between the different clinical specialists, doctors’ dealing with risks and uncertainty, and differences between technical communication about cancer disease and the doctor-patient-communication on the same subject. Furthermore, organizational factors are identified which strongly influence doctors’ decision-making. Examples which will be elaborated in presentation are the question how medical data on the patients are presented and the presence or non-presence of patients, relatives and nurses in the different settings.

The results which are gained by qualitative data analysis serve as a basis for an ethical analysis of the problems which have been identified and characterized empirically. This normative analysis will be based on empirical knowledge of the concrete circumstances under which the ethically difficult situations occur as well as on central ethical concepts such as doctors’ professional responsibilities and the enabling of patients to make informed choices. Thus, the qualitative study facilitates a practice-oriented way of analyzing ethically challenging situations which is context-related and at the same time empirically informed and ethically justified.
Title:
Futile treatment of legal malformation of two fetuses

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Abstract text:
Congenital anomalies of the kidneys tract constitute a wide variety of malformations. Bilateral renal agenesis and dysplasia are the most severe types of malformations, leading to renal failure. With advances in dialysis and transplantation it is possible to prevent the early death of at least some children with severe malformations.

Ultrasonographic screening for fetal anomalies can detect renal agenesis and multicystic dysplastic kidneys which are seen in a rate of 0.013%. Diagnosis of agenesis can be complicated because the adrenal gland can mimic a kidney in ultrasonographic scans.

Here I describe two cases with “lethal” kidney anomalies and try to discuss their outcomes from the point of perinatal ethics.

Case 1: A 20 years old primigravida woman had the diagnosis of bilateral renal agenesis on ultrasonography at 18th weeks of gestation. Her and her husband’s family history were uneventfull. At 20 th week a consultation was organized including the obstetricion, a pediatric nephrologist and a neonatologist with the family. Bilateral renal agenesis was described by all the consultants in detail and said that the result was dialysis for a long time with kidney transplantation if everything goes in its way. Magnetic resonance of the fetus revealed the diagnosis was correct and the family leaved for thinking. When the family decided for termination of the pregnancy they were referred to another hospital for termination at the 22 th week.

Case 2: A 32 years old primigravida woman had the diagnosis of bilateral polycystic renal disease of her fetus at 24 th week. Her and her husband’s family history were uneventfull. The family decided to continue the pregnancy and at 33 th week of gestation the baby was born prematurely. He was moved to Neonatal intensive care unit (NICU) for ventilatory support. During the first month of age bilateral nephrectomy was done because of massive kidneys resulting in suboptimal nutrition and respiratory compromise. Peritoneal dialysis (PD) catheter placement was performed and dialysis was began. After 1 month of NICU period he was discharged on home PD. He will wait for kidney transplantation as early as 1 years of age.

Lethal malformation can be described as “a condition that invariably leads to death in utero or in the newborn period, regardless of attempted supportive treatment”.

This description may not be completely correct. In the first case the anomaly was a lethal malformation and it ended with late termination of pregnancy. In the second case the baby was born with bilateral renal anomaly and ended as renal agenesis. Two cases came to the same end and the first fetus died while the second fetus was waiting for transplantation. If I compare two cases was the second case an
example of futile treatment? Could it be classified as qualitative futility which means treatment might be technically successful in sustaining life, yet it is perceived that this offers no benefit to the patient.

The diagnosis of an lethal malformation has potential ethical and legal implication which must be discussed in detail.
Title: Parent-clinician collaboration: friend or foe of the child’s best interests?

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Abstract text:

Introduction: In Western medical practice, patient-clinician collaboration is central to establishing a patient’s best interests. Where the patient is a child who has no antecedent wishes because of immaturity or illness, this collaboration still takes centre stage with the child’s parents as proxies. English law favours this process, and parents and clinicians must decide together what a child’s best interests are, with recourse to the courts if no agreement can be found. The most controversial of these disagreements centre upon situations where a child will survive if they are treated, but it is unclear if survival serves their interests. Because such decisions rely on judgements about the value and quality of life, controversy centres upon the lack of an authoritative decision maker, and, as such, collaboration seems an intuitive solution.

Concerns about parent-clinician collaboration.

The legal record shows only one case reaches the English courts each year, and we can surmise that most disputes are resolved privately between parents and clinicians. Little is known about how agreements are reached, and, while the primary consideration is intended to be the child, competing factors within the clinical environment have potential to confound attempts to keep the child’s welfare in focus. Current models of collaborative decision making based upon consensus and compromise may offer us a template by which to measure the success or failure of collaboration, but raise some concerns. Theoretical work by Benjamin, Moreno and, lately, Huxtable has centred on judges, ethics boards and policy committees, and it is unclear how much can be applied to disputes played out at the hospital bedside. Firstly, it is not clear if we can expect the degree of reflexivity and mutual respect these theoreticians demand from conflicting parties. Secondly, while consensus and compromise models of decision making promote the aims of liberal pluralism, and thus offer benefits to the decision making parties, these benefits primarily manifest at a societal level in cohesiveness and liberal toleration.

Moving the focus back to the child.

Liberal values may offer ethical reasons for a conventional model of doctor-patient collaboration, but contain no suggestion that collaboration helps us reach a better decision in moral matters. In paediatric decision making, it is therefore unclear what benefits are reaped by the child upon whom the decision is meant to be focused; indeed, by collaborating on these terms it is unclear if the collaboration process hinders rather than helps any attempt to remain focussed on the child’s interests. In this paper I lay out the position in English law, a position that has wider European resonance due to its connection to human rights law, and discuss the literature around compromise and consensus. Finally I examine arguments for intersubjective collaboration that may suggest it offers us greater ethical insight, and consider both how the process of decision making needs to change to accommodate these arguments, and indeed, if they are sufficient to suggest the child’s best interests are benefited rather than endangered by this process.
Title:
Decision-making in the context of neonatal intensive care units: deciding about transitions from curative to palliative care

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Abstract text:
We apply for presenting a paper at the next EACME annual conference in Bochum. This paper will be based on an ongoing project analysing treatment decisions concerning premature infants ("Behandlungsentscheidungen bei Frühgeborenen - eine theoriegeleitete, ethnographische Untersuchung") funded by the DFG (04/2012-03/2015).

Nowadays, with the help of intensive care, more infants survive being born early. The earlier a child is delivered, the worse his chance of survival is and the more likely a permanent health damage occurs. These medical facts are the starting point for taking a closer look at the clinical practice in neonatal intensive care units focussing on decision-making in this specific context.

In order to understand these decision-making processes we consider the following questions as relevant (non-exhaustive):

Which decisions are (to be) made by whom? How are decisions (to be) made and what are possible/actual results of the decision-making processes? How are decisions communicated (to whom), how do decision-makers explain to themselves and to others why they have made a particular decision?

Taking into account the normative dimension of decision-making in the local context of neonatal intensive care units it becomes clear that it takes place in a legal framework and that it is influenced by ethical considerations. This refers to the decision-makers´ own ethical considerations as well as the anticipated ethical considerations of others who are affected by a decision and/or also take part in the process of decision-making.

The empirical study with the help of which we analyse clinical decision-making in the given context is based on various data, e.g. ethnographic participatory observations as well as interviews with neonatologists (chief, senior and assistant physicians), nursing staff members, mothers who had a preterm delivery and any other persons who turn out to be relevant in the given field.

The paper we apply for presenting at the EACME conference focusses on decisions about the transition from curative to palliative care. Taking into account the ideal of shared decision-making between physicians and patients (in this case: parents) both parties ought to be part of the decision-making process. As data shows, when deciding about transitions from curative to palliative care, medical and nursing staff members meet and make a decision which is then presented to the parents. As a general rule, curative care does not end without the parents supporting the decision of ending it.

Thus, physicians also have to take into account the (anticipated) parents´ ethical orientations which may differ from their own. Not only do they have to ask themselves in how far the newborn itself, his anticipated needs as well as the anticipated quality of his (present/future) life are in the focus of their
own considerations. They also have to reflect about whether their concepts of e.g. quality of life are consistent with the parents’ ethical concepts.
Title:
Direct-to-Consumer Genetic Testing: Recasting Regulators as Educational Partners

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Abstract text:
Companies such as 23andMe and Genetic Testing Laboratories, Inc. provide a host of genetics-related information - ranging from predisposition to certain medical conditions to genealogical findings - directly to consumers. Though direct-to-consumer (DTC) companies maintain that they simply enable individuals to access their own genetic information, they have been criticised for offering these services in the absence of standardised regulatory criteria that would guarantee the scientific accuracy and clinical utility of the tests being offered, and therefore facilitate the informed choice of purchasers.

A central concern about the regulation of DTC genetic testing is whether purchasers should be treated as consumers or patients. How ought we determine whether genetic information constitutes a standard consumer good or specialised medical information, and thus who should be responsible for regulating its sale? This concern taps into our intuitions about harms and wrongs; namely, can individuals be “harmed” by access to genetic information if the majority of purchasers cannot understand how to interpret this information without expert guidance, and thus cannot provide informed consent? Furthermore, what, if anything, is wrong if patients are not able to fully understand the information provided to them? Is it the unknown harms and benefits, particularly if we view genetic information as medical information; threats to free choice and autonomy, particularly if we view DTC testing as a primarily consumer transaction; or something else entirely?

In exploring these concerns, we ultimately reject the notion that the provision of genetic information requires heightened regulatory scrutiny compared to other kinds of consumer transactions. We then turn from the theoretical to the practical, examining the current patchwork regulatory frameworks and published principles for DTC genetic testing in the US and UK, as well as the organisation and regulation of genetic testing in clinical settings. Drawing on concerns expressed by genetics professionals in clinical practice, we argue that regulators should re-conceptualise their role in this emerging marketplace as one of educational partnership with the consumer and DTC companies. Such a re-conceptualisation will address the principle concern of regulating DTC genetic testing: consumers are largely left in the dark with respect to managing the genetic information they receive.Handled appropriately, regulation can clarify and improve this process for consumers, clinicians, and companies.
Title:
Personal Genetic Testing: Ethical Issues

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Abstract text:

Personal genetic testing is becoming increasingly popular, in part due to direct-to-consumer marketing. Companies usually offer testing for a selection of genes, while genome-wide screening still remains less affordable. Outside of the medical setting proper, the purposes of personal genetic testing are health promotion and disease prevention. Despite these reasonable goals, ethical issues make personal genetic testing debatable at this time.

According to the principles of evidence-based medicine, the benefits of health interventions need to be proven in scientific studies or at least recommended by experts. However, testing companies typically report results that lack support from multiple, independent, high-quality clinical studies. The clinical validity and utility of the tests have been questioned. Consequently, there is a need for an expert consensus on the quality standards for personal genetic testing, including both the methods and the reports. Such a consensus is the prerequisite for a potential insurance coverage of testing, which will likely be sought after because of increasing public interest and dropping costs of tests.

Consumers are frequently overwhelmed by the result reports that they receive, and genetic counselling is often necessary to put the personal test outcomes into a meaningful perspective. Counselling can best be provided as part of the regular health care system, and so the problem is again whether it should be covered by insurances. The considerations from evidence-based medicine apply to this issue as well because the counselling process also needs to be examined in order to be assessed as both clinically effective and financially affordable.

Personal genetic testing raises issues about data protection because genetic information is partially shared due to its inheritability. Relatives possess a "right not to know", which is difficult to strengthen in practice. Consumers have been shown to worry about threats to the privacy of genetic information. Coercion may lead more clients to undergo affordable testing despite remaining concerns.

In summary, the ethical, legal, and social problems of personal genetic testing have not yet been
Title:
Ethical, Legal and Social impact of Direct to consumer tests: The results of a Community Consultation

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Abstract text:
Background and aim: Today’s world market is confronting with a great number of developed company’s that offer genetic tests direct to consumer (DTC). The Big flow of these companies and also different offers of testing raises many of problematic questions. The aim of our paper is to present that DTC is not a correct application of personalized medicine.

Methods: In order to collect the opinions of the different stakeholders about this topic we will perform a qualitative survey on the real perception of the Ethical, Legal and Social issues by the community (Community consultation).

Results and Discussion: Examining the literature from Genetics, Law and Bioethics we have learned the main problems that concerns the DTC. We will elaborate these themes in some questionnaires that will be given to an investigated community, in order to evaluate the real impact of DTC on them. First of all we must distinguish that there are emerging ethical problems in shifting from evidence-based medicine to a medicine based on individual characteristics. Among the outstanding ethical problems that remain unsettled, in public policy lack of regulation and the accuracy of tests, informed consent concerning reliability of these tests, control over claims made in direct-to-consumer advertising, and the need to articulate clear standards for when counseling is appropriate and by whom it should be provided. Which in most of cases not exists or it is practiced in insufficient way, like online or through the phone. Counseling must include 1) that everyone’s participation is based on free will, 2) informed consent. Most concerning is reliability of this tests, how are the information that the companies give reliable, in particularly case of using the biomarkers in genetic testing. There’s a big difference in how many biomarkers are used in individual testing for disease and reliability of the results. This question of “complete and valid information” entail also the validity of informed consent. we will try to present the problems that emerges in the DTC: shifting from the doctor to the patient responsibility of the interpreting data; the widening patient’s autonomy; the change in the way medical care is practiced; issue concerning the commercialization of medicine; a new way to consider medical training and education (that as to face these new challenges).

Conclusions: Although these Direct consumer tests (DTC) are represented like non harmful test which helps to predict possible develop of disease, they in reality consist a lot off ethical concerning issues. We consider that DTC before going out to the market should be evaluated by means of ethical consideration included in Health Technology Assessment (HTA).
Title: Person-centred medicine and end-of-life decisions in dementia patients

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Abstract text: Within the group of people with neuropsychiatric diseases, dementia patients belong to those who, in the philosophical discussion as well as in the clinical practice, are often deprived of their personal status and hence of the capacity for leading an autonomous life. The demographic change and the considerable increase in the number of dementia patients in the next decades will presumably further advance the already resulting deindividualisation in the care of the persons concerned. This also has effects on the decisions at the end of life.

Our contribution contrasts two end-of-life practices which are especially controversial with regard to people with progressive cognitive deficits: physician-assisted suicide in early-stage dementia and euthanasia in late-stage dementia.

In the first part, ethical arguments are discussed which, against the normative background of a person-centredness, speak for or against the two measures. Special focus will be laid on conceptual and empirical aspects of mental capacity which forms the fundamental premise for an individually shaped life and death. The second part will critically take into account the double role of the persons concerned, who, on the one hand, as citizens, are entitled to decide about their life conduct and hence also about the way and time of the end of their life, and who, on the other hand, as patients, are dependent on the medical care system which often restricts their opportunities for action because of its regularities.

As a last point, it will be demonstrated how a medicine which takes the dementia patient seriously as a person and hence as a citizen with equal rights could look like at the end of life. It will be argued that euthanasia in late dementia patients can usually not be reconciled with a person-centred medicine, while physician-assisted suicide in early dementia patients can, under certain circumstances, contribute to an individualisation of medicine which is desirable from an ethical point of view.
Title:
In control when out of control? Pro’s and con’s of Ulysses contracts in psychiatry

Authors:
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Abstract text:
Within a large multidisciplinary study that aimed to understand different conceptualisations of autonomy of patients in different health care laws, we focussed on challenges to patient’s autonomy in the context of coercion in psychiatry. One way for psychiatric patients to remain in control in situations of coercion is the use of advance directives (Ulysses contracts). Patients can, in a juridical document, describe under what circumstances (criteria) they want to be involuntary admitted in a psychiatric hospital and treated against their will.

The study used a responsive methodology to gather experiences and foster dialogue on pros and cons of the instrument. Data collection consisted of interviews and focus groups with patients, patient advocacy workers, and care workers as well as analysis of juridical documents, jurisprudence, guidelines and literature.

Results show that patients are positive about the opportunity in the law to control the situation when their ‘madness’ gets the better of them, but also that this instrument is not frequently used in practice. Patients are reluctant and care workers are unfamiliar with the juridical instrument or experience practical difficulties.

In this qualitative study the empirical data are analysed from an ethical perspective. We will discuss a success story of a patient and compare this to several obstacles that other patients and practitioners experience in practice. We will reflect on how positive aspects of the instrument could be retained, and negative aspects overcome. We propose to give a place to the preferences of patients within the practice of coercion in a less formal way, for example by using crisis plans, which are made by the patient and the professional(s) involved in the care. Such plans can lay down preferred actions, without legal procedures. This will enable professionals to take action based on joint decisions, and prevent further deterioration of the patient’s situation in situations of crisis. By integrating the notion of advanced planning into a context of care, rather than turning it into a legal construction, person-centred medicine in psychiatry can be made both more effective and more ethically sound.

This study was conducted in collaboration with dr. B. Frederiks, (VUmc) and prof.dr J. Legemaate (AMC), both specialised in Health Law.
Title:
"Should we press him to quit smoking?"
Dealing with the tension between assertive outreach and demand driven care

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Abstract text:
Keywords: Patient-doctor relationship, respect for the person and decision-making, concepts of care, assertive outreach vs. demand driven care, ethics support instruments.

Abstract: Do we respect a client's autonomy and expressed needs or do we overrule this in order to prevent harm or to do well? This is a general dilemma that many health care professionals have to deal with in every day decision making. Our presentation focuses on a specific type of this moral dilemma, i.e. dilemmas that arise from the tension between demand driven care and assertive outreach. Whereas the former lets patient autonomy trump, the latter favors beneficence. Both concepts of care are promoted by continuing but contrary currents in today's Dutch health care system. On the one hand, demand driven care should accomplish that health care is more sensitive to the individual wishes and needs of patients. Market mechanism in the healthcare domain and better informed patients are important drivers for this development. On the other hand, there is an increasing awareness that the emphasis on autonomy and freedom of choice deprives some people of treatment from which they could really benefit. In some situations, good care, it is argued, goes against a patient's uttered wishes. In addition, health care professionals are encouraged to focus on prevention in order to avoid further harm - and costs -, and therefore, on urging patients to change their lifestyle rather than waiting to treat the consequences.

Our present study investigates 1) how this tension between demand driven care and assertive outreach manifests itself in every day decision making, 2) how dilemmas that arise from this tension are dealt with, and 3) how we can provide effective ethics support based on our analysis. We do this by organizing about 40 moral case deliberations in a large healthcare institution in and around Amsterdam. This institution provides care for the elderly, the physically and mentally disabled, and clients in psychiatry. Former research has shown that professionals of this organization, within all its domains, frequently struggle with dilemmas around this theme. To illustrate this, there is the case of a 65 year old man with a mental disability, who receives ambulant care. He suffers from metabolic syndrome, which poses serious health risks. Ambulant care workers are urged by his GP and his family to press him to quit smoking and heavy drinking, and to provide treatment for this. At the same time, the man himself repeatedly makes clear he has no intention to make lifestyle changes: he actually 'feels fine', and 'is happy' with his life. Questions arise, such as: 'Is this man mentally able to assess the long term consequences of his lifestyle?' To what extent are we responsible for his health?, “What is good care in this specific case?”

In our presentation, we will mainly focus on the first two research questions on the basis of the outcome of the first phase of our research project: the analysis of fifteen moral case deliberations. This analysis 1) categorizes the diverse concrete manifestations of this tension in every day decision making of health care professionals, 2) maps the relevant different perspectives of this tension (for instance between a family member, GP and ambulant care worker), and 3) shows the different ways
health care professionals deal with this tension. Which principles are foundational in their decision making? Which solutions are found?

To end our presentation with, we will shortly go into a first draft of an ethics support instrument that these professionals can use in their decision making that we seek to develop in close interaction with the envisioned
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