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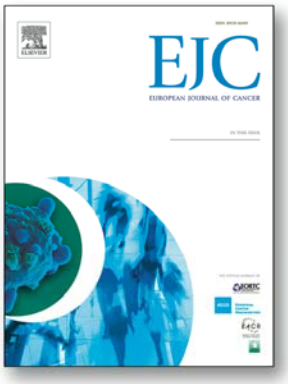

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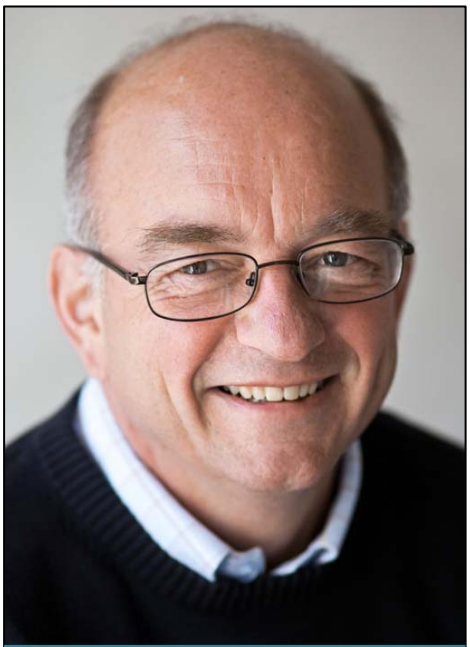
EUROFILE

Data Protection Regulation provokes intense lobbying

A concerted lobbying effort is underway by stakeholders in the cancer community as the European Parliament heads towards the summer recess before returning to vote in October on the General Data Protection Regulation (GDPR). To date, there have been more than 4000 amendments to the Draft Regulation proposed in January 2013 by the European Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE).A key concern about the LIBE draft is that it requires personal consent every time a subject's data are used.



Hans Storm

Hans Storm, (Danish Cancer Society) submitted a detailed list of amendments in February on behalf of the European Network of Cancer Registries, The Association of Nordic Cancer Registries and the Danish Cancer Society. On reading the report from the LIBE committee meeting, Storm said he was "stunned" by how little the MEPs and their researchers had understood about the importance of broad consent for biomedical research.

It was as a result of this LIBE meeting, he says, that the rapporteur requested that informed consent be sought from each individual – whatever type of data analysis was being carried out. "That was despite a derogation from informed consent or the use of such data for the purpose of the good of the population."

"The MEPs still haven't managed to agree on it so it's hanging in the air for the time being," Storm says. "The crucial point is that you cannot have informed consent for each individual, whatever the type of data analysis you do, when you are studying whole populations."

The proposed opt-out system is also known as implicit consent. The LIBE rapporteur has implied that a newspaper advertisement about the research, or letters sent out to the populations Involved (if they don't respond, they are considered to have accepted

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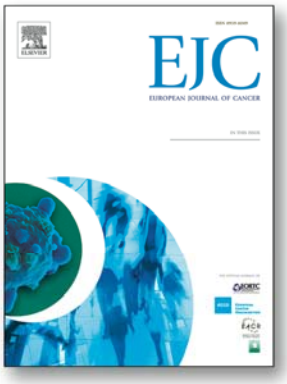

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use of their data) would be sufficient for a project to go ahead under this system. Storm disagrees: "From a legal point of view, in developed countries like the Nordic ones, this is totally unacceptable."

Storm believes that implicit consent would be worse than the present situation in which an ethical committee and a data protection agency oversee the use of personal data. Health registries, population registries and the European initiative to create large scale biobanking facilities – which are all used for public health research – would be at risk if the draft regulation were to be accepted.

In not grasping the importance of a broad consent, along with surveillance by ethical committees and data protection agencies (rather than an opt-out approach), Storm maintains that politicians are risking the public's health by preventing future important studies. An example would be research on cancer incidence in relation to proximity to power stations. If this had been undertaken using an opt-out approach, the study would have had inbuilt flaws.

> ***'This Regulation would slow down or even kill biomedical research in Europe'***
>
> **Denis Horgan**
> **EAPM**

"I would bet my salary for a year that people who live near a power station who have contracted any kind of disease would say yes to the study, whereas those who had no disease would not answer the advertisement or letter. So you lose from the study the people who are healthy, and get skewed data that over-estimates the effect," Storm says. "And if you need informed consent for each patient in electronic form that will cost a lot of money, which is not really donated to research. So many studies would not be able to be carried out because of financial and logistical reasons."

He also highlights the ethical dimension: asking repeatedly for consent would bother and scare many people who may be left with a lingering suspicion that something must be wrong.

Generally the GDPR would tend to make academic-funded research harder to do because of higher costs and for logistical reasons, Storm concludes. "The results may be biased and send us off on completely the wrong track."

Denis Horgan, (European Alliance for Personalised Medicine), said that while the EAPM is lobbying on behalf of all key areas of biomedical research, he acknowledges that cancer is different: "This Regulation will have a big impact on the cancer community. Breast cancer tissue is collected over a period of 45 years and stored in biobanks. The Regulation as amended by LIBE holds that if you want to draw on this data for a certain use you need to get specific personal consent from the patient. But

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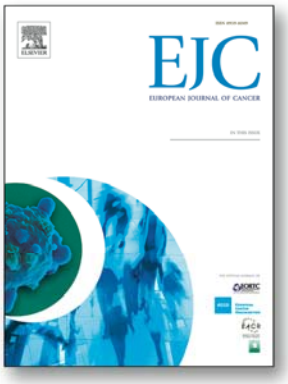

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often the donating patient cannot be traced. Therefore the research community wants the Regulation to be amended so that a one-off broad consent of the patient at the time of biopsy is sufficient to cover all future biomedical research uses of their data."

Horgan too is concerned by a lack of understanding among MEPs of the difficulty of the amendment requiring specific personal consent. "They are not taking account of the need of the cancer research community for broad consent," he explains. "They think that consent should be obtained on every occasion. You can't do this for thousands and thousands of patients; it will slow down or even kill biomedical research in Europe. You don't need to ask for every use of tissue; we don't know what future advances there might be."

> ***'The drive to protect right to privacy is in conflict with patients' right to donate their data for research'***
>
> **Paulo Casali**
> **ESMO and EAPM**

Another key EAPM concern is that politicians have not agreed that patient data can be shared between countries. This would limit the availability from valuable sources such as the EORTC melanoma network. Before you could look at tumour registry data of patients who had died you would have to contact members of their family to get permission. "The politicians want to ensure the privacy of patients but they are stopping the kind of research that patients want," Horgan argues.

The EAPM works closely with the European Cancer Patients' Coalition (ECPC) which is a member of EAPM and, according to Horgan, supports the principle of broad consent and of sharing of patient data between countries: "We have proposed parliamentary amendments on behalf of ECPC, which support this, and we have called on the MEPs to support the patient's wishes. They are the citizens they represent."

"Parliament does not fully appreciate that health data are regulated already and that there are safeguards to protect patients. It is looking at all data as if it's Google kind of data – the type of interest to advertisers," he says.

The EAPM alliance, which receives about half its funding from Government, NGOs, medical societies and patient donations, and the rest from the pharmaceuticals industry, is also lobbying on the right of data subjects to information. "It is not always possible or proportionate for researchers to provide information to data subjects because of the scale of the study or because data was collected a long time ago," Horgan explains. "So it is important that there is a 'disproportionate effort' exemption from the right of the data subject to information in Article 14."

A wide range of stakeholders will continue to make their views known to MEPs in the

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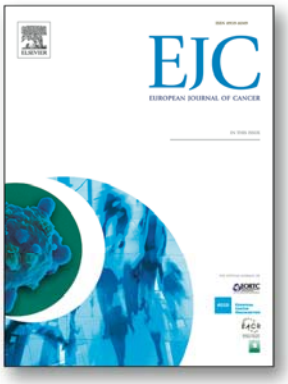

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run-up to the plenary session vote in Parliament in October; ESMO is taking the lead on behalf of the cancer research community. Paolo Casali, Chair of ESMO Public Policy Committee and of EAPM's Working Group for Regulatory Affairs, says: "Our main concern is to what extent consent of the patient to use their data, their clinical data, needs to be specific."

Casali points out that if it is really specific this would mean the patient would be unable to donate their data for research. ESMO's stance is that tissue banks should be precluded from any requirement for further consent every time something new is planned for patients' data, he says. Article 4, paragraph 8, on data subject consent means any freely given informed explicit indication signifies agreement to personal data being processed.

He says ESMO's main concern was that the word "specific" was being interpreted in such a way as to make it necessary to go back to the patient whenever some new use was made of their data/tissues. "We would like to see in the final Regulation the possibility of the patient to give broad consent. The drive to protect their right to privacy is in conflict with their right to donate their data for research."

Casali says the new Regulation would cause difficulty when new research was attempted using data from a previously completed trial. "You will have built up this precious source of clinical information for the future, collected regularly and rigorously," he explains, "And use beyond the aims of the trial will not be allowed." This would be a major loss, since, throughout the history of medicine, doctors have tried to learn from their previous patients, he says: "It would be crazy if the physician cannot improve his practice by referring to information from previous patients."

> ***'It could take years before this strict regulation becomes law and that will be a good thing because it might give Parliament time to come to its senses'***
>
> **Evert-Ben van Veen**
> **Medlaw Consult**

Every cancer patient has at least one biopsy stored, and these blocks of tissue form a precious source of data for future research, particularly in the Investigation of new disease-specific biological targets. Casali: ESMO has patient representation within the Society but it has also had talks with representatives from the ECPC. "They are absolutely in favour of broad consent because it is in the interests of patients to advance medical knowledge," says Casali.

He feels the combined voice of patients and oncologists will have a positive influence

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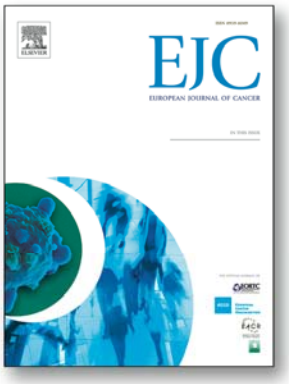

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on the progress of the GDPR. “I am optimistic. We at ESMO have spoken to a lot of people from the European Parliament. And I think everyone clearly understands the problem and sees the solution as some kind of broad consent. We are not politicians; we can only raise our concerns and hope they are taken into account.”

Evert-Ben van Veen, a specialist in the regulatory affairs of biomedical and health research (MedLawconsult), has been advising ESMO, the Dutch Federation of Biomedical Scientific Societies and other research associations affected by the GDPR. He said the Regulation was an overhaul of the previous Directive to put it in tune with the internet age and to be consistent throughout Europe, with no national exceptions.

The LIBE amendments of January 2013, he says, included at least two detrimental changes: the raising of the threshold for informed consent and the narrowing down of exemptions made for biomedical research.

Researchers need access to unique data about a person from various sources. “You want to have it all filed under the one person, not what we call administrative twins,” he points out. “Key-coded data get at the source a key number, a code number, and all that goes to the researcher. At the moment this is considered anonymous data but the Commission wants all key coded data considered as personal data. That is a huge change that would broaden enormously the scope of the Regulation. And because they make no exception for research type of data, consent would have to be sought every time a researcher wishes to use this data.”

A broad consent approach is used for UK biobanks, together with a system of governance which oversees the ethics of research and the protection of patient privacy. “The governance system in my view goes hand-in-hand with broad consent. But broad consent may not be possible under the amended regulations; it may not be considered valid consent.”

Van Veen considers that the lobbying effort needs to be directed at getting MEPs to realise that obtaining the kind of specific precise consent they are requiring is not always feasible. “My hope is that the Council of Ministers will take a more balanced approach and allow broad consent for biomedical research, he says.

The next stage is for the amended GDPR proposal to go to the European Parliament. The Council’s ministers will make a new first draft; Parliament will make a second draft, and the Council of Ministers will then make a third draft, negotiating compromises by taking account of input from Parliament.

However that timeline has already slipped and may do so again.

“By that time there will be a new Parliament because there are elections in May; so the whole circus might start again,” van Veen says. "This might be a good thing because it would take years before this strict regulation became law and that might give Parliament time to come to its senses."

Jim McGuigan

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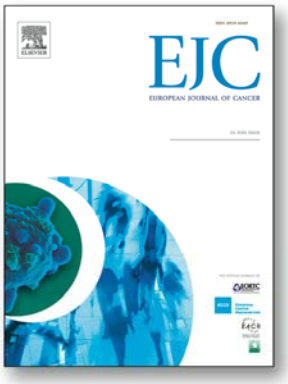

INTERVIEW

Facilitating choice at the end of life

Extensive evidence has shown that the majority of people, when confronted with an advanced illness, would prefer to die at home. Despite policies encouraging this, in many countries, less than one third of all deaths take place at home.

A Cochrane review was set up to quantify the impact of home palliative care services for adult patients with advanced illness and their caregivers.

It included 23 studies, identified through searches in electronic databases, 49 systematic reviews, four textbooks and recent conference abstracts. It found 'clear and reliable evidence' that home palliative care increases the odds of dying at home and reduces symptom burden in particular for patients with cancer, without impact on caregiver's grief.

***Barbara Gomes (King's College London, Cicely Saunders Institute, UK)** was lead author of the review (doi:10.1002/14651858.CD007760.pub2)*

How many of the patients included in the review had cancer?
Palliative care services in many countries were initially developed for cancer patients, so most of the evidence is in cancer. In this review, around two-thirds of the studies included only cancer patients, some included both cancer and non-cancer and a few included only non-cancer conditions. But it would be difficult to distinguish between conditions, as symptoms such as pain, fatigue and breathlessness are prevalent across different advanced diseases (in more than 50% of patients with advanced cancer, AIDS, heart disease, chronic obstructive pulmonary disease and renal disease, for example). Some symptoms are more common in certain conditions than in others, but the findings from the review are broadly applicable.

What proportion of patients would prefer to die at home?
Previous studies have found that the majority of people prefer to die at home, but precise numbers vary between countries. There seems to be more consensus within the general public than among patients and caregivers. We carried out a European survey of over 9,000 members of the public in seven European countries and found that two-thirds said they would want to die at home if faced with a serious illness such

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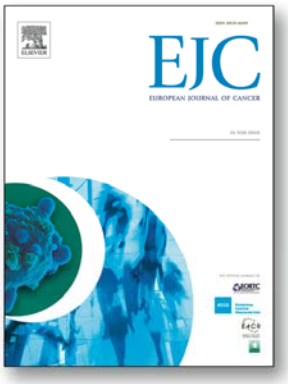

Barbara Gomes *continued.*

as cancer. There was no difference in preference between those who had experienced a serious illness in the previous 5 years and those who had not. But it varied between countries: 84% in the Netherlands compared to 51% in Portugal.

What factors influence preferences?

Living in a rural area was associated with increased odds of dying at home, but we're not sure whether that is the result of preference alone or if it relates to accessibility to hospitals, for example. Previous work has found an age effect but it's not linear. Young adults more often tend to prefer to die at home, but as the years increase, that preference becomes less pronounced. In older groups the trend reverses again and they more often tend to want to die at home, but there is also a high preference for dying in hospices or palliative care units, depending on country. Age is a difficult factor to interpret as it may involve generational effects.

What were the key findings of this review?

That people with access to home palliative services were more able to die at home, that they had a reduced symptom burden when compared to usual care and that there was no increase in grief among caregivers. The quality of care and its cost is a concern as more and more people die at home in the UK, Canada and US, for example, particularly those dying from cancer.

Why would the symptom burden be less for people receiving palliative care at home?

This is a plausible effect because home palliative teams are highly skilled multi-disciplinary teams with advanced training in palliative care and experience in dealing with the symptoms and problems people may experience as a result of an advanced illness. The criteria we used for defining a home palliative care team was that they should possess either experience or specialist knowledge. And as our earlier research at the Cicely Saunders Institute showed, people with diseases such as advanced cancer, respiratory failure and late stage neurological diseases, can suffer from as many as 12-14 different symptoms. The review shows that home palliative teams know how to deal effectively with this high symptom burden.

What about the effect on the family caregivers?

Family carers play an important role, and palliative care encompasses support for families as well as patients. The teams educate family carers in how to deal with symptoms and crises at home, and how to take care of themselves. These services had no impact on caregiver grief, which is important because there have been occasional findings of a negative impact on caregiver burden. We need to be aware of the potential for this negative effect on the family, and ensure that we support family caregivers. There is evidence from the review of positive effects from reinforcing home palliative care services with a specific component of caregiver support. But we also need more research on family outcomes.

How widely available is home palliative care?

It varies widely across Europe. In England, Wales and Northern Ireland, there are around 250 home palliative care teams (one team per 240 thousand inhabitants),

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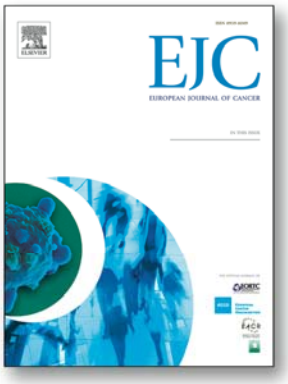

Barbara Gomes *continued.*

whereas in Portugal there is only one team per 1,170 thousand inhabitants. It is one of the possible reasons why fewer people in Portugal than in other countries opt to die at home. Also, the primary care support available to people in the community is scarce, and people may not feel safe. But there may also be cultural issues.

How expensive is the provision of home palliation?

There were only a few economic evaluations considering both costs and outcomes, although this analysis is important because service planners and providers need to weight the impact that this service has on patients and relatives alongside its costs. There were six studies which gave information about cost effectiveness but the evidence was inconclusive. Two recent, high quality trials, one from the US and one from the UK, both suggest that home palliative care is cost-effective compared to usual care, but these are two of the six, the results from the remaining four were difficult to interpret, and therefore there wasn't an overall consistent message.

How difficult is it to study cost-effectiveness?

There are huge challenges to applying cost-effectiveness measures to palliative care. Measures used in other fields of health research and drug development emphasise quantity of life, for example, and at the end of life, we know that this is not people's priority. The European survey we have recently conducted found that around 75% of people said quality not quantity of life would be their priority if they had a serious illness, such as cancer, and had less than one year to live. There are robust ways of measuring outcomes in palliative care but it is an area where cost-effectiveness is difficult to grapple with. However, home palliative care is an extra layer of care and if we're recommending it to health services facing financial restraints, we need to show that it is cost-effective.

You make the point that, with ageing populations, this situation is going to become more common?

The trends in different countries show the same thing: rapidly ageing populations, and dependency ratios that mean societies are less able to care for them. We have to face the issue of how we are going to care for an increasing number of people dying from progressive and advanced conditions at increasingly older ages, when professional and family carers are also ageing. We must start planning strategically and putting in place the resources necessary to deal with the growing need for palliative care.

What were the research implications from the review?

Future research must be appropriately powered. Some of the studies in the Cochrane Review were underpowered, partly because of the challenge of conducting trials in palliative care. There is natural attrition through death but people are also often lost from studies and we need to ensure that we have sufficient numbers to have the statistical power to detect differences where they exist. We're calling for appropriately powered trials which measure outcomes that matter to patients and families, and which use robust and validated tools. There are good examples; the Cochrane Review includes six randomised controlled trials (RCTs) which were rated high quality, according to standards applied in other healthcare fields. It can be done.

Interview by Helen Saul

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