The Devil is in the Detail: Best Practice, or Catholic Practice?

Charles Douglas, University of Newcastle (NSW)
Melanie Jansen, University of Queensland
Ian Kerridge, University of Sydney

Dr. Charles Douglas, PhD
Senior Lecturer in Clinical Ethics and Health Law
The University of Newcastle
University Drive,
Callaghan NSW 2308 Australia
charles.douglas@newcastle.edu.au

Dr. Melanie Jansen, B.Med
Associate Lecturer, School of Medicine
University of Queensland
Brisbane QLD 4072 Australia
melaniejansen@hotmail.com

Dr. Ian Kerridge BA, BMed(Hons), MPhil(Cantab), FRACP, FRCPA
Associate Professor and Director
Centre for Values Ethics and the Law in Medicine
University of Sydney NSW 2006 Australia
Email: ian.kerridge@sydney.edu.au

Bios
Charles Douglas is a practising surgical oncologist and Senior Lecturer in Clinical Ethics and Health Law at the University of Newcastle, NSW. His research interests include end-of-life decision-making, informed consent, moral philosophy and clinical aspects of melanoma and breast cancer. He is an atheist, but holds an appointment as Visiting Medical Officer at a Catholic medical institution.

Melanie Jansen is a Paediatric Registrar at the Royal Children's Hospital, Brisbane. She is also Assistant Professor in Medical Ethics at Bond University, Gold Coast and Associate Lecturer...
at the University of Queensland Medical School, Brisbane. Melanie’s main research interests are in clinical ethics with a special interest in paediatric issues.

Ian Kerridge is a practicing haematologist and Associate Professor and Director of the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. His research focuses on the philosophical, moral and socio-cultural concepts, frameworks and issues that underpin health, health policy and biomedicine including in public health, research and clinical care.

Rendell and colleagues state an honorable mission – “to safeguard the rights of research subjects in Catholic institutions” (Rendell, Casey et al. 2012). However we think a close inspection of their paper reveals a concern not with the rights of research subjects, but with the rights of Catholic health providers. If ‘Catholic moral teaching’ is ‘respected’ as a matter of policy in Catholic medical institutions, far from safeguarding the rights of subjects, it has the potential to deny patients options and to deny them the best possible medical care - regardless of the moral beliefs of the individuals. We illustrate these points by referring to developments at the Calvary Mater Newcastle, a publicly funded oncology hospital in regional New South Wales, Australia, that has come into conflict with local researchers and oncologists over the conduct of oncology trials (Robotham 2011).

There are two significant and related ideas embedded in the paper by Rendell et al, one regarding the dissemination of information to patients, and one relating to compromises that the authors believe should be made by study sponsors. We consider these in turn.

With regard to information, principles 4) and 5) seem straightforward: “...Potential subjects in clinical research studies must be given full information, including a complete description of any requirements not consistent with Catholic moral teaching”. However, the authors go on to say

investigators ... need not counsel regarding the various methods of birth control and/or issue prescriptions. Nor is it required to stipulate the methods explicitly in the informed consent...patients ...should consult with their personal professional care-giver.

In other words, potential subjects must receive full information, but Catholic institutions reserve the right to wash their hands of the responsibility to provide it. The patient may be advised to go to a website for information, or to talk to her family physician. While the authors seem to leave open the possibility that the recruiting doctor may discuss contraception explicitly or even provide written advice, we think it is likely that a Catholic institution will issue its own directives, to its employees and doctors working on its premises, in order that Catholic moral teaching is ‘respected’. This is exactly what happened in Newcastle. Administrators at the Calvary Mater Newcastle professed to not want to interfere with the doctor-patient relationship, but expressly opposed written advice about contraception being part of the interaction (Robotham 2011).

We believe that patients deserve the best communication possible, not a referral to find information from other sources. This is true in any setting, but particularly so in oncology where patients are usually anxious and overloaded with information. Communication of medical information is challenging, the patient is at high risk of forgetting and written
information may aid recall (Kessels 2003; Watson and McKinstry 2009). Furthermore, we think that therapeutic relationships are impoverished when a doctor chooses to delegate his or her responsibilities for communication – think of a doctor who refers all oncology patients to a psychologist because she feels uneasy about dealing with the emotional fallout from the diagnosis. In this regard it was noteworthy that many of the Catholic oncologists employed by the Calvary Mater Newcastle were outspoken in their opposition to the institution’s stance on contraceptive advice, believing that it compromised patient care (Robotham 2011).

The second important idea in the paper by Rendell and colleagues is that study sponsors should relax their requirements for including patients in studies of teratogenic drugs. Several compromises are suggested, including a less explicit consent form. It is also proposed that sponsors allow subjects to enrol on a promise of abstinence from sexual intercourse. We have no problem with inclusion on this basis, from a moral perspective. However, we think that in excluding such patients the sponsor addresses legitimate interests of its own. While we are not aware of any data for pregnancy during periods of (attempted) abstinence in sexually experienced adults, there is evidence that ‘abstinence education’ is associated with higher rates of teenage pregnancy compared to education programs that explicitly address contraceptive measures (Stanger-Hall and Hall 2011). It seems reasonable for a sponsor to decide that by including ‘abstinent-committed’ patients, (or by using less-than-explicit consent forms) the risk of negative legal or commercial consequences are increased, and we think it is quite likely that some sponsors will not be prepared to make the compromises Rendell and colleagues propose.

If compromise cannot be reached it is clear that the ‘contraception policy’ of the Catholic institution, as much as the commercial and legal interests of the sponsor, threatens to affect patients adversely. The threat of a lost opportunity is certainly real in Newcastle. Despite its Roman Catholic origins the Calvary Mater Newcastle is largely publicly funded, and it is the only publicly funded oncology hospital servicing a large regional population. Administrators at the hospital have indicated that they would be prepared to block trials of teratogenic drugs if explicit written advice on contraception were required. This could mean that all Catholic and non-Catholic patients in the Newcastle region would lose the option of going on trial, and with it their only chance of accessing a particular therapy. The equity issues in other regions may not be so stark - it may be possible for a patient with cancer to leave a Catholic hospital and/or Catholic doctor, after diagnosis, in order to gain access to a clinical trial elsewhere. However such change has its own problems, being a significant interruption in care for a vulnerable patient.

The notion that patients might have to go elsewhere to get the best possible care seems to sit uncomfortably with the Catholic Church’s commitment to care for all patients compassionately and justly. To make the moral argument more appealing, Rendell et al suggest that their proposed changes to research protocols are designed to protect the interests of patients by limiting the risk of coercion. Apparently without deliberate irony, the authors express particular concern about homosexual women. We have two comments to make about this coercion argument. Firstly, we note that 99% of all women, and 98% of Catholic women, have used a ‘non-natural’ method of contraception (Jones and Dreweke 2011). The moral view on contraception espoused by the Vatican does appear to be an extreme minority view, and we think that consumers generally, and even Catholic consumers, are largely unconcerned about the ‘evil’ of contraception. Secondly, the use of the word coercion is unreasonably used here in a pejorative sense, when what is really being offered is a choice to a patient in a difficult situation. We don’t think that women are being
coerced into using specified forms of contraception, any more than a person is coerced into wearing specified items of safety equipment as a reasonable condition for being allowed to participate in a potentially dangerous activity. The study sponsor is effectively saying, ‘if you have an objection to using this safety equipment, then I’m afraid you can’t participate in the activity that I am organising’.

If not about protecting patients, is there a good moral argument relating to the consciences of Catholic doctors (and/or administrators)? We do not think so. Quite apart from the probability that most doctors within a Catholic institution (like most Catholic women) don’t share the Vatican’s view on contraception, no-one is asking individuals who do believe that contraceptive measures are evil to recommend their use, let alone to use contraceptives themselves. Rendell and colleagues approve of language that “states the Catholic position without endorsement or prejudice by the investigator”. Conversely, Catholics should not object to documents that simply state the medical facts (on contraception) – the mere statement does not imply endorsement by the Church.

We are left with a very strong impression that Catholic health administrators want to uphold certain policies on contraception, not for the sake of protecting their patients from coercion, nor for protecting individual providers, but for almost political reasons – for the sake of ‘holding the line’ on Catholic sexual morality. In the context of oncology trials, this commitment to uphold Catholic moral teaching must surely represent a conflict of interest for institutions whose primary mission is to care for vulnerable patients.

References


