

Ethics Challenge

2011/2012

The case

Two cousins raised in California's rural Central Valley were both diagnosed with malignant melanoma after having spent most of their young adult lives working outdoors in the building trade. Both men were under 25 at the time of diagnosis and both had diseases with similar genetic profiles, specifically the mutant gene B-RAF. Together with stage IV disease, this mutation qualified them for enrolment in a Phase III trial comparing the efficacy of a new drug, PLX4032, with dacarbazine, the current standard of care. PLX4032 is produced by the Swiss pharmaceutical giant Roche and is a specific B-RAF inhibitor. Data from a recently completed Phase II trial demonstrated that PLX4032 halted tumour growth in 81% of patients for an average of eight months, compared to a dismal 15% of patients for an average of two months for dacarbazine. However, questions still remained as to whether PLX4032 actually increased survival since, when tumour growth did recommence, it was particularly aggressive in those having received PLX4032 compared with dacarbazine.

Both men were ultimately enrolled in the trial but the younger of the two was randomised to the treatment arm and the other to the control arm. Both the older cousin and the oncologist looking after him were devastated at the news that he was not to receive the new drug. His oncologist was powerless except to prescribe dacarbazine, despite being convinced that this was not the best care for his patient, and after suffering nine agonising months as the cancer spread to his bones, the older cousin eventually passed away. Conversely, the younger cousin receiving PLX4032 had a dramatic improvement in quality of life as his tumour regressed rapidly within two months of starting PLX4032, and he remains alive today.

This is the third instalment of the RCSIsmj Ethics Challenge. The editorial staff would like to congratulate Alison DeMaio and Nathan Clendenen for their winning essay in the 2010 Challenge. Please see page 6 for their submission.

Once again, we invite all students to submit an essay discussing the ethical questions raised in the case study presented here. Medical ethics is an essential aspect of the medical curriculum and we hope to encourage RCSI students to think critically about ethical situations that arise during their education and subsequent careers. All essays will be reviewed by a faculty panel of experts, and the winning essay will be published in the 2012 print edition of the *RCSIsmj*.

Key issues to be addressed:

1. Identify the ethical issues involved in this case. Think about the trial itself, and the role of evidence-based medicine and of the physicians in implementing the trial protocol.
2. How would you address these ethical issues?
3. As the prescribing physician, discuss how you can or cannot justify enrolling these two cousins in this clinical trial.
4. Consider weaknesses in your position and address potential challenges to your arguments.

Submission guidelines

Please construct a lucid, structured and well presented discourse for the issues raised by this case. Please ensure that you have addressed all the questions highlighted and discuss these ethical issues academically, making sure to reference when necessary.

Your paper should not exceed 2,000 words.

Your essay will be evaluated on three major criteria:

1. Ability to identify the ethical issues raised by the case.
2. Fluency of your arguments.
3. Academic quality with regard to depth of research, appropriateness of references and quality of sources.

Good luck!

This is a perfect opportunity to be published and is the only officially guaranteed publication in the *RCSIsmj*.

The deadline for submission of entries will be the same as the general submission deadline for the 2012 edition of the *RCSIsmj*. Please keep up to date by visiting our website at www.rcsismj.com.

Any questions? Don't hesitate to email us at editorsmj@rcsi.ie.