INTRODUCTION

The Olivieri symposium

Introduction to The Olivieri symposium

A M Viens, J Savulescu

Adrian Viens, Guest Editor of this Olivieri symposium, and Julian Savulescu, the Editor of JME, set the scene for the symposium.

In failing...[her] when she needed them most, it is now clear that some members of the University’s Faculty of Medicine heard her muffled cries of academic freedom from the back room, yet their response was to serve another round of drinks and turn the music up louder. With the bombshell revelations in the...affair, the plug may have been pulled on this business sponsored party, and hopefully a sober re-examination of the university’s neglected role and responsibility toward independent inquiry and academic freedom can begin.

These guys don’t get one thing—we’re not going away. This isn’t a personal vendetta. This is something I want patients to be protected from when I’m dead, fifty years from now.

The Olivieri affair is not a mystery novel, but instead the latest skullduggery at Toronto’s Hospital for Sick Children.

The legal assaults which you have endured in your battle against the drug company, and in your battle against the medical establishment appear to have been fought with the type of uncommon bravery that is rarely seen. It is for this reason that our trustees have unanimously chosen to recognise you for this most prestigious award.

The Olivieri affair resulted from a fundamental misreading of the issue as a mere contractual and scientific dispute...[It is] Canada’s worst academic and research scandal in decades...[Since 1998, Olivieri has been] demoted, then restored, then harassed. She has been smeared with allegations attacking her competence, integrity, sanity and personality.

The Olivieri affair is one of the most important events to occur in research ethics. From its dominance in the Canadian and international news media, to changes in the governance of public health, academic medicine, and biomedical publication that have resulted, to the lives directly touched and altered forever, the Olivieri affair has had a number of wide reaching effects on a number of people. There is much to be learned from this case.

Although there have been articles in the medical and bioethics literature discussing the Olivieri affair, this special symposium represents the first sustained analysis of some of the central ethical issues and lessons that can be learned from such cases. It is hoped that this symposium will provide for those engaged with similar issues and cases a fruitful and informative examination of professional ethics, research ethics, academic freedom, and related considerations.

The Olivieri affair has raised a number of important normative questions concerning the substance and limits of particular theoretical commitments and how ethical judgments and norms are implemented in practice. The issues surrounding the Olivieri case are not novel. Unfortunately, issues of patient safety, conflict of interest, and academic freedom continue to plague many areas of biomedicine. The Olivieri affair has, however, gripped the attention of physicians, researchers, and bioethicists around the world as a prime example of the limitations of ethics review at multiple levels.

In the introduction to this symposium, we shall begin by very briefly explaining the disease and therapy at the centre of this case. We go on to provide a timeline of the most salient events in the Olivieri affair. We conclude by discussing the contributions to this symposium and how they bear on the ethical issues surrounding this case.

I. THALASSAEMIA AND ITS TREATMENT

Thalassaemia major, also known as Cooley’s anaemia or Mediterranean anaemia, is an inherited blood disorder caused by a mutation in the beta chain of the haemoglobin molecule that results in the production of abnormal haemoglobin. The abnormal haemoglobin that is produced cannot properly bind and release oxygen, and, if left untreated, can result in symptoms such as chronic fatigue, failure to thrive, growth deficiencies, bone deformities, and eventually death.

Consequently, the primary goal of treatment is to provide frequent blood transfusions (approximately every three to six weeks) to maintain a normal haemoglobin level. As a result of the continuous blood transfusions, however, there exists a progressive accumulation of iron in organs such as the liver, heart, and pituitary gland. Haemosiderosis, or iron overload, can lead to hepatic fibrosis & cirrhosis,* cardiomyopathy, endocrinopathies, and even death.

Thus, the secondary goal of treatment is to remove the iron accumulation using a chelator to bind to excess body iron and promote its excretion from the body. For more information on the thalassaemias (thalassaemia major), see the papers by DJ Weatherall NF Olivieri.

Since the 1980s, Deferoxamine, also called Desferal®, has been the standard of care to treat iron overload for patients with thalassaemia. Deferoxamine is usually administered daily or on alternate days by subcutaneous infusion administered over 10 to 12 hours from a small battery operated pump.

The needle is usually injected in the abdomen, arm, or leg and is very uncomfortable and can leave needle marks, skin irritation, and scar tissue. As a result of the tedious and painful administration and issues of body image, some patients (especially adolescents and teenagers) find it difficult to comply with the demanding regime.

Given this, there was significant interest in finding an iron chelator that could be taken orally to improve compliance. While Deferoxamine had significantly improved the prognosis of thalassaemic patients, the prospect of finding an efficacious alternative therapy for iron overload was seen as a very

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*In addition to the cirrhosis that is caused by iron loading in the liver, as a result of the frequent number of blood transfusions received, there were also a very large number of thalassaemic patients who were more susceptible to contracting Hepatitis C from the tainted blood supply back in the 1980s and 1990s (which causes liver damage).

It can also be administered intravenously. While intravenous administration avoids side effects such as skin irritation, it also has other side effects associated with it, such as infection or thrombosis of the catheter. Patients are generally advised to use subcutaneous administration, and have intravenous administration as a secondary option.
welcome and promising improvement to the quality of life of thalassaemic patients.

Noted haematologist and researcher at the Hospital for Sick Children and professor of medicine at the University of Toronto, Dr Nancy F. Olivieri was a natural choice to investigate the potential safety and efficacy of a new oral iron chelator in thalassaemia. As head of the large and productive Hemoglobinopathy Research Program, Dr Olivieri (and colleagues) had the research experience and expertise, and patient population, to conduct such important research.

II. TIMELINE OF EVENTS

In the construction of this timeline primarily three documents were used: (i) the Canadian Association of University Teachers’ Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri, the Hospital for Sick Children, the University of Toronto, and Apotex Inc., hereafter referred to as the Olivieri Report; (ii) the report by Arnold Naimark, Bartha M. Knoppers, and Frederick H. Lowy, Clinical Trials of L1 (Deferiprone) at the Hospital of Sick Children: a review of the facts and circumstances, hereafter referred to as the Naimark Report, and (iii) the report of the College of Physicians and Surgeons of Ontario, Report of the Complaints Committee [complainant: Dr. Lawrence Becker, respondent: Dr. Nancy Olivieri] December 19, 2001, hereafter referred to as CPSO. Events not directly referenced are thought to be of a sufficiently public nature and/or uncontroversial as not to require direct referencing.

- 1989
  - Dr. Olivieri (and colleagues) begin to examine the effectiveness of an oral iron chelator, deferiprone (L1), in the treatment of thalassemia. Research grant by Medical Research Council of Canada (MRC) allows for L1 to be synthesised in capsule form (CPSO, p 3); (Olivieri Report, pp 104–5).

- 1991
  - MRC renews grant for an additional year (1992–3), but turns down Dr. Olivieri’s application for funding of short term randomised controlled trial to test clinical effectiveness of L1. MRC suggests that Dr. Olivieri seek an industry partner for funding of the clinical trial.

- 1992
  - Olivieri begins working with Dr. Brittenham.***

- 1993
  - Food and Drug Administration (FDA) informs Drs. Olivieri and Brittenham that completion of three studies—LA-01,**** LA-02,***** LA-03******—would be necessary before commercial licensing of L1 could occur.
  - Drs. Olivieri and Koren†† sign contract with Apotex for LA-01 trial (approximately 50% sponsored by MRC, 50% sponsored by Apotex).

- 1994
  - Planning for LA-02 is commenced.

- 1995
  - Research contracts are tendered to Drs. Olivieri and Brittenham for LA-02 trial. Contained within the contract is a confidentiality provision in which all information concerning the trial is to be kept confidential for three years after the termination of the trial (unless express written consent is given to do otherwise).
  - In April 1995, Dr. Olivieri et al publish a paper in the New England Journal of Medicine demonstrating a “favorable effect of deferiprone on iron balance”.***
  - Around time of publication, Drs. Olivieri and Brittenham become concerned about some patients enrolled in the LA-03 trial who display undesirable hepatic iron concentrations. (CPSO, p 5); (Olivieri report, pp 128–9).††
  - In July, Drs. Olivieri and Brittenham request permission to establish a separate trial protocol for patients in whom L1 appears to be functioning suboptimally. Within this request, it is noted that modification of patient consent forms would be necessary to advise patients of the negative results encountered. Apotex requests to examine the data before consent forms are changed and the Hospital for Sick Children (HSC) Research Ethics Board (REB) or research ethics committee is notified of findings (CPSO, p 5); (Olivieri report, pp 125–33).
  - In September, Dr. Olivieri submits separate protocol to Apotex investigating patients excluded from LA-03 trial to observe loss of sustained efficacy in L1. Dr. Olivieri also informs Apotex of her obligation to communicate her findings of reduced efficacy to HSC REB. (CPSO, p 6); (Olivieri report, §§ entitled “Progress of the Toronto trials [LA-01 and LA-03]” and “Concerns arising in 1995”).
  - In October, HSC REB requires a revised protocol for LA-03 study in order for study to continue. Apotex agrees to study patients in which response to L1 was suboptimal, but continues to refuse to agree to inform the REB of suboptimal findings. (CPSO, p 6); (Olivieri report, §§ entitled “Progress of the Toronto trials [LA-01 and LA-03]” and “Concerns arising in 1995”).

- February 1996
  - Drs. Olivieri, Brittenham, and Koren meet with Apotex to review data from long term trial. Upon examination of data, Apotex does not agree with the loss of effectiveness. Apotex restates that the claim that L1 has lost effectiveness in some patients should not be relayed to HSC REB or trial subjects (CPSO, p 6); (Naimark report, § entitled “Scientific disagreement about an unexpected finding”).

- March 1996
  - Dr. Olivieri submits research findings on LA-03 cohort to HSC REB. Findings maintain that a significant proportion of the subjects have liver iron concentrations above clinically desirable levels and Dr. Olivieri suggests that further study and observation of these patients is needed to evaluate the balance between risk and benefit.

***Dr. Gary Brittenham, hepatologist at Case Western Reserve University, and one of Olivieri’s coinvestigators.

****Prospective randomised controlled trial to compare effectiveness and safety of L1 to DFO (approximately 65 patients in Toronto and Montreal).

*****Safety study to assess particular risks associated with L1 (approximately 200 patients in Canada, Italy, and the United States).

††Continuation of the compassionate use long term study of L1 (approximately 25 patients).

†††Dr. Gideon Koren, clinical pharmacologist, HSC, and one of Olivieri’s coinvestigators.

In order to assess and monitor iron loading, thalassaemia major (TM) patients were required to undergo regular liver biopsies to obtain tissue to assess liver histology and to be tested to provide a hepatic iron concentration as a mean of evaluating total body iron stores. Clinical trials of L1, in the treatment of thalassaemia major (TM) patients were required to undergo regular liver biopsies to obtain tissue to assess liver histology and to be tested to provide a hepatic iron concentration as a mean of evaluating total body iron stores.
benefit associated with L1 (CPSO, p 6); (Olivieri report, ¶ entitled “Identification of the first risk”).

- Apotex submits documents to the HSC REB representing their interpretation of the data from LA-03 cohort. Dr Zlotkin responds to Apotex informing them that the REB does not act as an intermediary between researchers and sponsors and directs Apotex to direct further communications to Dr Spino for resolution of disagreements. (CPSO, p 7); (Olivieri report, ¶ entitled “Identification of the first risk”); (Naimark report, ¶ entitled “Report to the Research Ethics Board”).

**April 1996**

- HSC REB directs Dr Olivieri to amend patient information and consent forms to reflect findings of decreased sustained efficacy of L1, and to inform other physicians involved with patients receiving L1 and the Department of Health and Welfare (Canada). (CPSO, p 7); (Olivieri report, ¶ entitled “Identification of the first risk”).

- Application for a clinical trial of L1 for sickle cell anaemia is submitted to the National Institutes for Health (NIH).

**May 1996**

- Dr Olivieri submits revised patient information and consent forms for LA-01 and LA-03 trials to the HSC REB and Apotex. When Dr Olivieri attempts to inform patients of her findings (by directive of the HSC REB chair), Apotex terminates both LA-01 and LA-03 trials (CPSO, p 7); (Olivieri report, ¶ entitled “Trial terminations and legal warnings”).

- Apotex write to Drs Olivieri and Koren to inform them that their research sponsorship contract has expired and they would not be renewing it. Moreover, Drs Olivieri and Koren are told that all information obtained during the trials are to remain secret and confidential unless Apotex provide a disclosure waiver—otherwise, failure to do so would result in the pursuit of vigorous legal remedies (CPSO, p 7); (Olivieri report, ¶ entitled “Ongoing legal warnings” and “Trial terminations and legal warnings”).

- Dr Spino, pharmacist and vice president at Apotex, Inc, writes to Dr Olivieri giving her notice of termination of the consulting contract between her and Apotex for services related to the LA-02 trial. Letter also refers to the non-disclosure clause in her contact and threatened legal action for breaking that agreement (CPSO, p 7); (Olivieri report, ¶ entitled “Ongoing legal warnings” and “Trial terminations and legal warnings”).

- Drs Olivieri and Koren contact the Canadian Medical Protection Branch concerning Apotex’s legal pressures. Dr Olivieri follows Canadian Medical Protection Branch advice to inform Apotex of material she intends to disclose or publish (so that Apotex could exercise legal proceedings to block such disclosure/publication if they so desire).

**June 1996**

- Dr Olivieri contacts Dr Aberman (Dean, Faculty of Medicine, University of Toronto until 1999) to mediate the conflict between Apotex and the investigators. At the meeting, Dr Olivieri requests that L1 trial continue in order to study the effectiveness/loss of effectiveness and to ensure that patients who were responding favourably could continue receiving L1. Apotex did not agree to continue the trial, but did agree to the emergency release of L1, and that Dr Olivieri and Apotex would jointly contact the Health Protection Branch.

- In a subsequent meeting with a senior executive at Apotex, Dr Aberman asks Apotex to refrain from threatening legal action against Dr Olivieri (CPSO, p 7); (Naimark report, ¶ entitled “Involvement of the hospital and university administrations”).

**July 1996**

- Dr Spino informs Drs Olivieri and Koren (and HSC REB) of the findings of an expert panel convened by Apotex to review the data at the centre of conflict. The panel did not agree with Dr Olivieri’s conclusions about L1’s efficacy (CPSO, p 8).

- Dr Spino informs Drs Olivieri and Koren that in the process of closing out subjects enrolled in the trial, the study drug returned by patients appears to be improperly issued. Apotex informs Drs Olivieri and Koren that such an action constitutes a serious violation of the “standard of good clinical practice” (Naimark report, ¶ entitled “Consequences of non-renewal of Apotex sponsorship”).

- Apotex informs Drs Olivieri and Koren that information was incomplete or missing from data and records of the trial. Dr Olivieri replies to Apotex attributing problems with drug return and records to Apotex’s “abrupt” termination of trials.

- Drs Aberman, Olivieri, Brittenham, and Apotex meet with a representative of the Health Protection Branch.

- Dr Spino informs Dr Olivieri that Apotex does not agree with data analysis and interpretation in abstracts submitted to the American Society for Hematology for their annual meeting. Apotex denies consent to submit abstracts. (Naimark report, ¶ entitled “Consequences of non-renewal of Apotex sponsorship”).

**September 1996**

- Drs Olivieri and Brittenham are sent the report from Apotex’s panel. Both sides reaffirm their original interpretation of data.

- National Institutes of Health approves clinical trial of L1 for sickle cell anaemia.

**November 1996**

- Dr Spino informs Dr Olivieri that as a result of breaching contractual obligations she is no longer a member of the LA-02 Steering Committee (thus, not entitled to access data or results without Apotex’s consent). Dr Olivieri responds that such action violates regulatory guidelines and previous agreements made with all members of the LA-02 Steering Committee. Apotex disagrees (Naimark report, ¶ entitled “Consequences of non-renewal of Apotex sponsorship”).

**December 1996**

- Dr Olivieri presents research findings from LA-03 at the American Society for Hematology conference in Orlando, Florida.
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Dr Olivieri meets with Drs O'Brodovich and Koren to request data on patients who received L1 on compassionate grounds (to meet the requirement of regulatory bodies). A question of whether Dr Olivieri was meeting her obligations—that is, providing data, to regulatory bodies is raised by Apotex. (Naimark report, § entitled “Interaction between Apotex and the hospital”)

April 1998

Dr Olivieri, under increasing workload pressures, indicates to HSC administration that she cannot continue in her position under the prevailing conditions. Dr Olivieri intends to communicate the need for a change in the prevailing conditions. However, her letter is interpreted by HSC as an instance of constructive dismissal. (Naimark report, § entitled “Interaction between Apotex and the hospital”)

May 1998

Intensity of the events surrounding the L1 trials has substantially increased and intensive media attention begins.

June 1998

Apotex continues to attempt to secure data and a review of that data conducted by Dr Aideen Moore, Chair, HSC REB (after July 1996) and Dr Brenda Gallie, ophthalmologist and cancer researcher, HSC. Drs Olivieri and Brittenham maintain they have no ethical or legal obligation to provide Apotex with any further data (beyond what was already given in 1997). (Naimark report, § entitled “Interaction between Apotex and the hospital”).

August 1998

Dr Olivieri et al publish findings in the New England Journal of Medicine, detailing findings of liver toxicity in patients receiving L1.12

Drs Olivieri and Gallie met with Dr Aberman in an attempt to finally resolve issues surrounding L1

Pathologist, Toronto General Hospital

Dr Hugh O’Brodovich, Paediatrician in Chief, HSC.
trials. Among other requests, an independent review of the events which transpired, and an end to her constructive dismissal are sought.

- **December 1998**
  - The Naimark report is published, reviewing the events surrounding the Olivieri affair. Panel finds that HSC staff and executives did not act improperly.†††

- **January 1999**
  - Dr Olivieri fired/relieved of position as head of Hemoglobinopathy Research Program at HSC. A group of scientists supporting Dr Olivieri are instructed by HSC not to discuss their concerns publicly. (Olivieri report,pp 225–38)†

- **Later in the month, an agreement is reached in which Dr Olivieri’s position is restored, her right to academic freedom affirmed, and she is promised financial support in case Apotex pursue legal action. (Olivieri report,pp 265–70, 505–8)**

- **1999/2000**
  - After the use of forensic evidence, it is found that Dr Koren was the author of a number of anonymous letters and emails disparaging Dr Olivieri’s (and her supporters’) professional and personal integrity. The HSC and University of Toronto discipline Dr Koren for gross misconduct; he receives a suspension, a chair endowed in his name is removed, and he is ordered to make some restitution. Dr Koren is also cautioned by the complaints committee of the College of Physicians and Surgeons of Ontario for his unprofessional conduct. Veracity of Dr Koren’s previous allegations and testimony subsequently called into question—for example, by the Canadian Association of University Teachers.††††

- **European Agency for the Evaluation of Medicinal Products approves the use of L1 in limited cases. Dr Olivieri later requests judicial review through European court (on the basis that Apotex misrepresented data).‡‡‡‡‡

- **HSC (via its board of directors and its medical advisory council) seeks to leave out a number of details in the interest of length and readability. Most of the information was obtained from sources in the public domain and every effort was taken to provide accurate dates and an objective accounting of events. Any errors or omissions are entirely unintentional.**

## III. ETHICS IN THEORY AND PRACTICE

The Hospital for Sick Children and the University of Toronto initially saw the dispute between Dr Olivieri and Apotex as a scientific dispute best dealt with in the scientific arenas of peer reviewed conferences and journals. It soon became clearly evident, however, that it was much more than a scientific disagreement over the interpretation of data.

There were a number of reasons why the Olivieri affair took the form it did. Some of the failures in this case arose out of simple misjudgments and errors. Others arose out of ignorance of the gravity of what was occurring or an absence of full information that prevented appropriate action. Some, more seriously, arose out of personality conflicts and political considerations. The contributions to this symposium seek to explore and elucidate the issues arising from the Olivieri affair.

Arthur Schafer’s contribution to this symposium provides a detailed examination of the issue and historical context of conflicts of interest in research sponsored by private enterprise. In addition to examining the case of Dr Olivieri, he also examines another case at the University of Toronto—the case of Dr David Healy. By examining both the Olivieri and Healy cases, Schafer elucidates the context and norms governing partnerships between universities and private enterprise in academic medicine. One issue that has been central to the Olivieri affair is the relationship between Apotex and the University of Toronto. In addition to sponsoring research at University of Toronto affiliated hospitals, Apotex was a major contributor to the

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†Individuals interested in this case are encouraged to read the Naimark report.

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+++The complaint was not by HSC itself, but by a member of its staff, Dr Laurence Becker.
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and corporate interests. See also report m a j o r o u t c r ya n df u r t h e rt a k d i s t r u s t
president of the University of Toronto
possibility of conflict of interest. For
and hospitals, and especially about the
public institutions, such as universities
with how such relationships could affect
research and teaching activities.

However, many are rightly concerned
about a multimillion dollar donation.21 22
the Olivieri affair, Apotex was in dis-
University of Toronto—at the time of
Olivieri affair ultimately stemmed from the contract Dr Olivieri
signed with Apotex, especially from the
confidentially clause attached to the
contract. Clinical study agreements that
seek to protect patients’ and researchers’
to be primary considera-
tions when public institutions enter into
contracts with private enterprise.

Rosamond Rhodes and James Strain’s
contribution to the symposium high-
lights the failure of academic medicine
to identify and adequately respond to
unethical behaviour. Rhodes and Strain
maintain that it is the institutional
design of academic medicine that sys-

tematically ignores serious ethical prob-
lems, regards whistleblowers as
enemies of the institution and punishes
them, and thereby fails to provide an
ethical environment. These issues are
taken up by Bolsin, Faunce, and Chan.

This is, by most accounts, the experi-
ence Dr Olivieri (and her core set of

supporters) had.23 24

After not being supported in her effort
to bring forward what she found to be
serious ethical problems—for example,
the need to inform research subjects of
possible increased risk for liver damage
associated with the study drug. Dr
Olivieri found the need to pursue alter-
native and more forceful avenues to
protect her patients. Arguably, the
Hospital for Sick Children and the
University of Toronto should have sup-
ported Dr Olivieri more in this regard
and protected her ability to do what she
thought (and had sufficient warrant to
believe) was required as a morally
responsible researcher. Not only did
she feel the need to violate her con-
fidentiality agreement at great personal
and professional risk, but she also felt
obliged to speak out against those who
did not support her, and became per-
ceived as an enemy of the institutions to
which she belonged. As Rhodes and
Strain point out, the environment for
whistleblowers is very confrontational
and adversarial. Olivieri was allegedly
dismissed, sued, received harassing
correspondence, and had her named
dragged through the mud—the costs of
speaking out against the academic
medical complex can be great. Few
would have such conviction.

In addition to the Olivieri affair,
Rhodes and Strain examine whistle-
blowing in academic medicine in a
number of other cases. They point to
the serious and unfortunately repetitive
instances of institutions that fail to
support individuals and punish those
who seek to blow the whistle. Rhodes
and Strain advocate for the need to
attend to the failures of institutional
ethics in academic medicine, and also
for the need to create an environment in
which individuals feel they can do what
they believe is right without the fear of
being persecuted or punished. Bolsin,
Faunce, and Chan outline practical
strategies to train, encourage, and sup-
port professionals to follow their con-
science and, if necessary, criticise
internal regulatory decisions and pro-
cesses, in both clinical and academic
medicine.

Francoise Baylis’s contribution to the
symposium deals with a topic of para-
mount importance, which unfortunately
receives little attention in the litera-
ture—the ethics of bioethics. In addition
to the validity of bioethics as field of
academic inquiry, the legitimacy of
bioethics is often tested in situations
like that of the Olivieri affair. In
addition to methodological questions
concerning the practice of applied
ethics, how bioethicists respond to such
ethical failings as occurred in the
Olivieri affair can also affect the dis-

cipline. In a self critical analysis, Baylis
contends that bioethicists need to reflect
about the meaning and value of their
work. Using the Olivieri case as an
illustration, Baylis is very critical of
the silence of the bioethics community
and the countless opportunities for
bioethical heroism that were never
undertaken.

There are many lessons to be learnt
from the Olivieri affair. We hope this
symposium will begin a fair and pro-
ductive examination of these which will
lead to better ethical evaluation and
regulation of research, not just in North
America but globally.
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Adrian Viens was one of Dr Olivieri’s research assistants in the summer of 1998 and 1999. In addition, Viens and Olivieri collaborated on a journal article (along with six other co-authors) concerning iron overload and iron chelating therapy in Haemoglobin E-β thalassemia. This collaboration was not related to the L1 clinical trial (see: Olivieri NF, de Silva S, Premawardena A, et al. Iron overload and iron chelating therapy in haemoglobin E-β thalassemia. Journal of Pediatric Hematology/Oncology 2000;22:593-7).

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ECHO

Improved procedures may improve informed consent for neonatal research

Obtaining truly informed consent for neonatal research under difficult circumstances may be more achievable with new approaches. These originate from discussions of European neonatologists, ethicists, sociologists, and legal experts—all participants in the Euricon trial.

Urgent or emergency situations when parents are asked to consent to research treatment for their child are especially difficult. Most doctors would probably suspect that here informed consent is compromised by circumstances that hinder parents absorbing and processing complex information.

Alternatives to current process might seek consent in a stepwise or a continuous process—with information initially given by the doctor and later chances to withhold or withdraw consent. Both would allow more time for parents to deal with complex information. A stepwise process would see parents deciding from core information, with more detailed information given later, and a continuous process with them deciding from all information given up front, repeated at later stages, sparing them the realisation that they might have withheld consent at the outset, had they understood the full picture.

Importantly, parents should not assume that responsibility for their child’s welfare is theirs alone—it extends to researchers, grant awarding body, senior hospital staff, and research ethics committee. They may be reassured if they know that the research has committee approval, though this should not be allowed to interfere with their decision, and great care must be used to avoid coercive language.

At worst the Helsinki declaration would permit research treatment without parental consent, but this would be a rare event, occasioned by an extreme situation. ▲ Archives of Disease in Childhood Fetal and Neonatal Edition 2003;88:F166-F167.

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