Issue 64

'Yesterday, We Included Your Son in a Clinical Trial' Conducting Research in Critically Ill Patients, Without Prior Consent

Marjolein Timmers, Erwin J.O. Kompanje | Department of intensive Care, Erasmus MC University Medical Center, Rotterdam, The Netherlands
erwinkompanje@me.com

The mortality and morbidity rates in patients with acute, life-threatening conditions such as severe traumatic brain injury, cardiac arrest, severe sepsis, and stroke are high. Therefore, an ethical imperative exists to develop and test new therapeutic strategies for these conditions. Conducting research in emergency and critical care settings provokes several unique ethical, legal, and practical concerns: the emergency nature of the intervention, the incapacity of the patients (and their relatives) to give informed consent before inclusion, short therapeutic time windows, and a relatively high risk-benefit ratio that may be acceptable in view of an already bad prognosis. The issue of conducting research in emergency settings, *without* prior patient or proxy consent, is an especially challenging one. Stating that prior informed consent is absolutely necessary would mean that it is almost impossible to conduct emergency research.

For good reason, (inter)national regulations on principles of good clinical practice are applied to all medical research. In addition, ethical principles include respect for autonomy of the subject; protection against discomfort, risk, and exploitation; preventing harm; and the prospect of potential benefit.[1] Obtaining prior informed consent respects these basic principles. However, informed consent can seldom be obtained from patients in emergency and critical care settings. Most institutional review boards have pragmatically accepted that proxies should then provide prior informed consent. Nevertheless, these proxies are not always available in a timely manner or are, in the acute phase, too overwhelmed by the serious patient condition to understand the provided information in order to give a valid judgment.[1] So, can we include patients in research projects without prior consent in the acute phase? In most European countries it is nowadays legal to defer (patient and proxy) consent, but this issue is not always settled in domestic law. With deferred consent, patients are included in a trial without prior consent. After inclusion, the patient or his/her representatives should be informed as soon as ethically feasible and subsequent consent should be requested.[1] This principle of 'act first and ask later' is ethically, legally, and practically defendable.[2] From the patients' point of view, they can profit from the presumed benefit of the trial drug or intervention. From the representatives' point of view, they will be spared the burden of setting their mind on deciding to consent or refuse inclusion of their loved one in acute medical research. From a practical point of view, researchers do not have to wait with a possibly beneficial treatment until the moment it is ethically valid to approach

TOPICS

Anaesthesiology in the world
Editor
Education
ESA
Euroanaesthesia
Focus Meeting
NASC
Research
Scientific
Trainee Exchange Programme

TAG CLOUD

ESA CTN Focus Meeting Horizon 2020 Issue 60 Issue 61 Issue 62 Issue 63 Issue 64

AN INVITATION TO CONTRIBUTE TO THE CONTENT OF THE NEXT ISSUES OF THE ESA NEWSLETTER

The Newsletter Editor readers to contribute a 400 word short paper entitled: "The article (or the lecture) which changed my practice" to the next issue of the ESA Newsletter.

Look into your professional past and find that piece of information, offered in writing or verbally, by a researcher, clinician or teacher, who illuminated your professional way and made you change your daily practice, or views about our field of activity.

Please, send your materiel to the Editor: gurman@bgu.ac.il. We will reply as soon as possible.

the proxies of the acutely ill patient for the consent procedure. As long as the mortality and morbidity of severely ill or traumatized patients are high and the benefit of standard treatment is low, we have to keep on searching for additional and effective treatments.[3] Deferred consent is an ethically valid solution to such research; so, in many European countries, the family of a critically ill patient in intensive care can be asked for consent for inclusion in a trial starting the question with 'Yesterday, we included your son in a clinical trial'.

References

[1] Jansen TC, Kompanje EJO, Bakker J. Crit Care Med 2009;37(1 Suppl.):65-8.

[2] Kompanje EJO, Maas AIR. Intensive Care Med 2004;30:168–9.

[3] Kompanje EJO, Bernstein M. Consent in Emergency Clinical Research, in: Ammar A, Bernstein M (eds.). Neurosurgical Ethics in Practice: Value-based Medicine. Springer: Berlin Heidelberg, 2014;17:191-200.

More Articles

Join us at Euroanaesthesia, Berlin 30 May – 2 June 2015

This four-day congress attracts upwards of 6000 attendees from around the world to learn, share and network. Learn about the latest science and technologies by participating in this year's scientific programme offering more than 350 sessions, special lectures and hands-on workshops...

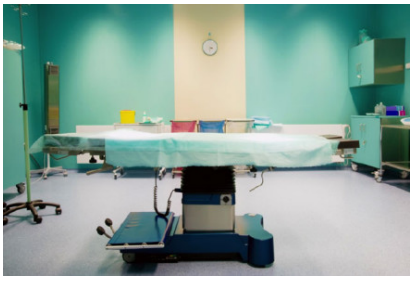
Issue 60

Trainee Exchange Programme: Utrecht Medical Center Pain Unit

Mauricio Polanco García
polmauricio@gmail.com

I applied to the trainee excha12-traineenge program driven by my desire to learn pain medicine from the experts on the field had the opportunity to spend three months at Utrecht Medical Center in The Netherlands through the

Issue 62



We Are Too Few ... Why So Few?!

Gabriel M. Gurman, Chief Editor
gurman@bgu.ac.il

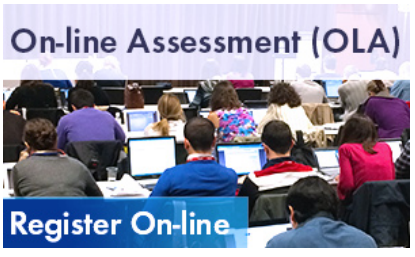
Here is the old news: there is a perennial shortage of anaesthesiologists in Europe. The news is old because this problem is as old as our profession.

But the paradox exists in the fact that the more European physicians choose anaesthesia as their future career, the more evident is this lack of anaesthesia manpower all over the continent.

Issue 64

Euroanaesthesia is coming to London!

Euroanaesthesia is coming to London!



OLA registration fee reduced by 50%!

The registration fee for the Online Assessment (OLA) has been reduced to €40 per candidate in

ESA Honorary Members

Daniela Filipescu
ESA President
daniela.filipescu@esahq.org

Prof Sellevold gained his PhD in 1990 and has been Professor of Anaesthesiology and Intensive care since 1996. He practiced mainly in Trondheim and Bergen where he was Director of Cardiac Anaesthesia and Intensive Care and Chairmen of the Department of Anaesthesiology and Intensive Care, respectively.