



UF

Re: Ansökan om tillstånd från lokal etisk kommitté

I *Utredning: Dnr 2-2184/2014 ("Utredningen")*, granskas en vetenskaplig publikation (i utredningen betecknad *Uppsats 1*), i vilken redovisas en operation, för vars genomförande författarna uppger att tillstånd erhållits från den lokala etiska kommittén.

Detta påstående har i *Utredningen* angetts som felaktigt.

Som ett led i klarläggandet kring om författarna sökt och erhållit etiskt tillstånd för operationen inkom Prefekten för Clintec, professor Li Felländer-Tsai, i mail 2015-07-09, ställt till Rektorsrådet, professor Jan Carlstedt- Duke med bekräftelse enligt nedan:

Chefläkaren Stefan Engqvist som kontaktades, och som finns refererad i utredningsmaterialet, var ordförande i sjukhusets etikråd. Han hade denna uppgift inom ramen för sitt arbete som chefläkare.

Vidare ringde professor Felländer-Tsai 2015-07-10, professor Carlstedt-Duke, efter samtal med Stefan Engqvist. Denne är numera pensionerad men uppger att han kommer ihåg alla detaljer om rubricerade ärende, eftersom det var så pass speciellt. Vid samtalet med professor Felländer-Tsai bekräftade Stefan Engqvist att:

Han deltog i förarbetet både i sin roll som chefläkare samt ordförande i etikrådet, samt att en viktig del av förarbetet inför beslutet om eventuell operation specifikt var en etisk granskning utifrån Helsingfors deklARATIONEN. Således var en aktiv etisk bedömning en integrerad del av det kliniska förarbetet.

Agneta Stålhandske
tf. universitetsdirektör

Jan Carlstedt-Duke

From: Li Felländer-Tsai
Sent: den 14 juli 2015 15:39
To: Jan Carlstedt-Duke
Cc: c.a.h.
Subject: Uppdaterd fil
Attachments: Uppdaterd fil.pdf; ATT00001.txt

Hej Jan,

Fick denna uppdaterade fil signerad av tidigare och nuvarande VC på ÖNH kliniken. Uppdateringen finns på sid 1 andra stycket nerifrån gällande Stefan Engqvists dubbla roll. Nu står den specificerad.

Med vänlig hälsning,

Li

Stockholm July 11, 2015

To whom it may concern

The ethical considerations applied to the investigation and operation of NN at the Karolinska University Hospital in 2011 followed the following principles.

The patient was referred to Karolinska from abroad on the basis of previously published reports stating the success of a new technique in the field of airway reconstruction performed in Spain and in the UK. The patient had previously been treated surgically and received external irradiation in his homeland but with local recurrence in the distal end of the windpipe pending suffocation.

Prior to the final decision regarding the surgical procedure, the ethical issue was seriously considered as the proposed method was new and consisted of the insertion of a synthetical scaffold as well as the use of mesenchymal stem cells.

Thus contact was taken with a representative of the Medical Products Agency. The opinion was that the responsibility for the decision to operate lay in the framework of the medical authorities at the Karolinska University Hospital in this case where the major indication was survival or not (*Lege Artis*). In this assessment can also be added the necessary urgency connected to this particular case suffocation pending.

Furthermore the regional Ethical Approval Committee was approached. Their representative shared the opinion of the Medical Products Agency that the present situation constituted a medical care ethical question rather than a scientific one. It was also stated that the case approval followed the Health and Medical Service Act, section 26b. It should also be emphasized that an ethical application could first be considered after approval from the Medical Product Agency and not concomitantly.

The chief medical officer, also chairman of the ethical committee at the Karolinska University Hospital, was now involved and he in his turn consulted the ethical branch of the Vetenskapsrådet (Swedish Research Council) who returned the International Society for Stem Cell Research guidelines for clinical translation of stem cell research. In Recommendation 34 is written that "Clinician-scientists may provide unproven stem cell-based interventions to at most a very small number of patients outside the context of a formal clinical trial" and with the addition of a number of prerequisites.

The patient underwent a thorough preoperative investigation followed by a multidisciplinary conference consisting of six different specialities. The conclusion was that no alternative treatment with the intention of cure was available beside the suggested airway reconstruction.

The patient was informed prior to the surgery concerning opportunities, risks and the nature of the operation. This was documented in the clinical chart. A "written consent" is not standard procedure in Sweden.

The different statements referred to above are available at the Karolinska University Hospital.

Sincerely



Richard Kuylenstierna MD, PhD

Senior Consultant, Past Chairman



Bo Tideholm MD, PhD

Chairman

Dept. of Ear, Nose & Throat, Head & Neck Surgery

Karolinska University Hospital

171 76 Stockholm

Sweden

Re: application for a permit from the local ethics committee

Inquiry: Ref. no. 2-2184/2014 ("the inquiry") examines a scientific article (referred to as Paper 1 in the inquiry) that reports on an operation for which the authors state that they obtained a permit from the local ethical committee to perform.

This claim the inquiry has judged to be false.

To help shed light on the question of whether the authors applied for and obtained a permit for the operation, the head of CLINTEC, Professor Li Felländer-Tsai, provided the following confirmation by mail dated 9 July 2015 to Jan Carlstedt-Duke, senior advisor to the vice-Chancellor:

Chief physician Stefan Engqvist, who was contacted and who is referred to in the investigation material, was chairman of the hospital's ethics committee, a post he held as part of his position as chief physician.

Further, Professor Felländer-Tsai called Professor Carlstedt-Duke on 10 July 2015 after a conversation with Dr Engqvist. Although now retired, he says that he remembers every detail of the case in question since it was so special. During this conversation, Professor Felländer-Tsai had it confirmed by Dr Engqvist that:

He took part in the preparatory work in his capacity both as chief physician and as chair of the ethics committee, and that an important part of this work ahead of the decision whether or not to operate was specifically an ethical review on the grounds of the Helsinki Declaration. An active ethical assessment was thus part of the preliminary clinical work.

Agneta Stålhandske
pro tem University Director