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Ethical perspectives and ramifications of the Paolo Macchiarini case

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Abstract

The Paolo Macchiarini case has several ethical ramifications. Professor Macchiarini, formerly of the Karolinska Institutet (KI), became famous for the tracheal surgeries he conducted between 2008 and 2014. His rapid rise to fame was followed by an almost equally rapid fall from grace as official reports, articles in newspapers and television programmes revealed

several aspects related to misconduct in his curriculum vitae, professional practices and publishing-related activity. Formal misconduct reports issued by four KI co-workers in late 2014, then again in 2016, coupled with social scandals, including the tricking of a famous US television newscaster into a false marriage, a previous arrest in Italy for apparent bribery, and acute narcissism, all tainted Macchiarini's legend. In the short space of just two years, Macchiarini was no longer remembered for the revolutionary changes he had claimed to have brought about in stem cell research and regenerative medicine. Instead, at least seven dead patients later, Macchiarini faces potential aggravated manslaughter charges and an uphill battle to save his published research, now shrouded in scandal and scientific doubt, from being retracted and scratched out from the list of verified medical science. This paper examines some of the possible ethical ramifications of the Macchiarini case.

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Brief background of the Macchiarini case

Legendary scientists become legendary because they seek to break new barriers in science, both in research and publishing, but such aspirations carry high risks. High-profile scientists who fall from grace, and who lose their legendary status, tend to do so swiftly and fairly violently in terms of the fallout, and tragedies tend to occur as a domino effect. In recent years, one need only consider the ongoing Swiss scandal in plant science involving Olivier Voinnet, and the Japanese scandal in STAP stem cell research, with Haruko Obokata as its centrepiece (1). One thing that characterises high-profile scandals are published scientific papers making claims which are almost too good to be true and which might not be fully substantiated by the evidence presented. In contrast, the Voinnet and Obokata scandals were based primarily on the manipulation of figures. This manipulation invalidated the reported results to some extent, and thus downplayed their initially grandiose claims. Since a single scandal is enough to erase a lifetime of honest or fruitful effort, these scientists were plunged into personal tragedy, strife and struggle. Apart from this, what punctuated the shock-and-awe revelations of these biomedical scandals was the incredible nature of the events that followed. It was almost as if the entire scientific community was not expecting these events, phenomena that I term "black swan events" (2). The ultimate feeling that these scandals left in their wake was a sense of mistrust, not only among peers and other professionals, but also in society, in the stability of the ethical institution of science. This paper discusses some ethical perspectives and ramifications of the case of Paolo Macchiarini, formerly of the Karolinska Institutet (KI) within the field of regenerative medicine. Readers are referred to Kremer (3), Schneider (4) and Retraction Watch (5) to obtain more details of the intricacies and background of the Macchiarini case.

Unresolved and new ethical issues

Even though the Macchiarini case is still evolving and is most likely far from over, the fact that several high-profile heads have rolled thus far as a result of ethical oversight presents the biomedical community with a unique opportunity to review the oversight related to surgical medical procedures, associated not only with allotransplantation and xenotransplantation, especially in high-risk cases, but also with surgery more broadly. Directly related and peripheral issues (there are likely to be more), discussed next, deserve greater debate and scrutiny, as well as resolution. There are at least six possible distinct, but related, ethical ramifications and points of departure for debate.

1. *Ethical guidelines and laws for high-risk ethical procedures, transplantation and clinical trials*

Human-based transplantation has always been closely linked to ethical issues, with the most frequent ethical debates pertaining to the fairness and transparency of donor selection, the harm caused to a living individual to save a dying one, the risk of coercion to obtain an organ, the use of dead sources for organs, and what in fact constitutes a state

of death (6, 7). The ethical transplant debate is more intense in xenotransplantation, in which non-human organs are harvested to improve or save human lives (8), especially when human sources of organs do not suffice to satisfy the demand. Associated with these debates are the issues of insurance; laws and liability; international black markets for organs and "trade" versus "trafficking"; including the debate regarding the sale and purchase of organs, even with written consensus; pressure by the media and pro-life activists; the status or age of recipients; the ability of a patient to rehabilitate and socially reintegrate following a transplant, among many other issues (9–11). In high-risk cases (ie, when a qualified ethical board at a hospital has determined that the only option to death is a high-risk surgery), what are the ethical rules that may protect surgeons from claims of manslaughter in case a patient dies, and what protections are they offered in their professional capacity? After all, it cannot be claimed that Macchiarini was unqualified, especially with his extensive experience in research and clinical practice. Reading Macchiarini's defence of the ethical permissions obtained for his experiments and surgeries (12), it seems that there are large loopholes and/or ambiguities in the Helsinki Declaration and the guidelines of the International Society for Stem Cell Research. However, a declaration made by Hörnlund (13) suggests that Macchiarini had obtained insufficient (or no) ethical approval from the Swedish academic authorities. How then are international guidelines and local laws pertaining to medical procedures explained to foreign personnel, and what responsibility does the host institute hold in ensuring that all ethical and legal paperwork is in order before any procedure takes place, or is this exclusively a personal responsibility? Is it possible to hold the Russian authorities accountable for the surgeries that took place at Kuban State Medical University (3)? This indicates that around the world, there are pockets of jurisdiction in which medical practitioners are allowed to perform high-risk transplants, organ harvesting or organ transplants with impunity, possibly being above the law, and out of the reach of criticism or scrutiny by the international medical community. The debate surrounding the possible culling of organs from executed prisoners in China or forced organ donations (14) illustrates the profound ethical and legal complexities of this topic. If, in fact, this was the case with Macchiarini and his patients who are now deceased, one will never know the precise terms of the agreement between him and those patients, and if any of those terms may have been violated in these covenants (15).

Macchiarini (16) appears to have first dabbled in stem cell research when he hosted a human trachea derived from human embryonic cells in a mouse and transplanted a section of the trachea into piglets. He claimed that the procedure was a success. However, other papers by Macchiarini (17–20) described certain complications associated with such procedures, which suggests that at minimum, there were conflicting details, as well as risks and many unknowns in the matter of what might happen should such a trachea be transplanted into humans (xenotransplantation, or the transplantation of non-human cells, tissues or organs

into human beings). Most likely, the mixed results and an altruistic desire to help dying patients spurred him on to try tracheal and tracheoesophageal allotransplantation (the transplantation of cells, tissues or organs into a genetically similar organism) as a solution. Should the tracheal transplants have been subjected to sufficient rigorous animal tests first? Most certainly, but what constitutes “sufficient” in the medical field, and how are “suitable” test animals selected? Finally, can the results of animal trials truly be extrapolated to human beings, and does success with a rat necessarily translate into success with a human being? All these are the core issues underlying the ethics of xenotransplantation (8). In early 2016, Macchiarini issued a letter to the editor of *The Lancet*, detailing his explanation of the ethical approval for the now-retracted Jungebluth et al (2011) paper (21), stating, “We realise that the final wording – ‘the transplant procedure was approved by the local scientific ethics committee’ – was imprecise and did not convey the full extent of the ethical coverage. We hope that this note will reassure any concerned readers that such an extensive and experimental treatment, carried out by a large, international, and multidisciplinary team at a prestigious university hospital, was not done without appropriate ethical consideration and consultation.” (12)

As reported by Berke, in the Sjöqvist et al (2014) (22) paper (23), the Swedish authorities officially claimed that this was a case of misconduct. Will Nature Publishing Group retract this paper? Moreover, does (or should) the funding that supported this research have to be refunded, and how can tax-payers and funding agencies recover their lost money after a case of misconduct, when the funds are likely to already have been utilised? The acknowledgements list the following financial sponsors: “This study was supported by Swedish Research Council, project number K2012-99X-22333-01-5 and ALF Medicine, project number 20120545. European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement number 278570 supported D.R. and StratCan supported Y.Z. G.L. is supported by fellowships from Harvard Apparatus Regenerative Technology Inc.” Harvard Apparatus appears extensively involved in the Macchiarini case (24). An editorial expression of concern was published on October 14, 2016 (22).

2. **The true value and weight of “ethical guidelines”**

What is the legal value and weight of so-called “ethical” guidelines? As discussed earlier, the term “guidelines” is frequently used in ethical circles for organ donations and transplant-related cases. This tends to dilute the ethical and legal content/perspectives when compared to the terms “rules” or “laws.” The same applies to publishing. For example, the term “guidelines” is often used to describe the regulations of the Committee on Publication Ethics (COPE) and International Committee of Medical Journal Editors (ICMJE) for authors, editors and publishers. *The Lancet* is a COPE member journal, but inconsistencies in its leadership’s positions (see critique of Richard Horton below) and retraction policies and/or implementation call into question the value of the COPE and ICMJE guidelines, and what they are supposed to achieve.

Moreover, they raise the question of whether the guidelines are serving as mere tools to offer an ethical mask to politically powerful biomedical journals and their editors. Inconsistencies and opacity dilute the value of such guidelines, such as among COPE members (25).

3. **Plagiarism, self-plagiarism or professional victimisation?**

Macchiarini already holds one retraction for a plagiarised table (26). Did KI and the Swedish academic authorities conclude that this constituted academic misconduct? In such a case, one can only wonder if there was professional retaliation or excessive editorial imposition, since it might have been easy to simply correct the paper with an erratum indicating that the original source of the table had not been indicated. Was the retraction of the Gonfiotti et al (2012) paper (26) a punitive act of editorial aggression, or did it follow COPE guidelines for retractions? Retracting the entire manuscript because the source of one table has not been indicated may give readers a false signal that all the scientific claims made in that paper are invalid, which, in fact, might not be true. This is not the first time a transplant-related study has been retracted for plagiarism. Just recently, two papers from a group from China, working with stem cells in autism patients, were retracted for plagiarism (27–29).

In a bid to better understand the Macchiarini case, the author of this paper personally investigated the papers published by Macchiarini and his colleagues between 2008 and 2016 (30), as part of a post-publication review (PPPR). Multiple “irregularities” were detected between September 10 and 14, 2016. These were reported to the authors and to the respective editors, as well as KI, which acknowledged the receipt of that report. In select cases, Macchiarini and/or his co-authors acknowledged the errors, including apparent figure duplication and manipulation, and offered written (e-mail) assurances that they would correct the published record. Thus far, two corrections have been promised, but how will KI and the Swedish academic authorities formally handle these whistle-blowing allegations? Even though KI acknowledged the receipt of the report on September 23, 2016, no update or feedback has been provided yet, more than five months later. Whistle-blowing in the wider context of PPPR and the rise of a new class of self-proclaimed science (ethics) “watchdogs” (31) are a new phenomenon in science and deserve much greater attention, as more and more instances of anonymous whistle-blowing and reports of apparent fraud and misconduct begin to emerge in the public domain. Biomedical papers may start to come under increasing scrutiny as the PPPR culture begins to evolve, mature and become a more accepted part of the science publishing landscape (32, 33).

Thus, the risks facing researchers extend far beyond the ethical limitations imposed by the approval of organ transplants, patient–researcher agreements, consent forms and institutional approvals; it extends to journal- and publisher-imposed ethical guidelines and definitions of authorship, which may, in fact, differ, even among COPE member journals (34,35).

4. **Ethical inconsistencies by Horton and call for pitchforks and torches before a fair investigation**

In Horton's editorial (36), Delaere calls for the retraction of all papers related to the tracheal transplants: "The sooner the publications on the engineered windpipe and gullet are withdrawn, the sooner there will come an end to what may be the biggest lie in medical history." However, is it ethical to make such calls publicly – no less in an editorial by the Editor-in-Chief of a leading medical Elsevier journal, *The Lancet* – before an ethical investigation has been carried out? It does not seem correct that Richard Horton should make a call for mass retractions before KI has completed a thorough ethical investigation. Given his standing in the biomedical community, and the praise recently showered upon him by David Clark, the senior vice president of Health and Medical Sciences at Elsevier, for his support of Elsevier's academic-business model ("Richard has seen *The Lancet* more than double its Impact Factor and overtake leading titles such as the *Journal of the American Medical Association*. As the longest serving editor of *The Lancet* since the Second World War, Richard has built upon *The Lancet's* long-standing reputation as both an authoritative and highly respected title and an independent and, at times, radical voice within medicine.") (37), one would expect more moderation from him and fewer comments of the pro-vigilante type (38). Moreover, Horton used to earlier defend Macchiarini vehemently, so should Horton's words and *The Lancet's* editorials (36,39) also be retracted to follow a fair principle? The 2015 editorial in *The Lancet* had firmly proclaimed Macchiarini's innocence, while hinting at internal disorganisation in the KI, and offered a stark warning about research in this field: "The allegations made against Paolo Macchiarini were not only harmful to one individual. They also raised questions about the quality of research into regenerative medicine itself. Rebuilding confidence in the field of tissue engineering may take some time to achieve." (39)

5. **The open data debate: need to show ethical consent forms**

The open data debate is raging in biomedical science. Two of the arguments in favour of open data are that they hold authors more accountable for what they have published, and they fortify the reliability of the results being presented (40). In published medical papers, should authors be required to submit documents which prove that ethical consent has been obtained for surgeries, and should these be added as an open access supplement, even if in an anonymised form? Given the reality of the Macchiarini and Karolinska University Hospital ethics debacle, should authors be requested to show the ethical permission documents received for papers published in the past in part of a truth and reconciliation PPPR process? The issue of releasing patient-related data and/or patients' consent forms for public scrutiny was recently highlighted in the "PACE" trial case, in a paper published by *PLOS ONE*, which has an open data policy (41).

6. **The ethics of a factually inaccurate and outdated CV or resumé**

Scientists and medical practitioners are expected to have accurate and up-to-date public profiles of their professional

activities, including their publishing record. It is no longer acceptable to permit biomedical researchers and medical practitioners to conceal any information on their academic and professional records, including academic degrees, training, patents, and a full and thorough list of their publications. These curriculum vitae (CVs) or *resumés* should be maintained on the institution's official web page, and may be supplemented – but not substituted – by CVs on social media and popular social sites, such as ResearchGate or Academia.edu. Research institutes and medical facilities that fail to show the full CVs/*resumés* of their staff and researchers should be considered guilty of misconduct and professional negligence for not holding their staff and researchers accountable for irresponsibility and professional negligence. The public can hold scientists and researchers accountable only when it is presented with a full complement of facts about them. This issue becomes even more pertinent when such scientists or researchers are on the public payroll and when their work and research is funded by tax-payers. Scientists who fail to maintain a CV/*resumé* that is up-to-date, or who are caught concealing information such as retracted papers, or who are found to be showing false or inaccurate information that is misleading to the public should face serious penalties and consequences. A pertinent question arises: had KI enforced strict CV/*resumé* procedures for Macchiarini, would many problems or issues with academic papers not have been detected much earlier? According to Dr Mattias Corbascio, it is uncertain whether all the degrees and titles listed in Macchiarini's CV were actually authentic, and a comparison of his CVs from different time periods and sources makes it difficult to ascertain where he actually was when he obtained the titles he claimed to have. This served as one of the formal reasons for his dismissal from KI. A *Vanity Fair* article revealed that Macchiarini had made false claims in his CV, and these had been used to secure his position at KI (42).

Concluding statements and the take-home message

The Macchiarini scandal has far-reaching consequences, not only for stem cell research, but for biomedical science in general. The ethical issues underlying this case are also not exclusively restricted to hospital wards and Swedish research institutes. What this case indicates is that ethical experimental standards in medical science should be thoroughly reviewed. High-risk procedures require strict ethical approval and institutional oversight, and must also be subjected to international scrutiny, and even approval. It does not suffice to simply claim that the approvals or procedures conform to international guidelines or declarations; each published paper should be supplemented with solid evidence/proof. How do the laws of informed consent for organ donation and transplantation differ in various countries? What ethical and legal limitations exist if the organ donors and doctors are from different countries (43)? Signed permissions and consent forms should form part of a standard open data policy for medical journals. They can easily be anonymised to avoid privacy issues, with the original non-anonymised forms maintained in secure databases, either by the publisher or the research

institute. However, such forms should always accompany a published paper, as part of an open data and open access policy. Those who use outdated, incomplete and inaccurate CVs/resumés must be considered guilty of misconduct, and institutions that fail to oversee the CVs of their employees should be held guilty of professional misconduct. Journals and publishers are doubling up on the verification procedures that take place when a paper is submitted and published to try to rein in misconduct. Increased scrutiny is meant to supposedly decrease fraud and abuse. This increasing trend of the militarisation of the publishing process (44) is attracting more and more lawyers, as evidenced by the Macchiarini case and other more recent high-profile cases, including the Fazlul Sarkar vs the PubPeer Foundation/ACLU case (45).

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Enhancing the autonomy of Indian nurses

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Abstract

With additional training and qualification, nurses in several countries are recognised as independent professionals. Evidence from several countries shows that capacitating nurses to practise independently could contribute to better health outcomes. Recently, the idea of nurses practising independently has been gaining momentum in Indian health policy circles as well, and the Ministry of Health and Family Welfare (MoHFW) is contemplating the introduction of nurse practitioners (NPs) in primary healthcare. We briefly assess the policy environment for the role of NPs in India. We argue for the need to conceptualise health stewardship anew, keeping the nursing profession in mind, within the currently doctor-centred health system in India. We argue that, in the current policy environment, conditions for independent nursing practice or for the introduction of a robust NP in primary healthcare do not yet exist.

Introduction

Nurses constitute a major proportion of the health workforce, and some of the innovations in health

workforce management across the globe have focused on *task shifting* to non-physician health workers, such as nurses, to decentralise and transform the health system. Apart from playing their traditional roles, nurses in a few countries are performing extended roles with titles such as advanced practice nurse, nurse practitioners (NPs), clinical nurse specialists and nurse anaesthetists. Nurses practise independently in several high-income countries, such as the USA, Australia, Canada, Ireland, the UK, Finland and the Netherlands, and even in some middle- and low-income countries, such as Thailand and Nigeria. In some of the provinces of these countries, the nurses need to have collaborative practice agreements with the physicians to practise independently. There is evidence across the globe to show that NPs are increasingly being used as the point of first contact and that patients are as, or more, satisfied with NPs than doctors (1,2). The cost of health service is also lower with NPs. Several studies have found that there is no difference between the clinical outcomes with NPs and general practitioners (1,2).

In recent times, the concept of independent practice by nurses has gained significant momentum within India's health policy circles as well. The Ministry of Health and Family Welfare (MoHFW) is contemplating the introduction of NPs in primary healthcare and is already in consultation with the Indian Nursing Council (INC –the national regulatory body for nurses and nursing education) and other stakeholders to take the move forward. The aim of this article is to examine the issues involved in independent nurse practice and its relevance in India.

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