

ON THE SCOPE AND TYPOLOGY OF 'RESEARCH MISCONDUCT':  
THE GAZE OF THE GENERAL MEDICAL COUNCIL, 1990-2015

Marie-Andrée Jacob\*

*Abstract:* Violations of research integrity are understood to have wide-ranging negative consequences for the trustworthiness of science and the health of the public. My goal in this article is not to cause further outrage about research misconduct. Instead this article queries research conducts expressly as seen through the eyes of a specific regulator and over a specific period (1990-2015). The result is an assessment of the strengths and limitations of the application of the General Medical Council's (GMC's) fitness to practice model in this area. It provides with an opportunity to shift the analytical attention back onto the existing typology of research misconduct – the classic Fabrication, Falsification and Plagiarism or FFP --, point to its deficiencies, and imagine how it could be refined in light of what the fitness to practice casework tells us about concrete, context-specific instances of research misconduct committed by medical practitioners. In the literature there has been neither a systematic examination of research behaviours as they get apprehended – when they do - through the lens of the British medical professional regulator, nor a case-based reflection on whether the existing frameworks and typologies used in the scientific community describe adequately the practices of medical research misconduct. The article aims to fill these two gaps.

*Keywords:* General Medical Council, medical regulation, professional discipline, research ethics, research integrity, research misconduct.

I. INTRODUCTION

Research misconduct is understood to have sweeping negative consequences for the trustworthiness of science and for the health of the public.<sup>1</sup> In turn the literature in this area operates almost solely as either a bashing of those committing misconduct or a commendation of sanctioning bodies. The goal of this article is not to cause further outrage about 'research misconduct.' Instead this article queries research misconduct *as* professional misconduct: it chronicles research behaviours expressly as seen through the eyes of a specific professional regulator, over a specific period (1990-2015). The result is an assessment of the strengths and limitations of the application of the General Medical Council's fitness to practice model in this area. In turn, this assessment provides with an opportunity to shift the analysis back onto the existing typology of research misconduct – the classic Fabrication, Falsification

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1 S Coughlin, A Barker and A Dawson, 'Ethics and Scientific Integrity in Public Health, Epidemiological and Clinical Research' (2012) 34:1 *Public Health Reviews* 1-13; R.G. Steen, 'Retractions in the medical literature: how many patients are put at risk by flawed research?' (2011) 11 *J. of Med Ethics* 688-92; H Lytton, 'This is How It's Always Been Done': The Treatment of Academic Misconduct in Canada' (1996) 21 *The Canadian Journal of Sociology* 223-231.

and Plagiarism or FFP --, point to its limitations, and imagine how it could be refined in light of what the fitness to practice casework tells us about concrete, context-specific instances of research misconduct.

The article covers a field overlapping two communities, each with a long tradition of aversion towards state law regulating its affairs: the scientific community, with its perceived ‘tribal culture,’<sup>2</sup> is known to be recalcitrant to state oversight, and medical professionals have long championed self-regulation.<sup>3</sup> In other words, the field is populated with individuals trained as scientists and medical professionals, thus doubly challenging to regulate. To complicate things, both these communities extend this ‘isolationism’ in their interrelationship with one another, and do not have a history of making discursive interventions for each other. The high degree of disconnection between scientific research governance and medical professional discipline is a key finding of the present research. It has implications for the critical analysis of both the GMC fitness to practice model and typologies of research misconduct.

My dataset of disciplinary decisions makes manifest the invisibility of certain forms of research misconduct *as* professional misconduct. Behaviours that fall short of ‘good research practice’<sup>4</sup> but do not constitute research misconduct have been increasingly the focus of attention in the public sphere and policy circles because of their potential impact on the integrity of the research record that informs and influences the daily practice of tens of thousands of GPs worldwide.<sup>5</sup> Yet the present casework shows that these practices rarely make it to disciplinary proceedings. The article ponders what this near absence from the archive can tell us. Equally, the casework shows what kinds of research behaviours have been under the GMC’s heightened scrutiny. It also makes explicit the connection – contested in parts of the literature -- between research integrity and research ethics. The article reflects on how the

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2 W Grunzweig, ‘Science-in-Fiction: Science as Tribal Culture in the Novels of C Djerassi’ in P Freese & C.B. Harris eds, *Science, Technology, and the Humanities in Recent American Fiction*, (Verlag Die Blaue Eule, Essen, 2012)

3 Self-regulation is now penetrated with a high level of state oversight. Excellent work details how GMC sustains the self-regulatory disciplinary model: R Smith, *Medical Discipline* (Clarendon Press Oxford Socio-Legal Studies 1990); M Stacey, *Regulating British Medicine: The General Medical Council* (Ashgate 1992); M Brazier, ‘The Age of Deference – A Historical Anomaly’ in M Freeman ed *Law and Bioethics* (Oxford University Press 2008) 464-473; M Davies, *Medical Self-Regulation: Crisis and Change* (Ashgate 2007); and more recently: M Davies, ‘The future of medical self-regulation in the UK: Renegotiating the state–profession bargain?’ (2015) *Medical Law International* 14 (4); P Case, ‘The Good the Bad and the Dishonest Doctor: The General Medical Council and the Redemption Model of Fitness to Practise’ (2011) 31 (4) *Legal Studies* 591–614.

4 M-A Jacob, *Scientific Research Integrity: Background Paper* (London, Nuffield Council on Bioethics, 2013)

5 R Van Noorden, ‘Meeting targets lab lapses’ (2013) 497 *Nature* 300-1.

FFP typology coming from the field of ‘misconduct studies’ might have missed the hybrid nature and implications of many research conduct cases.

The article proceeds as follows: it first clarifies my methodological approach, before turning to a brief overview of current debates on research misconduct, and then to explaining the frameworks under which the GMC can assess it as a form of misconduct impairing a doctor’s fitness to practice. Next it turns to intriguing ‘dark matter’: types of conduct that are at once notoriously widespread (although we do not know exactly to what extent amongst research active doctors), condemned within the scientific community, and yet nearly or even totally absent from the casework. Then the article examines how specific categories of research misconduct, namely interference with data, research ethics and authorship issues have been conceived in the casework. I suggest that the high number of hybrid cases that are hard to classify under the classic FFP framework signals problems with the typology rather than with the GMC fitness to practice model *per se*. In the conclusion I assess how the GMC has fared in assessing research misconduct as a form of professional malpractice and finally consider learned lessons and avenues for further inquiry.

In July 2012, the adjudication of fitness to practice hearings transferred from the General Medical Council’s Fitness to Practice Panels to the Medical Professionals Tribunal Service (MPTS).<sup>6</sup> The potential implications of these regulatory reforms on the oversight of medical research governance have yet to be fully grasped,<sup>7</sup> and are not part of the discussion here. The paper focuses on GMC cases including MPTS cases up to October 2015.

## II. METHODOLOGICAL ISSUES

This paper queries the way the GMC addresses research and indexes the category of ‘research misconduct’ in its written disciplinary casework, not the extent to which doctors engage or not in fraudulent research. I am all too aware that the 86 cases that inform this article are likely to constitute

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<sup>6</sup> The MPTS is still part of the GMC but it is ‘operationally separate’ and accountable to Parliament. See: [www.mpts-uk.org/](http://www.mpts-uk.org/). For academic discussions on changes in medical self-regulation in the UK, see Brazier (n 3); A.C. L. Davies, “‘Don’t Trust Me, I’m a Doctor – Medical Regulation and the NHS 1999 Reforms” (2000) 20: 3 *Oxford Journal of Legal Studies* 437-456.

<sup>7</sup> RCUK, *Report of the UK Research Integrity Futures Working Group* (Research Councils UK 2010); Academy of Medical Sciences, *A new pathway for the regulation and governance of health research* (AMS 2011); *Third Report, Clinical Trials*, H.C. Science & Technology Committee 2013.

only a part of the total occurrences of research misconduct amongst UK medics.<sup>8</sup> I left out for practical but also analytical reasons the notoriously ‘opaque’<sup>9</sup> triage process performed by the GMC case examiners prior to hearings.<sup>10</sup> Although from a socio-legal perspective there would be methodological advantages to studying complete proceedings of hearings of the FTP,<sup>11</sup> here a critical reading of the written work was found more suitable to study that part of legal discourse rendered public by the text of the GMC rulings themselves. The article chronicles cases from 1990 onwards because the nineties mark the first major investigations of scientific misconduct in the UK.<sup>12</sup>

Decisions of the Professional Conduct Committee and Fitness to Practice Panels related to research activities have been located in the GMC Minutes held at the British Library (for 1990-3), and via *Freedom of Information Act* requests to the GMC (for 1994-2014).<sup>13</sup> Prior to 2014 the GMC public database of cases allowed for a search only by the doctors’ name, which made technically impossible a search tailored by types of misconduct. Given this limitation I contacted the GMC’s Freedom of Information team and requested cases involving specific relevant keywords.<sup>14</sup> Access to these cases posed methodological problems, first because of the lack of alignment between the classic typology of research misconduct coming from the science and policy literature and the terminology the GMC used in its determinations, and second because the GMC lacked a working typology of its own cases.<sup>15</sup> For

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8 Only a small portion of cases of research misconduct are reported, or complained about to the GMC, and only a fraction of complaints ends up with a hearing of the GMC disciplinary panels. On the uses and limitations of data held by the GMC to research risk factors, see S Lloyd-Bostock, ‘The creation of risk-related information: The UK General Medical Council’s electronic database’ (2010) 24: 6 *Journal of Health Organization and Management* 584. When they study court cases, historians and socio-legal scholars are very conscious that the pre-hearing screening process eludes their gaze. See: J Conley and W O’Bar, *Just Words: Law Language and Power* (2nd edn, University of Chicago Press, 2005)

9 M Davies (n 3) 26.

10 Including Interim Order Panel hearings. See *Medical Act 1983 (Amendment) Order 2002/3135*, Sch. 2. s. 35C. The GMC can also take steps to deal with concerns (e.g. agree undertakings or issue a warning) without the case needing to go to panel.

11 Excellent new work mixes observations of hearings with documentary research in the field of financial regulation for example, see: A Jordanoska, *Regulatory Enforcement in the UK Financial Services Industry: Constructing Misconduct* (PhD dissertation, QMUL 2015).

12 Although Lock had traced the ‘first’ reported GMC medical research misconduct case back to 1975, Lock’s research was interested in case histories and in discussing their settings, motives, and identifying the disciplines particularly at risk: S. Lock, ‘Research misconduct: a resume of recent events’ in S Lock and F Wells, eds, *Fraud and Scientific Misconduct in Medical Research* (2nd edn., BMJ Publishing Group, 1996).

13 Scholars have used freedom of information policies to study research misconduct. See for e.g.: M Shapiro and R Charrow ‘The role of data audits in detecting scientific misconduct’ (1989) 261 *JAMA* 2505-11; Lock *ibid*, 38.

14 The following keywords have been used by the GMC’s access to information team to locate decisions: ‘research’; ‘dishonesty’; ‘research misconduct’; ‘probity - research’; ‘experiment’; ‘principal investigator’; ‘dishonesty - false claims to qualification/experience’; ‘dishonesty - false certification/false reporting’; ‘dishonesty/criminality - clinical drugs trials and research’; ‘clinical trial’; and ‘clinical study’.

15 When I began my correspondence with them in 2010, the GMC Freedom of Information team officer did not have a proper uniform searchable keywords for its database. A dozen of ‘new’ cases from the 1990s and 2000s, which had not been found during prior searches, were located by a Freedom of Information Officer in 2014.

the year 2014-5, I was able to retrieve the cases by myself by conducting a keyword search on the new website's search engine of the Medical Professional Tribunal Services.

The need to transpose the cases into an analytically manageable dataset posed another kind of problem. Although the article problematizes the classic FFP typology,<sup>16</sup> I still relied on it initially for analytical convenience to manage the dataset. The methodological problem I encountered in trying to fit the pre-existing grid of research misconduct typologies onto the detailed account of research conducts provided by the determinations showed the glaring inadequacy of existing typologies to describe a number of problematical medical research conducts. It is not the goal of this article to provide an alternative overarching heuristic to understand deviance in research; instead, it aims to provide a novel, case-based angle from which we can disrupt the current dominant typology.

### III. EXISTING TYPOLOGY OF RESEARCH CONDUCTS

The very category of research misconduct suggests that there is an ideal standard of good research practice that is inherently valuable, independently of the substantive quality of research results. This 'ideal' is difficult to pin down, but an expanding body of literature has made this ideal explicit under the name of research integrity. The distinction between what does or does not constitute 'research' has been fundamental to these debates, in particular the distinction between research on the one hand and treatment, audit, and service evaluation on the other.<sup>17</sup> Research ethics and governance apply to the former but not to the latter, and the boundary around research activities has been drawn and re-drawn strategically in order to obviate regulatory remit and legal accountabilities.<sup>18</sup>

Debates are ongoing as to what constitute the exact nature, remit and function of 'research integrity'.<sup>19</sup>

A narrow account relates the integrity of an individual scientist to his or her adherence to

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16 For an interesting typology of allegations of questionable research conduct at the Committee on Publication Ethics between 1997 and 2013 see: I. Hames et al., 'Publication Ethics: 16 Years of COPE', paper presented at the Seventh International Congress on Peer Review and Biomedical Publication, Chicago, 8 September 2013, Plenary Session Abstracts, p20 <http://www.peerreviewcongress.org/index.html>.

17 E Cave and C Nichols, 'Clinical Audit and Reform of the UK Research Ethics Review System' (2007) 28 *Theoretical Medicine and Bioethics* 181-203.

18 See *Walker-Smith v GMC*, as discussed below.

19 S Haack, 'The Integrity of Science: What It Means, Why It Matters' *Etica e Investigacao nas Ciencias da Vida – Actas do 10 Seminario do CNEV* (CNEV, Lisboa, Portugal 2007) 9-28

epistemological values of 'evidence sharing and respect for evidence' and commitment to intellectual honesty.<sup>20</sup> Under this account, ethical considerations are neither necessary nor sufficient to good scientific work.<sup>21</sup> However, policy accounts tend to be broader and to list ethical values such as fairness and care as core values of research integrity.<sup>22</sup> The U.S. Institute of Medicine defends a broader understanding of scientific integrity involving 'a commitment to intellectual honesty and personal responsibility for one's actions as a researcher and to practices consistent with the responsible conduct of research and protection of the research participants.'<sup>23</sup> Integrity can also be understood as being free of bias. Randomisation, blinding and other refinements of the randomised controlled trial (RCT) were introduced to reduce research bias.<sup>24</sup>

It is only since the late part of the 20<sup>th</sup> Century that a distinct body of misconduct studies literature defining its meanings and implications has developed.<sup>25</sup> To sociologists of organisational deviance, the category of 'misconduct' is interesting because misconduct tends to be hidden and risky. Deviant and harmful events would be more habitual than we might think, and have social and public health costs, thus representing the 'dark side' of 'organisational life' such as professional, academic, scientific life. The sociological literature on disasters taught us that various shades of non-conformity acts within organisations range from mistakes, to misconduct, to disasters.<sup>26</sup> Of course disastrousness vary in degrees and scales (e.g. Bhopal, Chernobyl, mad cow food poisoning), but to these sociologists the vaccine 'scare' could admittedly be seen through the lens of disaster studies, for it is claimed to have caused enormous harm to public health.<sup>27</sup>

Focusing on the U.S. context, Montgomery and Oliver have traced how institutions have mobilised to deal with deviance specifically in the field of science. They note that prior to 1975, the discourse was

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20 M Polanyi *Science Faith and Society* (London: Cumberledge, 1946); Haack *ibid*.

21 For instance, someone may do innovative, important solid scientific work even though she is unkind to animals or ungenerous in giving collaborators credit. In turn, someone may do poor science whilst behaving in a way that is morally impeccable: Haack (n 19).

22 *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations*, 2013, date accessed 5 October 2015: [http://www.icsu.org/icsu-asia/news-centre/news/MontrealStatementonResearchIntegrityJune21\\_2013.pdf](http://www.icsu.org/icsu-asia/news-centre/news/MontrealStatementonResearchIntegrityJune21_2013.pdf)

23 Coughlin, Barker and Dawson (n 1).

24 H Marks, 'Trust and mistrust in the marketplace: statistics and clinical research, 1945-1960.' (2000) 38 *History of Science* 343-355.

25 K Montgomery and A Oliver, 'Shifts in Guidelines for Ethical Scientific Conduct How Public and Private Organizations Create and Change Norms of Research Integrity.' (2009) 39(1) *Social Studies of Science* 137-155.

26 D Vaughan, 'Mistake, Misconduct, Disaster: The dark side of organisations' (1999) 25 *Ann Rev of Sociology* 271-305.

27 F Godlee, 'Institutional research misconduct' (2011) *BMJ* 343:d7284; C Dyer, 'The fraud squad' (2003) *BMJ* 342:401-7.

about the norms and counter-norms of the ‘normal practice of science.’<sup>28</sup> It then moved, between 1975 and 1990, to a focus on the prevention of scientific misconduct; and from 1990s to the present, to promoting research integrity.<sup>29</sup> Today, research integrity and misconduct are often dealt together in policy documents, as definitions have been expanding to encompass newer forms of behaviours (e.g. data editing and ghost writing, amongst others).

The ‘hard core’ definition of research misconduct is comprised of fabrication, falsification, and plagiarism, or FFP.<sup>30</sup> Fabrication is defined as ‘making up data or results and recording or reporting them;’<sup>31</sup> and falsification as: ‘manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record;’<sup>32</sup> Plagiarism constitutes ‘the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.’<sup>33</sup> LaFollette’s influential study of academic misconduct made clear the connection between appropriation of one’s work and dishonest research.<sup>34</sup> Yet plagiarism has also been cast as one of the less grave forms of misconduct, for having allegedly less ‘public health implications.’<sup>35</sup> There is an assumption that research integrity always serves the public interest and that misconduct harms it. However, something unique characterizes health research vis-à-vis other scientific and academic research more generally given that health research findings are used as part of the evidence base for clinical and public health practice, and hence there exist real risks that inaccurate or misleading research findings might compromise patient safety. This is distinct from practices such as

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28 These norms, proposed by sociologist Robert Merton, were: communalism, universalism, disinterestedness, originality and scepticism, and the counter norms were: solitariness, particularism, interestedness, and dogmatism. See R Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, 1979).

29 Montgomery and Oliver (n 25); M LaFollette, ‘Paycheques on a Saturday night: a brief history and analysis of the politics of integrity in the United States’ (1996) in Lock and Wells (n 12), 1-13.

30 National Academy of Science, Committee on Science, Engineering, and Public Policy, Panel on Scientific Responsibility and the Conduct of Research, *Responsible science, Volume I: Ensuring the integrity of the research process* (Washington, D.C: National Academy of Science, 1992).

31 European Science Foundation (ESF) and All European Academies (ALLEA), *European Code of Conduct for Research Integrity* (ESF 2011); Office of Science and Technology Policy, Executive office of the President, *Federal Policy On Research Misconduct. Federal Register* (2000) 76260-4.

32 PHS, *Public Health Service Policies on Research Misconduct* (PHS 70 (94) Federal Register 2005) cited in D Fanelli, ‘The black, the white and the grey areas – towards an international and interdisciplinary definition of scientific misconduct,’ in N. Steneck and T. Meyer eds, *Promoting Research Integrity in a Global Environment* (World Scientific, 2011)

33. PHS, *Public Health Service Policies*, *ibid.*

33 Code of Federal Regulations 45, S. 689.1

34 M C LaFollette, *Stealing Into Print: Fraud, Plagiarism, and Misconduct in Scientific Publishing* (University of California Press, 1996)

35 Lytton (n 1).

appropriating someone's work or attaching one's name to a project when she was not in fact involved in the research.

Fanelli refers to 'conceptually open' definitions that are broader than the core FFP and encompass the 'grey areas' of research conduct, by aiming to 'include any potential breach of integrity'.<sup>36</sup> Even broader definitions would include behaviours termed Questionable Research Practices (QRPs), to encompass such practices that depart from acceptable research practice of the relevant research community,<sup>37</sup> but do not constitute research misconduct strictly speaking. To Fanelli these could include for instance, breaches of research ethics, thus suggesting that research ethics breaches are less serious than fabrication or plagiarism as a form of misconduct. Whereas Steneck insists on a clear analytical separation between research integrity and research ethics,<sup>38</sup> Lemmens and Waring willingly conceive of recruitment procedures of human participants and disclosure of conflicts of interests as issues of scientific integrity.<sup>39</sup>

Recently within the scientific research integrity community, the emphasis has been on pre-empting instances of 'lap lapses' and 'cutting corners' as these ordinary, low scale events make science irreproducible and are considered the most important threat to a reliable research record. This stands in contrast with the idea that harmful science is the remit of so-called 'bad apples,' that is, those rare and extraordinary fraud cases that capture the media's attention.

The academic community has seen a proliferation of open-ended type definitions through the enactment of numerous codes of conducts, declarations and programmatic statements about good research at the institutional, national, regional and international levels. But in the UK there are currently no statutory frameworks that regulate research integrity and sanction research misconduct apart from state-supported medical self-regulation.<sup>40</sup>

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36 Fanelli (n 32),

37 N Steneck, 'The role of professional societies in promoting integrity in research' (2003) 27 (Suppl. 3) *American Journal of Health Behavior* S239-S247.

38 N. Steneck, 'Fostering integrity in research: Definitions, current knowledge, and future directions' (2006) 12 *Science and Engineering Ethics* 53-74.

39 T Lemmens and D Waring, eds, *Law and Ethics in Biomedical Research*, (Univ of Toronto Press, 2006)

40 J Smith, *Fifth Report of the Shipman Inquiry*, Summary cited in Davies (n 3); House of Commons Science and Technology Committee, *Report on Peer-review*. To remediate this, scholars have suggested using analogies from foundational fields of law: T Lemmens and Waring, *ibid* ;

Given the GMC's statutory purposes – today both self-proclaimed and state-directed – towards 'the protection of the public,' as expected one can find open-ended guidance related research in GMC documentation. The GMC's guidance (for example *Good Medical Practice*, *Good Practice in Research and Consent to Research*, and *Research: the Role and Responsibilities of Doctors*)<sup>41</sup> tends to address the issue of 'research integrity' ('probity' in the language used by the GMC) instead of misconduct, in line with Montgomery and Oliver's observed patterns.

The fact that self-regulation has eroded and become increasingly supervised and bureaucratised via state oversight also supports a programmatic approach to research misconduct by the GMC. However, the increased juridification of GMC disciplinary processes have contributed to the use of more restrictive definitions, as explicated below.

#### IV. FITNESS TO PRACTISE AND IMPAIRMENT

In its decision on Andrew Wakefield, the GMC made explicit that "this case is not concerned with whether there is or might be any link between the MMR vaccination and autism."<sup>42</sup> In other words, the case was not about whether Wakefield and his colleagues' findings were right or wrong. The issue was the way they conducted their research, whether it was ethical and genuine to begin with. This distinction resonates with medical sociologist Charles Bosk's seminal distinction between technical and normative medical errors.<sup>43</sup> 'Technical errors' are easily forgiven by peers and elicit restitutive forms of sanctions. Those who make technical errors are supported. Normative errors however go to the

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C Hodges, "Investigating, reporting and pursuing fraud in clinical research: legal aspects and options," in Lock and Wells eds, *Fraud and misconduct in medical research* (2nd edn BMJ 1996) 74. However, the new UK *Concordat to support research integrity* is a step towards better enforcing research integrity by sanctioning, via cuts in research funds, institutions that do not respond adequately to allegations of research misconduct: <http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf>.

41 The GMC's *Good Medical Practice* states that: 'You must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines and our guidance': GMC, *Good Medical Practice*, updated March 2013, Para. 67. The GMC thus refers explicitly to additional norms that govern the conduct of those who do scientific research: the rules of the scientific community, formal and informal, produced and distributed by employers (research institutions), research funders and sponsors, and academic journals. Research guidance outlines principles governing research and their applications into practice: GMC, *Good Practice in Research and Consent to Research*, 2010; GMC, *Research: the Role and Responsibilities of Doctors*, 2005. The areas covered by the guidance are: law and governance; good research design and practice; protecting participants from harm; honesty and integrity; avoiding conflicts of interest; consent to research; respecting confidentiality. The 2005 version of the guidance included two additional areas: funding and payments; and teaching, supervision and managerial responsibilities for research.

42 GMC Fitness to Practice Panel, 28 January 2010.

43 C Bosk, *Forgive and Remember: Managing Medical Failure* (University of Chicago, 1979)

heart of the integrity of the professional actor, and hence would not be easily forgivable. Normative errors trigger responses that ‘degrade’ the wrongdoer and may lead to his or her ‘banishment’.<sup>44</sup> In the UK context, it is normative errors that might impair the fitness to practise of the individual medical professional, whilst bringing the profession into disrepute. The GMC uses an analogous distinction when defining research integrity itself: the technical notion of integrity as wholeness and intactness of a clinical trial, is made distinct from the normative notion of probity as an individual virtue.<sup>45</sup> The problem with the technical/ normative heuristics coming from professional practice is that they implicitly set up a hierarchy according to which technical breaches are considered less of consequence than normative ones.

The current test for assessing impairment to fitness to practise is that proposed by Dame Janet Smith in the *Shipman Inquiry Fifth Report*. According to the ‘Smith test’, a doctor’s fitness to practise is ‘impaired’ when she either is a risk to patients, or has brought the profession into disrepute; or has breached one of the fundamental tenets of the profession; or her integrity cannot be relied upon.<sup>46</sup> In addition, fitness to practise must ‘be judged by reference to past misconduct and, looking to the future, whether the misconduct has been remedied and whether it is likely to be repeated in the future.’<sup>47</sup> Fundamental considerations include the need to protect the individual patient, the protection of the public, and of the public interest, the latter of which encompasses the need to maintain the public’s confidence in the medical profession, and declaring and upholding proper standards of conduct and behaviour.<sup>48</sup>

An impairment finding is established by answering three questions: first, are the facts proved on the balance of probabilities; second, do the proved facts amount to misconduct; third, is the fitness to practice impaired by the misconduct. Subsequently, if impairment is found, an appropriate sanction

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44 Bosk, *ibid*, at 169. For similar and ritual-based treatments in the scientific community, see: S Th rese and B Martin, ‘Shame, scientist! Degradation rituals in science’ (2010) 28:2 *Prometheus* 97-110.

45 FtPP 14 February 2003.

46 See GMC, *Reform of the Fitness to Practise Procedures at the GMC: Changes to the Way we Deal with Cases at the End of an Investigation*, (GMC 2011) para 25.50.

47 *Council for Healthcare Regulatory Excellence v NMC and Grant* [2011] EWHC 927 (Admin)71,74, and 76 (referring to a decision from the Nursing and Midwifery Council). See also: *Meadow v GMC* [2006] EWCA Civ 1390 [2007] 1 QB 462, 32.

48 Davies, *Medical Self-Regulation* (n 3); *Cohen v GMC* [2008] EWHC 581 (Admin). See also: J Glynn and D Gomez, *The Regulation of Healthcare Professionals: Law, Principle and Process* (Sweet & Maxwell, 2012)

must be applied.<sup>49</sup> Sanctions include conditional registration (for instance, conditional upon not conducting research activities), suspended registration, and erasure from the register (and historically, reprimands). In cases where there is no finding of impairment, a warning may be issued.<sup>50</sup>

Misconduct itself can be of two principal kinds. First, it may involve sufficiently serious misconduct in the exercise of professional practice such that it can affect the fitness to practise. Second, it can involve conduct of a morally culpable or otherwise disgraceful kind which may, and often will, occur outside the course of professional practice itself, but which brings disgrace upon the doctor and thereby prejudices the reputation of the profession.<sup>51</sup> The criterion of ‘bringing the profession into disrepute’ is articulated as a tension in regulatory procedures, as the regulator must consider mitigating information in particular individual circumstances, whilst remaining critically sensitive to upholding professional standards.<sup>52</sup>

‘Dishonesty’ is treated separately as a type of misconduct, and is particularly relevant to the GMC’s understandings of research misconduct. The *Indicative Sanctions Guidance (ISG)*,<sup>53</sup> published in 2004 as part of the procedural reforms of the GMC, conceives of ‘research misconduct’ as a subspecies of the overarching misconduct category of dishonesty:

110. ... The term is used to describe a range of misconduct from presenting misleading information in publications to dishonesty in clinical drugs trials.

Such behaviour undermines the trust that both the public and the profession

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49 *Cheatle v GMC* [2009] EWHC 645 (Admin)19.

50 Pre-2004, there were two stages to GMC proceedings; a finding of serious professional misconduct (‘SPM’) had to be made before a sanction could be imposed. If the offence was at the lower end of the spectrum of SPM and it was not considered sufficient to conclude the case with no action, a reprimand was the lowest sanction that could be imposed. Reprimands no longer form part of the GMC sanctions regime. Since the enactment of the *Indicative Sanctions Guidance* in 2004, the GMC approach is more methodical and explicit in its discussion on mitigating factors, as these have had a critical role in the determination of what is considered an appropriate sanction. They have included, for instance: delay in proceedings (between action and hearings); abilities as doctor, based on testimonies of colleagues and patients; admissions, expressions of regret, or apology; no previous or subsequent findings; character evidence; evidence of having made a significant contribution to the field. The issue of mitigating factors and the stories and apologies they elicit requires further research.

51 *Remedy UK Ltd, R (on the application of Remedy UK Ltd) v General Medical Council* [2010] EWHC 1245 (Admin).

52 P Case, ‘Putting Public Confidence First: Doctors, Precautionary Suspension, and the General Medical Council’ (2011) *Medical Law Review* 19: 339-371.

53 GMC, *Indicative Sanctions Guidance for the Fitness to Practise Panel* (April 2009, with 7 August 2009 revisions, March 2012 revisions and March 2013 revisions).

have in medicine as a science, regardless of whether this leads to direct harm to patients. Because it has the potential to have far reaching consequences, this type of dishonesty is particularly serious.<sup>54</sup>

With this paragraph the GMC normatively highlights that research misconduct is particularly serious and could lead to erasure, and also descriptively informs its public that an intention to mislead, i.e. ‘dishonesty,’ is required for research misconduct to constitute serious professional misconduct, and to be grave enough to amount to impairment of fitness to practise.

In contrast, ‘seriously deficient performance,’ another ground for impairment that could include for instance ‘poor record-keeping, poor maintenance of professional obligations of confidentiality,’<sup>55</sup> would not fall under the research misconduct definition of the GMC. This means that a departure from research integrity does not automatically translate into research misconduct and, in the context that interests us here, research misconduct does not necessarily amount to a serious professional misconduct that impairs the fitness to practise of a doctor. Indeed, it is pertinent to attend to what was underrepresented or not found in the archive.

## V. THE DARK MATTER

The dataset contains no references to poor research practices and ‘lab lapses’, unless they are accompanied by systemic attitudinal problems on the part of the doctor. Neither ‘seriously deficient performance’, nor ‘posing a risk to patients’<sup>56</sup> or to participants, has in itself been evoked as grounds for impairment in the cases I reviewed. Misuse of research funds was found in one determination only. Nondisclosure of conflicts of interests<sup>57</sup> was discussed in two determinations, in one of which it was conceived as a ‘breach of duty’ but not dishonest.<sup>58</sup> Others (like suppression of negative results,<sup>59</sup>

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54 *ISG* para 110, at p. 29.

55 *Sadler v GMC* [2003] UKPC 59; [2003] 1 WLR 2259 Lord Walker of Gestingthorpe, para 63.

56 See the above discussion on the Smith test in the text accompanying n 46.

57 S Krimsky, ‘The Legal and Ethical Foundations of Scientific ‘Conflict of Interest’ in T Lemmens and D Waring, above n. 39.

58 MPTS, 18 February 2015.

59 I Chalmers, ‘Underreporting research is scientific misconduct’ (1990) 263:10 *JAMA* 1405-8; J. Brown, ‘Self-Censorship’ in T Lemmens and D Waring, *ibid*; G Edmond, ‘Judging the Scientific and Medical Literature: Some Legal Implications of Changes to Biomedical Research and Publication’ (2008) 28: 3 *Oxford J of Legal Studies* 523-61.

image and photo manipulation,<sup>60</sup> self-plagiarism and citation manipulation, breach of integrity or conflicts of interests in the peer-review process (of articles and grant applications),<sup>61</sup> maltreatment of laboratory animals,<sup>62</sup> ghost authorship and ghostwriting,<sup>63</sup> writing fake reviews, creating fake journals, and impersonating reviewers),<sup>64</sup> did not get discussed. Admitted errors or omissions in the conduct of research may be ‘inappropriate and below the standard to be expected of a senior lecturer and consultant,’ without being characterised as misconduct, as mentioned by the FtPP.<sup>65</sup> So far it has been impossible to verify whether the above misconducts are simply non-existent, have been left off the complainants’ radar, or have been screened out by the GMC case workers’ triage as being insufficiently serious to warrant a full GMC hearing.

Many other practices known to pervade medical research were absent from the dataset. Take for instance the over-interpretation of ‘significant’ findings in small trials,<sup>66</sup> or inappropriate subgroup analysis. Even though neither tarnishing the individual integrity of a researcher nor impairing fitness to practice, poor science conducted in good faith<sup>67</sup> and lazy or sloppy research undeniably affects the integrity of the research record.<sup>68</sup> In fact, ‘lab lapses,’ and poor science more generally, have become the biggest concerns of the research integrity community.<sup>69</sup> Given that ‘deficient performance’ has been found sufficient to call into question a doctor’s registration<sup>70</sup> and that poorly done medical research can have immense public health dimensions, could such risky lapses be envisaged as a form of SPM leading to impairment? Malicious intention and dishonesty are most likely to be absent in such

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60 See: E K Frow, ‘Drawing a line: Setting guidelines for digital image processing in scientific journal articles’ (2012) 42:3 *Social Studies of Science* 369-392.

61 M Biagioli, ‘Recycling Texts or Stealing Time? Plagiarism, Authorship and Credit in Science (2012) 19 *Int’l J of Cultural Property* 453-476.

62 Council of Science Editors, *White Paper on Promoting Integrity in Scientific Journal Publications* (CSE, 2012). Note that the first U.S. definition of research misconduct included a reference to the protection of human subjects and of animal welfare in labs: Fanelli (n 33).

63 S Stern and T Lemmens, ‘Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles’ (2011) 8:8 *PLoS Med* e1001070.

64 These are cases that are on the rise in the deliberations of the Forum of the Committee on Publication Ethics: [www.publicationethics.org](http://www.publicationethics.org).

65 FtPP, 20 May 2010, at p. 17.

66 A Marusic et al., ‘Interventions to prevent misconduct and promote integrity in research and publication’ (2013) *Cochrane Methodology Review Group*, DOI: 10.1002/14651858.MR000038

67 S Lock, ‘Fraud and the editor’ in Lock and Wells (n 12).

68 Van Noorden (n 5); R Smith, ‘Research misconduct: the poisoning of the well’ (2006) 99:5 *Journal of the Royal Society of Medicine* 232–237.

69 Van Noorden (n 5). See the programme, reports and the Montreal statement on the website of the 3rd World Conference on Research Integrity at: [http://www.wcri2013.org/Montreal\\_Statement\\_e.shtml](http://www.wcri2013.org/Montreal_Statement_e.shtml).

70 E. Jackson, *Medical Law: Text Cases and Materials* (2nd edn, Oxford University Press, 2010) 144.

instances, but grossly negligent behaviour putting into question whether this person should be a registered professional does meet the threshold of SPM, especially given the high stakes for the health of individuals and populations. Recall that one of Smith's criteria for impairment is the fact that a doctor 'is a risk to patients.' Despite this, risk-analysis of research misconduct is absent from the casework.

For example, following the organ retention scandal at Alder Hey, the GMC's reactions resulted in a finding of impairment of one 'overzealous and dysfunctional pathologist.'<sup>71</sup> Seventeen doctors had been referred to the GMC and three had a full hearing but were exonerated, despite the fact that they were aware or should have been aware of the harmful practices that occurred for years at Alder Hey. Whilst the case epitomised 'inherent cultural flaws in the medical profession',<sup>72</sup> as claimed in the public inquiry reports, it also raised individual accountabilities and forms of impairment posing risks to patients and their families, which only a body like the GMC *could* have tackled. Indeed, amongst the absentees we find newer and more controversial forms of 'misconduct' that have been concerning regulators in the aftermath of the Francis Report, such as negligently closing one's eyes and not reporting on someone else's misconduct, and in this sense lacking candour.<sup>73</sup>

The GMC's comprehension of the contemporary scale of research misconduct thus leaves unaddressed many areas of individual misconduct as well as systemic forms of misconduct pertaining to research. And yet the GMC's focus on individual's fitness to practice succeeds in capturing conducts otherwise left beyond the scrutiny of research integrity approaches and their 'light touch'<sup>74</sup> focus on education and prevention. Despite clear regulatory deficits, the GMC retains an important role in generating individualised accountabilities understood on their own terms and in their own contexts.

## VI. INTERFERENCE WITH DATA

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71 D Hall, 'Reflecting on Redfern: What can we learn from the Alder Hey story?' 84:6 (2001) *Archives of Disease in Childhood* 455-456.

72 E T Hurren, 'Patients' rights: From Alder Hey to the Nuremberg Code' (2002) *History & Policy: Policy Papers*, available at: <http://www.historyandpolicy.org/papers/policy-paper-03.html#further>

73 Robert Francis (Chair), *The Mid Staffordshire NHS Foundation Trust Public Inquiry*, Mid Staffordshire NHS Foundation Trust 2013.

74 Janet Finch (Chair), *Report of the UK Research Integrity Futures Working Group*, RCUK 2010.

Richard Smith, the past editor of the *British Medical Journal*, recalls how he first heard of the Pearce case: one morning over breakfast, Geoffrey Chamberlain, then editor of the *British Journal of Obstetrics and Gynaecology* and president of the Royal College of Obstetricians and Gynaecologists (which owned the journal), told him that there had been ‘a bit of trouble.’<sup>75</sup>

In 1994, Malcolm Pearce wrote a Case Report describing the first intrauterine relocation of an ectopic pregnancy, followed by a healthy term delivery. His report was accepted and published in the *British Journal of Obstetrics and Gynecology*. The Report turned out to be based on medical records entirely falsified by Pearce. That same year Pearce submitted another Report to the journal, discussing this time a RCT involving 191 women with recurring miscarriages, a trial which in fact never took place. In addition to having fabricated data, Pearce had assigned authorship to his Head of Department at St George's Hospital Medical School, Professor Geoffrey Chamberlain. In a short determination, the GMC Professional Conduct Committee charged Dr Pearce with ‘deliberately including false and misleading data’ in a research paper and for committing ‘scientific fraud,’<sup>76</sup> and sanctioned him with erasure. In the determination the PCC expressed in more general language its concerns about the dangers of scientific fraud for future medical researchers who could follow in good faith ‘techniques and treatments described in published papers which are fraudulent,’ and for the future safe treatment of patients. The PCC decision on Pearce is perceived to be the first ‘real’ major research misconduct case in the UK.

29 cases address misconducts that relate to the integrity of core elements of the research process and the validity of methods, data and results. Allegations have included: the use of false dates of birth of some patients; misleading information about results in a paper; the duplicate use of identical data; the submission of identical printouts for pairs of participants, or the pooling of data from two studies; not randomising;<sup>77</sup> including participants in trials whilst they should have been excluded; and assigning one randomisation number to more than one patient.<sup>78</sup>

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75 Smith (n 68)

76 PCC, 7 June 1995.

77 For instance: PCC, 27 November 2000; PCC, 7 December 2001.

78 For instance: FtPP, 30 June 2008.

16 of these cases have led to erasure. The casework does not show consistent sanctions for this kind of research misbehaviour. A doctor was erased by the PCC for breaking a trial code<sup>79</sup> designed to prevent bias in RCT.<sup>80</sup> In a more recent decision, the FtPP volubly characterised the deliberate inclusion of false/misleading data in a paper as ‘dishonest’, ‘misleading’, ‘in breach of scientific integrity’, and a failure ‘to conduct research in an ethical manner’. The FtPP justified its sanction of 12-month suspension on several explicit grounds, taking into consideration the public interest, the interest of the practitioner, and the issue of proportionality.

At times the more blatant forms of misconduct were perceived as less ‘sophisticated,’ and in turn led to lenient sanctions. In a noteworthy case a doctor had used the term ‘audit’ to describe his work in order to avoid ethical approval, and subsequently misrepresented the work as a ‘randomised, controlled, double-blinded’ study. This case involves the first reference by the FtPP to the idea of a scale of seriousness of research misconduct. The doctor’s misrepresentation fell within the remit of research misconduct as a form of dishonesty, but the FtPP found it ‘unsophisticated’ and ‘not at the top end of the scale, such that it does not suggest a planned attempt to mislead others.’<sup>81</sup> Hence it led to a 12-month suspension.

Another case involved the destruction of research records and ‘setting the record straight’ in a wholly inappropriate and clandestine manner’ as well as forgeries of signatures and dual recruitment and its disguising.<sup>82</sup> The FtPP highlighted the standards on the conduct of research as required by the GMC’s *Good Medical Practice* (2006) on ‘probity’ (paras 56-7) and ‘research’ (paras 70-1), and engaged with a technical norm of ‘good research practice’. The FtPP then addressed the doctor in these terms: ‘... the nature of your research fraud and its potential damage to the integrity of research as an important arm of medical science is such that public confidence in the profession would be undermined if a finding of impairment were not made in the particular circumstances’.<sup>83</sup> It sanctioned this transgression by a senior researcher with a 4-month suspension.

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79 The case mentions ‘and/or asking someone to do so.’

80 PCC, 4 October 1999.

81 FtPP, 13 November 2007.

82 FtPP, 13 January 2012.

83 Ibid at p. 13.

Research that put the safety of research participants at stake was considered explicitly by the FtPP as affecting the ‘integrity’ of the clinical trial,<sup>84</sup> thus alluding to a close connection between research ethics and research integrity. And yet the potential harm to participants (and to the patients who would eventually consume the medicine or treatment whose efficacy and safety is tested by medical research) was often left unspoken in the casework. For instance, a case discussed a doctor reclassifying patients who did not fill a trial’s eligibility criteria in order to include them as participants to the trial, along with his forgery of signatures and fabrication of letters to GPs related to such participation. There was no mention of posing a risk to patients/participants – a breach of research ethics – as its own source of misconduct.<sup>85</sup> The conduct was instead mitigated as the FtPP believed that the motive for dishonesty may have been a belief that the doctor was benefiting his patients: to provide the ‘opportunity for your ... patients to receive drugs that were otherwise unavailable on the NHS’. Despite this rather sympathetic depiction, the conduct was nevertheless determined as inappropriate, dishonest, unprofessional, and not in the best interests of patients. It led to 12-month suspension.<sup>86</sup>

Other similar cases stood at the boundary between data interference and research ethics breach. For instance, not randomising participants with the purpose of influencing a trial was seen as a ‘misguided attempt to establish efficacy of treatment in which [the doctor] had come to believe’. In this case the PCC noted the importance of research integrity for public health and that the reliability of trials may affect generations of patients, hence highlighting the integrity dimension of the case, and framing it as a case of falsification of data. Nevertheless the PCC concluded the case with only a reprimand.<sup>87</sup> In another case, a patient died in the course of a trial in which the doctor had included a patient as a participant contrary to research protocol’s eligibility criteria (it is not made clear whether it was the same patient). The PCC found that the doctor’s decision was not ‘inappropriate, irresponsible or contrary to research protocol or contrary to best interests, although it was not for the patient’s personal benefit’.<sup>88</sup> It thus did not constitute SPM. These cases are surprising for their lack of engagement with the risks and research ethics dimensions of data interference as a form of professional misconduct.

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84 FtPP, 14 February 2003.

85 FtPP, 7 April 2008.

86 An appeal of this case was partially allowed on one ground (that forging one document does not imply forging other documents), see: *Sharief v GMC* [2009] EWHC 847 (Admin).

87 PCC, 28 March 2003.

88 *Ibid.*

## VII. RESEARCH ETHICS AND HYBRID CASES

25 cases addressed explicitly 'ethical' issues pertaining to research, including misrepresentation to Research Ethics Committee (REC), and/or forgeries of REC approval or consent forms' signatures. Three milestone UK research 'scandals'<sup>89</sup> of the last three decades were treated as 'research ethics cases' by the GMC: Liverpool-Alder Hey, the MMR autism study, and the North Staff study.

The infant pathology research programme at Liverpool Alder Hey became well known for its 'systemic'<sup>90</sup> disregard of parents' consent about the retention of their embryos' or deceased infants' organs between 1988 and 1994.<sup>91</sup> The GMC determination on pathologist van Velzen described numerous breaches: examination of research material (organs of infants) carried without the authority of the person legally in possession of the body by reason of the Human Tissue Act 1961, and examination carried in breach of the limited consent obtained, and having 'knowingly disregarded parents' wishes and expectations'; failure to complete post-mortem reports within proper and reasonable time; and misleading or false post-mortem reports with respect to weight and sections of organs.<sup>92</sup> The FtPP described the behaviours as 'inappropriate, improper, irresponsible towards families and/or your colleagues'. Other questionable research practices included inadequate cataloguing and poor storage, such as human remains being stored in a cellar in a not fitting, haphazard and disorganised state'. The description of such poor research practices defies traditional typologies of research misconduct and also shows the difficulty in seeing ethical considerations as separate from the integrity of scientific research.

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89 See M Dixon-Woods, K Yeung and C Bosk, 'Why is UK medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors' (2011) *Social Science & Medicine* 73 (10) 1452–1459.

90 This tension between individual and systemic or institutional research misconduct is a key pattern in medical regulation more generally, and deserves separate treatment. See M-A Jacob (n 12).

91 The main finding was the retention and poor storage of organs from foetuses and infants obtained without parental consent. The programme on sudden infant death syndrome ran at the Liverpool Alder Hey hospital between 1988 and 1994.

92 The Redfern-Keeling Inquiry Report revealed 'workload laundering,' 'fabrication,' and that van Velzen admitted to the Inquiry that 'he lied in post-mortem reports, describing the results of examinations he had never done'. See H Pennington, 'Myrtle Street,' (2001) 23: 5 *London Review of Books* 21-23.

Three 2010 determinations<sup>93</sup> about the MMR study also detail numerous ethical breaches. The determinations indicate that the GMC sanctioned the doctors because it conceived the research as unethical rather than fraudulent.<sup>94</sup> The determination on Wakefield mentions carrying out a programme of investigations of research on 12 children without REC approval; misleading and dishonest description of the patient population; the irresponsible and misleading description of the project and of the referral process in correspondence with journal and funders, contrary to the duty to ensure that information in the paper is accurate; dishonest statements about REC approval; a breach of ‘fundamental principles of research medicine’; and the use of an invasive procedure when not clinically indicated. The FtPP carefully describes the funding arrangements in relation to the research, indicating although not explicitly, that the misconduct also included the non-disclosure of conflicts of interests. To the FtPP: ‘the research misconduct collectively amounts to serious professional misconduct, but when considered individually constitute multiple separate serious professional misconducts’.<sup>95</sup> This suggests that individual forms of research ethics breaches such as the non-disclosure of conflicts of interests could on their own constitute misconduct in the eyes of the GMC. The Wakefield determination is thus particularly significant in the sense that it suggests a broadening of the kinds of research misconduct that can amount to serious professional misconduct.

Three decisions dealt with doctors working on the continuous negative extrathoracic pressure (CNEP) research trial and treatment of premature babies with respiratory distress at the North Staffordshire hospital (1989-1993).<sup>96</sup> The cases concerned various allegations: inaccurate descriptions in applications to the REC; failure to report adverse events (as required by the Association of British Pharmaceutical Industries Guidelines since 1990); changes to the scoring systems and trial protocol, delegation of the consent-taking process; misrepresentation in an information leaflet and failure to obtain informed parental consent; and incorrect scoring. Again, many of the alleged actions, such as incorrect scoring or reporting adverse events clearly jeopardise the safety of human participants but also distort data in significant ways.

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93 FtPP, 28 January 2010 and 24 May 2010.

94 See: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(97\)11096-0/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/abstract) FtP 20 January 2010; See Dyer (n 27).

95 Ibid.

96 The *Journal of the Royal Society of Medicine* published a special issue on the CNEP Stoke saga in 2010.

The determinations mentioned that the onus was on the REC to prove the misconduct. The FtPP pointed to the tenuousness and weakness of evidence of serious professional misconduct and questioned in passing the independence of expert witness and honesty of lay witnesses. The FtPP justified the conduct of the doctors in light of the ‘context’ by explicitly mentioning that ‘ethical standards have changed in the last twenty years.’ In light of the intense media attention over the case,<sup>97</sup> the FtPP thought it was critical to show its impartiality by mentioning that the breach of research protocol for one baby could not be reasonably taken as evidence of ‘systemic failure’. It found the doctors not guilty of SPM.

I hope by now the casework has showed how ambiguous and even untenable the demarcation between research ethics and research integrity can be in light of the detailed facts populating research misconduct by medical doctors. The casework facts indeed reveal a high number of hybrid cases. But characterising these cases as hybrid obscures a problem with existing typologies coming from research misconduct studies. Whilst typologies can be analytically helpful, in the context of this study they often seem unsuitable as a grid to examine the actual facts of misconduct revealed by the dataset.

Breaches of the protection of research participants are often characterised as part of research ethics, but in some instances (if a participant is included in a trial against eligibility criteria, for example) a research ethics breach also impacts on the reliability of results and ultimately on the integrity of the research record, no less than narrowly-defined fabrication and falsification do. As we saw, in the examined cases, the protection of research participants and protection of the public against unreliable research sometimes co-existed and were examined together. Yet at other times the integrity of medical research was mentioned as an overarching general goal, echoing the importance, abundantly reiterated in GMC disciplinary cases, of maintaining public confidence in the medical profession.<sup>98</sup> In these cases, programmatic statements about the importance of research integrity for sustaining public confidence in science often eclipsed the more immediate and tangible issue of protecting individual participants against actual harm or risk of harm by researchers. Unlike what Bosk observed in a hospital setting, in scientific research, the ‘technical’ is no less significant than the ‘normative.’ Indeed, technical errors

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97 There had been reports about long-term brain damages allegedly caused by the trial.

98 Case (n 52).

and poor research practices can cause as much if not more public harm than normative errors, which rather signal failures to be a conscientious, prudent, professional individual.<sup>99</sup>

#### VIII. AUTHORSHIP AND HYBRID CASES

Rather than dealing exclusively with plagiarism -- the third prong of FFP – the casework deals with authorship issues more generally, including the appropriation not only of someone’s work but also of someone’s name without their consent.<sup>100</sup> We shall see that, when meddling with authorship, researchers can and do also interfere with data.

I located 17 cases related to appropriation/authorship. They include cases ranging from persistent plagiarism, misrepresentation of co-authors’ consent, no acknowledgement of sources, forging of co-authors’ signatures in copyright documents or funding applications;<sup>101</sup> applying for funding on behalf of colleagues without their knowledge,<sup>102</sup> mislabelling and use of a colleague’s images without their knowledge and permission;<sup>103</sup> misleading statement about one’s publications in one’s CV;<sup>104</sup> and in one case, a ‘series of dishonest actions’ including the construction of emails, citing an invented and fictitious author, and including the names of people as co-authors who are not co-authors.<sup>105</sup>

In the 1995 Pearce determination discussed above, the GMC addressed directly Chamberlain as the honorary author on the fraudulent *BJOG* articles. It mentioned the ‘rush to publication’ and maintained that despite ‘pressures upon researchers,’ their ‘total integrity is paramount’. In generic terms, it said that ‘the responsibility for published work rests on every participant – the main author, any co-authors, all others involved in the research, assessors, referees and the editorial board’.<sup>106</sup> More specifically targeting honorary authorship, it added: ‘Perhaps the most important of these is the active participation

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99 Bosk (n 43), 44.

100 MPTS, 19 February 2015.

101 PCC, 28 November 1997; FtPP, 2 March 2005; FtPP, 16 June 2006; FtPP, 30 November 2007.

102 FtPP, 20 June 2005.

103 FtPP, 1 February 2011.

104 FtPP, 29 May 2012; MPTS, 27 March 2013; MPTS 26 February 2015.

105 FtPP, 30 November 2007.

106 PCC, 7 June 1995.

of each named author in verifying the final manuscript. All individuals' names in a research paper must have made an intellectual contribution and been able to verify the raw data.'<sup>107</sup>

As it becomes clear in the age of research metrics, honorary or gift authorship meddles not only with authorship but with the integrity of the record, since a paper published by a reputable scientist inflates the credibility of the paper, its citation rankings and 'impact,' from research circles to GP consulting rooms. The FFP typology does not capture this with sufficient nuance.

The above cases thus provide ample illustration of the difference in registers between the abstract typologies of research misconduct coming from the scientific community and the complex and often disordered conduct of research projects as chronicled by a regulatory body. The next section explores further this detachment, and ponders the relevance of the GMC fitness to practice adjudication as a response to research misconduct.

#### IX. FITNESS TO PRACTICE: HOW FIT TO EXAMINE RESEARCH CONDUCTS?

By virtue of being increasingly tailor-made, the various forms of positive legality<sup>108</sup> that surround modern medical research are often increasingly disjointed from one another. This hampers their intelligibility to researchers. 'It's a mess', to use the words of a research integrity officer.<sup>109</sup> This mess is exacerbated by the fact that forms of misconduct are becoming increasingly creative and responsive to metrics game.<sup>110</sup> New misconduct like the impersonation of reviewers or manipulation of citation indexes, have so far remained unscrutinised by the GMC (or other institutions for that matter), whilst medical journal editors and publishers take the lead in addressing the increasingly creative ways researchers navigate and play the research game.<sup>111</sup>

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107 Ibid.

108 B De Sousa Santos, 'Law: A Map of Misreading: Towards a Postmodern Conception of Law' (1987) 14: 3 *Journal of Law and Society* 279–302, at p. 294. And see: J Braithwaite, 'Transnational Regulation of the Pharmaceutical Industry' 525 (1993) *The Annals of the American Academy of Political and Social Science*, SAGE 12–30; E Jackson, *Law and the Regulation of Medicines* (Hart, 2012)

109 Personal communication, AHRC Stakeholders workshop on research integrity, London, 27 September 2013.

110 M-A Jacob, 'Misconduct Hunting: research integrity via law, science and technology' in E Cloatre and M Pickersgill eds *Knowledge, Technology and Law* (Routledge 2014) 137–153; M Biagioli, 'New Misconduct and New Opportunities,' *Innovative Communication in Scholarship*, IFHA Project at University of California at Davis, date accessed 30 October 2015: [http://icis.ucdavis.edu/?page\\_id=265](http://icis.ucdavis.edu/?page_id=265)

111 See; Editorial, 'A numbers game,' 523 (July 2015) *Nature* 127–8.

Given the collective, complex and increasingly global form that research misconduct can take, is fitness to practice adjudication still relevant to assess it, then? It is true that the GMC disciplinary adjudication has not been sufficiently alert to the various ‘tailored legalities’<sup>112</sup> that populate research integrity literatures and infrastructures and to the institutional environments of research. The GMC’s analytical framing of research misconduct differs from that conveyed by the research community itself and by scholarship on research integrity, as illustrated above.

The rehearsed typology comprising of FFP, as well as the differences between shades of questionable practices (like that proposed by Fanelli) are not reflected in the GMC’s own understanding of research misconduct. In addition, in the scientific literature the issues of research integrity and misconduct have so far been mulled over mostly as a matter for prevention, education, advising, and training, but not as a matter for regulators. In light of suggestions by the Government that approaches to research integrity are ‘unsatisfactory,’<sup>113</sup> the GMC and now the MPTS is indeed one of very few key sites of regulatory oversight with ‘teeth’ when it comes to research misconduct.<sup>114</sup>

The GMC’s open engagement with the contextual facts, rather than the formal categorisations of misconduct, is to be welcome. We have seen in Wakefield for instance, that the GMC considered the non-disclosure of conflicts of interest as its own form of research misconduct.

Let us not forget that that the category of ‘research misconduct’ can be and is abused. Allegations are often found to be ill founded, and can be used as a tactic in research rivalries, to shut down research perceived as controversial, or to serve different interests.<sup>115</sup> As much as complainants and whistleblowers need protection when they raise issues of research misconduct in their institution or with their professional regulator, those suspected of research misconduct also need the assurances of the principles and processes of fundamental justice. The GMC has been criticised for its procedures,

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112 See De Sousa Santos (n 108).

113 HoC Science & Technology Committee *Report on Peer-review in science* (28 July 2011).

114 Ibid; J Barrett, ‘Conduct of an inquiry into alleged misconduct’, in F Wells and M Farthing eds, *Fraud and Misconduct in Biomedical Research* (4th edn., London, RSM Press, 2008) 267.

115 For example, in a famous 2009 case, representatives of the medical industry brought medical researcher Peter Göttsche before the Danish Committee on Scientific Dishonesty for research misconduct. Göttsche had made a study of ghost authorships in industry-sponsored trials. The industry would not hand him the records needed and so he had published a study based on what he had. The industry then accused him of fraud for making conclusions without proper evidence. The Committee eventually dismissed the claim, but this case reveals the complexity of grappling with the regulation and adjudication of research misconduct.

particularly in the aftermath of its handling of the North Staffordshire hospital saga.<sup>116</sup> However, its increasingly juridified approach, and its transfer of fitness to practice matters to the MPTS could be welcome safeguards in the context of a politicized area such as research misconduct. It is imperative that such an independent approach to research misconduct be sustained. Given how political and strategic the category of ‘research misconduct’ has become in certain milieus, the detachment of the GMC vis-à-vis scientific research culture highlighted above also carries true benefits.

However the GMC should be criticised for not being sufficiently alert to a vast array of dubious research conducts, and being seemingly oblivious to the risks associated with malpractice in research. The fact that practices such as not reporting adverse events or recruiting ineligible participants in a trial are being tolerated or responded to by a mere reprimand, is worrisome.

## X. CONCLUSIONS

Albeit not exhaustive as far as the incidence of medical research misconduct is concerned, this article has chronicled twenty-five years of adjudicatory decision-making in respect of research misconduct by a single regulatory body, working in relative isolation. A look at the application of the General Medical Council’s fitness to practise model to research conduct cases has allowed a better understanding of which context-specific elements of research misconduct have captured the attention of a professional regulator, and which have been overlooked or deemed irrelevant. This article has discussed the causes and implications of the flagrant absence from the casework of many forms of questionable research conduct. The nature of the casework also elicited shifting our attention from specific instances onto the overarching typology of research misconduct, and turning that grid inside out. This analytical shift showed that the typology might have missed the hybrid character and implications of many research conduct cases, and overlooked a connection between research integrity and research ethics that is more intimate, multifaceted, and consequential than we might think.

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116 The successive forms of adjudication (public inquiry, civil case and disciplinary cases) meant double jeopardy for the researchers. For a postmortem of the GMC’s treatment of the case, see the special issue of the *Journal of the Royal Society of Medicine*, and in particular: G Catto, ‘The Stoke CNEP Saga – a view from the General Medical Council’ (2010) *J R Soc Med.* 1; 103(8): 313–316.

Researching this casework elicited familiar and even cliché moments, when one realises that *plus ça change plus c'est la même chose*. Back in 1995 the GMC admonished doctors on the importance of making sure each author is genuinely an author. Twenty years later, journals and their associations (the Council of Science Editors and the International Committee of Medical Journal Editors for example) still struggle to streamline the process securing consent from authors. Disputes between co-authors break out regularly and are discussed in forums devoted to providing assistance to increasingly overwhelmed editors.

The above cases stress the need for an approach to regulatory responses to research misconduct that could examine together medical self-regulation and other types of possible legal and other responses to alleged misconduct in science. The advisory work of the international charity Committee on Publication Ethics (COPE), and the work of national bodies with a legal mandate to adjudicate and sanction research misconduct (such as in Denmark and Norway for instance) need to be further unpacked as distinct yet allied to the long tradition of self-regulation amongst professionals. Fitness to practice adjudication has to work on a knowledge base comprising of medical professional guidance, read in conjunction with institutional, local, and national higher education infrastructures (a key one being the Research Excellence Framework (REF)). The co-penetration of scientific norms and professional standards is already happening, but their interpretation, at times, needs to be more organic and more alert to real institutional contexts whilst remaining as independent as possible.

More empirical work on decision-makers' styles of reasoning is needed to capture the likely epistemological challenges that decision-makers face whilst utilising the terminology of research misconduct studies to decide on particular research misconduct allegations in concrete regulatory settings. Given the recent expansion of creative and responsive forms of misconduct – impersonation of reviewers, the mention of fake journals and conferences in CVs, and the gaming of metrics, to name a few of the examples discussed above -- it is clear that the large encompassing terminology of 'interference'<sup>117</sup> would be more apposite than the 'dishonesty' definition of research misconduct

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117 U.S. Department of Health and Human Services Part III: *Public Health Service Policies on Research Misconduct, Final Rule, Federal Register* 42 CFR Parts 50 and 93, 1995.

regarding research in the lab put forward by the GMC. Without minimising forms of misconduct having to do with data, one can see that even the policy language of ‘interference’ has been too narrowly interpreted as having to do with ‘interference with data,’ whereas novel forms of misconduct also engage with how scientists *display* their work in CVs, grant applications, impact and other metrics, as opposed to how they conduct their work in labs.

By spelling out the register and style with which the GMC speaks about research integrity, the above material also adds to current understandings of probity. In looking carefully at the cases, one can detect a doubling of the notion of probity: first the probity of individual doctors and second the probity of a regulatory framework that has been struggling to respond to attacks (in the media and from activist patients groups) over its legitimacy and efficiency. This means that in a perhaps unpredictable and surely unintended way, the GMC adds to the normative and descriptive definitions of research integrity suggested by Steneck, Fanelli and Haack by putting forward a performative understanding of research integrity. In other words, the casework refines our understanding of research integrity by making explicit not only what it *is*, but what it *does*. Indeed, research integrity as a category has done important work for the GMC. Research integrity has been deployed by the GMC to achieve certain regulatory aims, such as enhancing the reputation of the medical profession, but also to uphold its own reputation as a regulatory body.<sup>118</sup> The GMC consistently needs to maintain its authority through the assent or imagined assent of its publics – whom it speaks to: the High Court, the ‘lay public’, victims of misconduct, and ‘the profession.’ The GMC’s engagement with research integrity has contributed to its view about its own probity and transparency towards the public and in the face of increasing legal controls. Further, Fanelli’s and others’ well-intended programme to categorise and delimit the scope of research misconduct leave unattended the question of what political work such highly specific typologies do for scientists and their cultural autonomy. The powerful political dividends of mobilising the language and expertise of research integrity and misconduct have been understudied so far, and hopefully this article begins to address this gap.

Ten years ago the then president of the GMC Donald Irvine cited sociologist of the professions Eliot Freidson to urge the medical profession to become ‘enthused with a spirit of openness, driven by the

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118 See for instance: Case (n 52).

conviction the one's decision must be routinely open to inspection and evaluation, like the openness that pervades science and scholarship.'<sup>119</sup> The deliberations of the new MPTS can be an ideal laboratory for scholars to study how misconduct continues to be legally and culturally conceived. Publicly accessible, they should provide ample opportunities to assess whether the medical profession's regulator indeed adjudicates research misconduct by emulating the alleged openness and critical scrutiny of science whilst remaining distant from some of its politics.

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119 D Irvine, *The Doctor's Tale* (Radcliffe Medical Press, Oxford, 2003) at 206, citing E. Freidson, *Professionalism, Reborn: theory, prophecy and policy* (Cambridge, Polity Press, 1994).