Institution: University of Warwick

Unit of Assessment: B10 - Mathematical Sciences

Title of case study: Statistical Expert Witness work in Medical and Life Expectancy Litigations

Period when the underpinning research was undertaken: 2000 - 2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Jane Hutton	Professor	October 2000 - present

Period when the claimed impact occurred: 2014 - 2019

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact (indicative maximum 100 words)

Professor Hutton's research improves legal professionals' understanding of statistical evidence and enables resolution of medical litigation and life expectancy cases. The beneficiaries of this international economic and societal impact include legal professionals, pharmaceutical and medical device companies and patients. About £150m of awards for 200 personal injury cases was due to Hutton's reports.
Statistical evidence prepared for Gee & Others v DePuy International Limited [2018] was key to the outcome; the ruling has been cited as a definition of defect under the Consumer Protection Act (CPA) 1987. Professor Hutton's reports contributed significantly to the $11.7m settlement between Allergy Therapeutic PLC and Inflamax Research.

2. Underpinning research (indicative maximum 500 words)

Hutton's `Expert evidence: civil law, epidemiology and data quality' [3.1] summarises the insights on data and specific questions which inform her work in statistics and the law. Hutton's research has substantial impact on legal processes and decisions. She collaborates with lawyers to provide resources and training as well as on particular cases. Two important issues are the phrasing of questions, and confirming the desired level of specificity for a particular case. Changing the phrasing of a question can alter the assumptions made, and the probabilities or estimates provided. Given a well-posed question, statisticians can find what data are available, directly or through research publications. [3.1].

Easily obtained large data sets are often biased due to selection of people, and affected by missing data, limited measurement accuracy and coding errors. Hutton's research considered methods for assessing whether missing data can be assumed to have little effect on conclusions, or whether adjustments can be made, or whether the robustness of conclusions must be evaluated. She worked with a PhD student and her colleague Professor Smith to use a recent approach to graphical models for asymmetric data, chain event graphs, as a technique to explore the nature of missing data [3.2]. Bayesian methods allow expert information to be included in the assessment, and the resultant graphs are effective in communication with non-specialists. Studies which follow cohorts of people typically lose touch with some participants. With another PhD student, she developed methods to model changes over time, with repeated attempts to contact non-participants, and to assess robustness of conclusions [3.3].

Hutton's work in statistics and ethics has shown that requiring informed consent can lead to particular sub-populations being excluded from clinical research. Cultural differences with regard to privacy mean that it can be critical to use data from different countries to assess the effect of such selection biases [3.4]. Inadequate diagnostic tests and resulting subsequent procedures can result in unnecessary treatments [3.4]. This problem is particularly serious with large scale

screening of people, such as that which followed media reports of adverse events associated with metal-on-metal total hip replacements [3.4]. Two main issues arose: whether rates of revision estimated from medical registers were unbiased and accurate; and the extent to which revision surgery decisions relied on weak diagnostic test based on blood metal levels. It was essential to observe that revision rates reported by Nordic registers differ from those of England and Wales.

Hutton's substantive publications on survival of people with cerebral palsy continue to be cited by other experts in reports across a variety of jurisdictions [3.5]. The estimates of life expectancy which she provides include the consideration of data quality. In addition, it is also necessary to consider different approaches to combining published results, with missing data within studies and different covariates reported across studies. There is no standard approach to providing estimates of mortality, either in medical journals, or in expert witness reports, so Hutton has surveyed approaches and outlined future research [3.6].

3. References to the research (indicative maximum of six references)

[3.1] Hutton, J. L. (2018) *Expert evidence: civil law, epidemiology and data quality*. Law, Probability and Risk, 17 (2). pp. 101-110. doi: 10.1093/lpr/mgy004

[3.2] Barclay, L. M., **Hutton, J. L.** and **Smith, J. Q.** (2014) *Chain event graphs for informed missingness*. Bayesian Analysis, 9 (1). pp. 53-76. doi: 10.1214/13-BA843

[3.3] Akacha, M. and **Hutton, J. L.** (2011) *Modelling the rate of change in a longitudinal study with missing data, adjusting for contact attempts*. Statistic in Medicine, 30 (10). pp. 1072-1089. doi: 10.1002/sim.4165

[3.4] Hutton, J. L. (2017) *Medical Ethics and Statistics*. In: Wiley StatsRef: Statistics Reference Online. London: John Wiley & Sons, pp. 1-15. ISBN 9781118445112

[3.5] Hemming, K., **Hutton, J. L.** , Colver, A. and Platt, MJ. *Regional variation in survival of people with cerebral palsy in the United Kingdom*. Pediatrics, 116:1383–1390, 2005.

[3.6] Hutton, J. L. (2020) *Forensic statistics: How to estimate life expectancy after injury*. In A Pollice, N Salvati, and FS Spagnolo, editors, Book of short papers - SIS 2020, pages 564–569. Pearson, www.pearson.com, 2020. ISBN 9788891910776.

4. Details of the impact (indicative maximum 750 words)

Hutton's research has international economic and social impact by improving lawyers' use of statistics and by underpinning expert witness reports, benefiting plaintiffs, defendants, companies and lawyers. Three examples of Hutton's impact in litigation are highlighted, after a note on dissemination.

Hutton is the current Chair of the Royal Statistical Society (RSS) Statistics and the Law section. As Chair, she responded to a House of Lords Inquiry into Forensic Science and Forensic Science Regulatory concerns. She co-authored best practice guides for advocates and judges and gave 6 professional development seminars on statistical issues for barristers and judges since 2016 for, inter alia, American Association of Justice, Welsh Judicial Society and Inns of Court College of Advocates [5.1].

1. Gee & Others v DePuy International Limited [2018]

Statistical evidence prepared for the metal-on-metal hip trial Gee & Others v DePuy International Limited [2018] was key to the outcome that DePuy was not liable; the ruling is a prime example of what defines a defect under the Consumer Protection Act (CPA) 1987, and has since been cited.

This case was brought under the Consumer Protection Act (CPA – 1987). Plaintiffs claimed that DePuy Pinnacle MoM hip prostheses were defective, tending to cause adverse reaction to metal debris (ARMD), hence further surgery. Hutton's review of the research and registry information focused on whether the statistics were robust, and was submitted as evidence for DePuy's defence. Hutton's key contributions [3.4] were assessing the potential effects of registry completeness and missing confounding factors, and how the low threshold for diagnosing ARMD might inflate failure rates.

Finding DePuy not liable, Justice Andrews stated "one cannot possibly conclude" there was a "materially greater risk of failure than the comparator" [5.2]. Any pay-out would have been a significant proportion of DePuy's equity (£130m, DePuy International Limited 2018 Annual report). In contrast, USA, plaintiffs with Pinnacle hip plants were awarded over $1bn [5.3].

Hutton's evidence directly informed the process for the legal team and interacted effectively with other experts' work. Her joint report provided a focused basis for cross-examination. She provided live responses to the Claimants' experts' evidence under cross-examination [5.4].

The impact of Gee has already been extensive. The ruling is now an authoritative example of how medical defects are considered under CPA, "starkly different" from previous rulings [5.5]. The High Court and other Senior courts have endorsed this precedent on the standard of evidence required to prove causality for medical devices. [5.5].

Gee has also been cited as an exemplar product liability case in the textbooks and practitioner guides [5.6].

2. Allergy Therapeutics PLC (ATL) v Inflamax Research (IR) Settlement

Hutton's expert reports were "invaluable to us and no doubt a factor in this settlement" between ATL and IR, worth $11.7m to ATL [5.8]).

Cooley LLP, acting for ATL, instructed Hutton in a claim against IR regarding the quality of a trial of hayfever treatments, which required exposure of participants to pollen concentration within a target range. However, pollen measurements were variable and often out of range. Hutton evaluated the opposing expert evidence, which claimed that failure to maintain correct pollen concentration did not affect outcomes. Drawing on her methodological research on the potential influence of missing data plus how averages of measurements on a person over time can hide important effects, Hutton prepared a joint report with the IR expert, and explained to ATL's barristers why the trial results were not reliable.

The settlement was key for ATL achieving profitability in 2019: "The strong operating performance and the settlement of the legal case with Inflamax led to a net profit of £3.5m" [5.7].

3. Informing international life expectancy settlements

Hutton's reports made a difference of about £150m in 200 personal injury cases, out of total awards of £500m - £700m. Awards cover ongoing care costs for those with debilitating permanent conditions, impacting directly on quality of life.

Canada: "These cases and settlements are life changing for the clients, and an accurate life expectancy opinion is crucial to ensure that the child has enough funding to care for his or her lifelong needs. We have requested Hutton as an expert witness on 3 occasions due to her well-known expertise on life expectancy, including the nuances of the statistics in the area. She is very knowledgeable in understanding the debate over the various databases on life expectancy for children with cerebral palsy and talented in writing reports in this regard."[5.9]

UK: “We have requested Hutton as an expert witness on six occasions due to the impeccable quality of her statistical evidence and reputation as a leading life expectancy expert witness.” [5.9].

Australia “We have requested Hutton as an expert witness on at least 15 occasions due to the deserved reputation as leading legal consultant for life expectancy in catastrophic injury cases. Overall in every instance that Slater & Gordon has worked with Hutton, she has provided a detailed analysis of great quality.”[5.9]

The range of injuries affecting survival include traumatic and acquired brain injuries (51 reports), spinal cord injuries (19) and cerebral palsy (70). Cases come from the UK (141 reports), Australia (34), Canada (7) and Eire (18). The few UK neurological injury life expectancy witnesses typically cite Hutton's research, as do the California-based Life Expectancy Project experts.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[5.1] References for legal practioner guides and RSS liaison, and list of professional development seminars. (Dissemination5.1.docx)
[5.2] Justice Andrews’ Judgement of *Gee & Others v DePuy International Limited* [2018]
[5.3] *Orthopedics This Week* article detailing $1bn compensation payment
[5.4] Professor Hutton’s contributions, and statistical arguments relevant to *Gee v DePuy*: Alexander AntelmeQC, Crown Office Chambers testimonial letter, (AAntelme-ProfessorJaneHutton.pdf)
and the Crown Office Chambers case summary and analysis, highlighting the role of the statistical evidence (https://www.crownofficechambers.com/2018/05/21/pinnacle-metal-on-metal-hip-group-litigation/)
[5.5] An example of legal citations of *Gee v DePuy*:
Opinion of Lord Tyre on *Hastings v Finsbury Orthopaedics Ltd and Stryker UK Ltd* [2019] is provided. (*Bailey & Ors v GlaxoSmithKline (UK) Ltd* [2019] Court of Appeal ruling is another example).
[5.6] An example of pedagogical and practitioner impact of *Gee v* DePuy :
The International Comparative Legal Guide to: Product Liability 2019 (Global Legal Group) is provided. (Other examples: *A short introduction to the Consumer Protection Act* (Jan 2020, T2G); *Tort Law* (2019, 6th ed., Horsey and Rackley, Oxford University Press) online description)
[5.7] Exerts of Allergy Therapeutics PLC (ATL)’s 2019 annual report
[5.8] Sasha Grimm, Partner of Cooley (UK) LLP, testimonial letter (ATL-GrimmS.pdf)
[5.9] Three letters: Canada, UK, Australia: life expectancy expert witness impact.
(SlaterGordonAustraliaProfJLHutton2020.pdf, SlaterGordonProfJLHutton2020.pdf, WeirBowdenProfJLHutton2020.pdf)
[5.10] Excerpts of other expert witnesses’ reports, citing Professor Hutton’s reports or research (Redacted5million.pdf, RedactedInventoryProductionsforDefenders.pdf, RedactedUCSF.pdf)