

Data Capture for the Public Good – a matter of trust, or of science and public understanding?

Sheila M. Bird, MRC Biostatistics Unit, CAMBRIDGE CB2 0SR

Among statisticians generally, there is considerable experience in issues of data definition and collection [1, 2, 3, 4]. This experience deals in particular with the tensions between data completeness and accuracy, and the preservation of privacy – to which I shall return.

Importantly, fellows of the Royal Statistical Society (RSS) abide by a professional code of conduct which, inter alia, abhors analysis of data obtained under duress or punitively. This applied to UK's random mandatory drugs testing (rMDT) of prisoners until the European Court of Human Rights outlawed punishment for cannabis or opiate positivity by lost days of remission. Thanks to parliamentary questions, rMDT results have since been used to monitor the roll-out of Integrated Drug Treatment System in English prisons (<http://www.straightstatistics.org/article/what-random-mandatory-drug-testing-reveals-about-methadone-prescribing-prisoners>).

The UK Statistics Authority and UK's Statistics Act are long-gestation fruits of '*Counting with Confidence*', the report of RSS's Working Party on Official Statistics in 1991 [2]. The Statistics Authority's code of practice for official statisticians is entitled: *Official statistics serving the public good* [5]. Even so, in June 2011, the National Statistician recommended that, despite her trust in the integrity of Home Office statisticians, the conduct and analysis of the British Crime Survey (BCS) should come under her purview to allay mistrust in crime statistics [6]. Her fire might have been better directed at politicians who knowingly – for political ends – seed confusion between police-reported crime (which includes homicide) and BCS's victim-reported crimes which include the crimes that respondents in representatively-sampled households may have failed to report to police.

Knowing misuse of official statistics by parliamentarians [7] should, I suggest, be recognised as a 'statistical felony', for which the member is obliged to apologise to the House. Those who hold national databases – whether BCS, the NHS Organ Donor Register [8], the Scottish Drug Misuse Database or the National DNA Database (see <http://www.straightstatistics.org/article/home-affairs-committee-case-national-dna-database>) – have a professional responsibility for ensuring data quality of existing data-fields, and that all necessary data-items have been collected to permit regular, insightful, substantive analyses of the data held. Substantive analyses include, but are not limited to, policy-relevant analysis [9]. Those analyses which inform public policy should, with few exceptions, be valued as a public enterprise, and parliamentarians, public and press should have access to them when policy is being debated, not in retrospect [9], or even on time-scales determined by peer-reviewers and journal editors. How else can the public have trust that there has been timely, as well as adequate, scientific scrutiny of the evidence on which policy relies?

Official statisticians are responsible for a nation's statistical checks and balances. The post of Registrar General has an honourable history and yet, in England (unlike Scotland), there is - in the 21st century - no requirement that the fact of death be registered within 8 days of death having been ascertained. This has disastrous consequences for the monitoring of epidemics – whether H1N1, as Sir Liam Donaldson discovered (see RSS evidence to Science and Technology Select Committee's Inquiry into Scientific Advice in Emergencies), or drugs-related deaths as I have highlighted in the context of cocaine versus mephedrone [10] – or for the timely evaluation of interventions (randomized or by political fiat) to reduce opiate-related deaths. What matters epidemiologically is the date of death, not the date of death-registration, which may be delayed

by several months for coroner-referred deaths. Moreover, unless the fact of death is registered within 8 days of ascertainment, we cannot even properly estimate the life-table for 'delay to verdict' in coroners' cases [11].

England's Registrar General need not be a professional statistician, but properly counting deaths is a fundamental public duty which is not being adequately discharged. Is the public aware? Surely, the public expects professional responsibilities to be met? Honoured predecessors must be turning in their graves!

The RSS's Working Party on Performance Monitoring in the Public Services sought to redress another major misuse of statistics by UK plc by reporting on: *'Performance Indicators: Good, Bad and Ugly'* [3]. The recent read paper by Spiegelhalter et al. [12] alludes to the great effort that was required within the Healthcare Commission for a statistical - rather than arithmetical - notion of 'target compliance' to be accepted. Even Tony Blair, eventually (so I'm told), got to appreciate that if performance was within 'tramlines', then he should not intervene officiously!

The appointment of professional statisticians by UK's Medicines and Healthcare products Regulatory Authority (MHRA) in the 1990s was a key recommendation in 1991 of another RSS Working Party on *'Statistics and Statisticians in Drug Regulation in the United Kingdom'* [13]. Yet, MHRA's safeguards for approval of first-in-man studies were insufficient in 2006 to prevent all six participants who had received the novel monoclonal antibody TGN1412 from being admitted to intensive care because they rapidly developed cytokine release storm, an anticipated potential adverse event. Design faults, see 'Statistical Issues in First-in-Man Studies' [4], included the short dosing-interval between participants, barely 10 minutes. Yet, dosing-interval was not a feature that MHRA (or its equivalent: European Medicines Authority) was routinely aware of. Worse, the Academy of Medical Sciences had given due warning in the previous year [14].

Statistical science matters widely outside of government too – in industry, in courts of law, in the monitoring of epidemics, in the cost-effectiveness of health technologies [15], and in the statistical modelling of climate change data. Interventions by RSS recent-past-presidents Smith ('Mad cows and ecstasy' [16]), Green (Sally Clark case, see <http://www.rss.org.uk/uploadedfiles/documentlibrary/745.pdf>; see also the Statement of Professor Phillip Dawid on Sally Clark Appeal) and Hand on 'climategate' serve as illustrations. The RSS had to appeal to England's Chief Medical Officer (CMO), Professor Sir Liam Donaldson, for better public monitoring of the H1N1 pandemic when other counsel had been ignored – even before the envisaged enfolding of the Health Protection Agency into Public Health England [17]. Sir Liam took action. Soon, there was weekly reporting of England's numbers hospitalised for suspect H1N1 and improved reporting of denominators, and later the CMO's Statistical Legacy Group was convened. Moreover, the Science and Technology Select Committee's Inquiry into Scientific Advice in Emergencies included as one of its recommendations that there should be a statistician-member of Scientific Advisory Group in Emergencies [18]. In 2011, the RSS Working Group on Statistics and the Law has released the first of a 4-part guide, see RSS for Part 1. Fundamentals of Probability and Statistical Evidence in Criminal Proceedings (by Aitken C, Roberts P, Jackson G). And the RSS President's input was crucial on the committee convened by the Government's Chief Scientist to investigate the modelling of climate change data at the University of East Anglia [19].

Because statisticians have admired (and learned from) journalists' ability to write well and understandably about complex matters and wanted to encourage them to write well on statistical issues, the RSS in 2006 introduced both annual awards for statistical excellence in journalism and

twice yearly statistical seminars for journalists. The seminars home-in on four or five questions that journalists can most usefully ask to probe what is going on in: epidemics, observational studies, surveys, formal experiments, risk assessment, and various types of statistical adjustment. Both initiatives seem to have paid dividends for the RSS as journalists not only engage more readily with statisticians but recognise that they and we are engaged similarly in a type of detective work, whereby misuse of statistics sometimes cloaks a more trenchant story than first meets the eye.

Straight Statistics, the brain-child of Lord David Lipsey and directed by Nigel Hawkes, formerly Health Editor at the Times, was established with funding from the Nuffield Foundation and embraced by the RSS. A ginger-group of statisticians, journalists and parliamentarians, Straight Statistics has a web-site which praises good statistical exposes by journalists but takes to task those who use statistics so as to traduce the evidence; or distort the real story. Straight Statistics aimed to restore public confidence in statistics and for their better use by parliamentarians and in the press. The word cloud for Straight Statistics displays habitual themes, among them H1N1 influenza, military matters, crime statistics and the National DNA Database. Thanks to Straight Statistics, there is now an All Party Parliamentary Group on Statistics. The UK's parliamentary election in May 2010 saw the emergence of media fact-checkers (such as the Today programme's partnership with Tim Harford from Radio 4's More or Less) to such an extent that politicians seemed to shy away from statistical arguments for fear of falling foul of them! Indeed, statisticians in some government departments now offer a service of pre-checking Ministerial 'facts' so that their Ministers do not air 'statistical felonies', which is excellent news. Imitation is the sincerest form of flattery . . . The autumn may herald a merger of Straight Statistics and Full Facts.

Meanwhile, in 2010, RSS launched 'Getstats', its own campaign to promote public understanding of statistics which, in 2011, recruited former Guardian journalist, David Walker, as its director. Chief among those whom the RSS should inspire with the need to grasp statistical thinking are parliamentarians & Select Committees. Co-working between statisticians and parliamentarians may be a very good way to do this. For example, in 2010, statisticians in the House of Commons Library specifically set out to acquaint new members with the resources that they could bring to bear in assisting the work of MPs and their parliamentary researchers.

Statistics in the News matter, because it matters for statisticians to be seen to serve the public good. Prime examples include: early exposure in the Times of the TGN1412 design-faults (for more than just a single participant to have ended up in intensive care); the 'egregious' knife-crime press-release made so infamous by Sir Michael Scholar that Ministerial apologies to the House followed and also remedial edicts from the Cabinet Secretary, Sir Gus O'Donnell; revelation by Straight Statistics that only one in 20 initial callers to National Pandemic Flu Service in July 2009 for Tamiflu was reckoned by Health Protection Agency to be H1N1-infected; the RSS's inveighing – in the person of vice-president Jill Leyland - against the planned change from RPI to CPI as the measure by which pensions are inflation-adjusted [20]; or obfuscation about helicopter cover per 1,000 UK troops in Afghanistan versus corresponding provision for US or Canadian troops [21]. Spiegelhalter (see <http://understandinguncertainty.org/micromorts>) has popularised the 'micromort' (see <http://plus.maths.org/content/os/issue55/features/risk/index>) as a measure for comparison of attributable risks, and castigates epidemiological researchers who promote relative risks without also explaining risk-attribution.

Press-releases [22], policy reviews, briefing papers, and reputable peer-review journals [23, 24], quite apart from journalists, may still fall foul of Seven Deadly Statistical Sins.

My seven include: percentages without denominator (or standard error), surveys without participation-rate, before/after comparisons which laud percentage-change without specifying both the before and after levels, post-hoc selectivity, and ‘pilot’ studies with no heed to experimental design [22]. Almost always, when these ‘sins’ are perpetrated in submissions to peer-review journals, there is fire behind the smoke; and referees would be wise to question why basic reporting standards, such as like-with-like comparison, have been obscured by regression-adjustments – for example, to conceal poorly ascertained data which belie like-with-like comparison [23, 24]! Statisticians should use their analytical skills to give insights, not to cloak data-deficiencies. But editors should also be aware that limitations on word-count carry risks for investigators who have to pare their descriptions of methods or results to such an extent that crucial detail may be lost. In the extreme, authors may have to decline publication rather than prejudice their research integrity.

Evidence-synthesis is a tricky business, especially when the evidence bears only indirectly on the comparison that analysts wish to make: A versus B, say, when the available evidence is, for example, two suites of randomized controlled trials (RCTs), conducted in different regions, which compare (A versus control treatment, C1) and (B versus control treatment, C2). To make analytical progress, common-sense tells us that *either* strong assumptions have to be made about the comparability of control treatments C1 and C2, and about the quality of - and patient eligibility for - the RCTs conducted in different regions *or* decision-making has to be delayed until specifically-designed RCTs are commissioned, conducted and analysed *or* access has been granted to individual patient data from the two suites of RCTs. Subject-matter knowledge and judgement (including statistical), not just explicit assumptions in statistical, mathematical or health-economical models [25], count in the final appraisal. Perhaps for this reason, there have been only two occasions in nearly 12 years in which a NICE Appraisal Committee interposed special studies to inform their decision-making on the cost-effectiveness of drug treatments for: a) multiple sclerosis and b) Alzheimers disease.

Disciplines differ, studies differ; funding and time for data acquisition differ. And so does the gamut of questions that any given research study was designed to answer. Principal investigators normally expect to complete, and to publish, their primary analyses before disseminating data more widely – as in the recent studies of bovine tuberculosis (subject to farmer confidentiality), see[1].

Rights have complementary duties. The notions of proportionality commensurate with public good and of privacy-rights balanced by citizens’ responsibilities to contribute to knowledge are equally important across all fields. For example, should there be more emphasis on an implied duty to take part in *scientifically and ethically approved* clinical trials, cohort studies, and research-oriented social science surveys; and for principal investigators to set out a time-scale for disseminating data more widely or a process by which others may make applications for access?

Recent controversies (such as personal-data disclosures by HM Revenue & Customs [26], and under-analysis of NHS Organ Donor Register [8] and National DNA Database [9, 27]) have undermined public trust in accredited data capture and their competent management; and put in jeopardy public perceptions about the benefits of research and professional perceptions about competent data-management and analysis. The balance should be redressed by recalling the sorts of substantive discovery that have been made from data capture for public good. For national databases particularly, the RSS made detailed observations to the Royal Society (for its inquiry into Science as a Public Enterprise) about data quality and the regularity of analyses.

Broadly speaking, the Royal Statistical Society saw merit in accredited data capture, with analysis, for the public good; and in transparent, *approved* record-linkages either across studies or between databases to create new study-potential. The ESRC gave an early lead. Its Research Data Policy, which required all research grant award holders to offer data collected during the course of their research for preservation and sharing, has recently been updated [28].

Data-sharing raises pertinent questions [1] about ownership, consent for data-sharing, scientific purpose and methods, and permissions for data release: when, why, to whom, collaboratively or competitively, and under what safeguards. There are technical issues to be resolved, particularly in respect of record-linkage, as set out in RSS's 15 **Points of Note** to the Royal Society. Scientific standards need to be met by those who create new study-potential by data-sharing. The RSS also cautioned that those who collected data may have considerable 'tacit knowledge' that may not have been fully documented.

The Royal Statistical Society made **three recommendations** and endorsed the *Rawlins principles*. The RSS recommendations were:

- a) Standards of data management need to be sufficiently high that research data **can be** shared for the public good – such as to create new discovery-potential;
- b) For transparency, national databases should have a publicly-available protocol which describes the data held, their regular analysis, and any approved record-linkages; and
- c) Better public understanding is needed about databases, their linkage, and value-added analyses. The Royal Statistical Society's Getstats campaign could contribute to this goal.

Rawlins 1: Safeguard the well-being of research participants.

Rawlins 2: Facilitate high-quality research to the public benefit.

Rawlins 3: Be proportionate, efficient and co-ordinated.

Rawlins 4: Maintain and build confidence in the conduct and value of research through independence, transparency, accountability and consistency.

The RSS also recognised that substantial progress had been made by others in three key reports [29, 30, 31]. The *Data Sharing Review* in 2008 [29] addressed **why** is it appropriate to share personal data for a particular purpose (answer – because proportionate) and **how** (which data are to be shared, and by what means). In *Sharing research data to improve public health* [32], funders of health research endorsed the **how**: entrench standards of data management so that research data can be re-used effectively; professional recognition for data-management; and due acknowledgement by secondary analysts to data-generators.

However, in 2009, Anderson et al. [30] had called into question the legality, effectiveness and cost of the *Database State*. The UK Government has built, or extended, central databases that hold information from health and education to welfare, law-enforcement and tax with the intention to make public services better or cheaper; but has been challenged by controversies over effectiveness (NHS Organ Donor Register), privacy (Revenue and Customs), legality (National DNA Database) and cost (NHS Detailed Care Record). Many question the consequences of giving increasing numbers of civil servants, and others, daily access to our personal information.

In spring 2010, the UK Government invited the Academy of Medical Sciences to review the regulation and governance of health research involving human participants, their tissue or their data. In January 2011, the Academy's working party proposed: *A new pathway for the regulation and governance of health research* [31] to resolve the delays, complexity and inconsistency across the regulation pathway; to address a lack of proportionality in regulating clinical trials, and

inappropriate constraints on access to patient data; and to bring about a cultural change in healthcare to promote, and value fully, the benefits of health research.

The dual notions of proportionality commensurate with public good and privacy-rights balanced by citizens' responsibilities to contribute to knowledge are equally important outside of healthcare. **But, medical data are different.** In particular, biological samples for diagnostic and other testing are obtained by doctors under a strong duty of confidentiality, and for declared purposes. The duty of confidentiality is crucial because test results **may reveal information hitherto unknown, even to the patient**, and which the patient cannot rescind without recourse to falsification of, or deletion from, their medical record. Neither action is in the interest of either the patient or epidemiology.

Controversies in the 21st century have undermined public trust in accredited data capture [8 9 19 20 23 26] and put in jeopardy public and professional perceptions. We need to redress the balance by recalling the sorts of important discovery made from data capture for public good. Each of us will have a list of these.

References:

1. Keiding N. (with Commentary by Breslow NE; Cox DR and Donnelly C; Deangelis CD and Fontanarosa PB; Donoho DL; Goodman SN; Groves T; Peng RD). Reproducible research and the substantive content (with Commentaries). *Biostatistics* 2010; 11(3): 376 – 396.
2. Official Statistics: Counting with Confidence. Report of a Working Party on Official Statistics in the UK (Chair: Professor Peter G Moore). *Journal of the Royal Statistical Society Series A* 1991; 154: 23-44.
3. Royal Statistical Society Working Party on Performance Monitoring in the Public Services (chair: Professor Sheila M. Bird). Performance indicators: good, bad, and ugly. *Journal of the Royal Statistical Society Series A* 2005; 168(1): 1 – 27.
4. Royal Statistical Society Working Party (chair: Professor Stephen Senn). Statistical issues in first-in-man studies. *Journal of the Royal Statistical Society Series A (Statistics in Society)* 2007; 170: 517 – 579.
5. UK Statistics Authority. *Official statistics serving the public good*. London: January 2009.
6. Government Statistical Service. *National Statistician's Review of Crime Statistics: England and Wales*. London: June 2011.
7. Blastland M, Dilnot A. Comparison – Mind the Gap. In: *The Tiger That Isn't. Seeing Through a World of Numbers*. Profile Books, London: 2007; 142 – 145.
8. Duff G. *Review of the Organ Donor Register by Professor Sir Gordon Duff*. DH, London: 19 Oct. 2010. (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120563).
9. Hawkes N. Home office keeps the lid on DNA-retention analysis. *Straight Statistics* 2011; 12 July. (see <http://www.straightstatistics.org/article/home-office-keeps-lid-dna-retention-analysis>).
10. Bird S. Banned drug may have saved lives, not cost them. *Straight Statistics* 2010; 22 November. (see <http://www.straightstatistics.org/article/banned-drug-may-have-saved-lives-not-cost-them>).
11. Bird S, Mercer P. Too long a wait for Afghanistan inquests. *Straight Statistics* 2009; 19 August. (see <http://www.straightstatistics.org/article/too-long-wait-afghanistan-inquests>).

12. Spiegelhalter DJ, Sherlaw-Johnson C, Bardsley M, Blunt I, Wood C, Grigg O. Statistical methods for healthcare regulation: rating, screening and surveillance (with Discussion). *Journal of the Royal Statistical Society Series A (Statistics in Society)* 2011; to appear.
13. Royal Statistical Society Working Party (chair: Professor Stuart Pocock) Statistics and Statisticians in Drug Regulation in the United Kingdom. *Journal of the Royal Statistical Society Series A* 1991; 154: 413-419.
14. Report of Academy of Medical Sciences FORUM with Industry (chair: Dr. Geoffrey Schild). *Safer Medicines*. The Academy of Medical Sciences, London: November 2005.
15. Garner S, Littlejohns P. Do NICE's recommendations for disinvestment add up? *British Medical Journal* 2011; 343: 349 - 351.
16. Smith AFM. Mad cows and ecstasy: chance and choice in an evidence-based society (presidential address). *Journal of the Royal Statistical Society Series A* 1996; 159: 3637 - 383.
17. McKee M, Hurst L, Aldridge RW, Rosalind R, Mindell JS, Wolfe I, Holland W. Public health in England: an option for the way forward? *Lancet* 2011; 378: 536 - 539.
18. Science and Technology Select Committee (chair: Andrew Miller MP). *Scientific Advice and Evidence in Emergencies*. House of Commons, March 2011: Recommendations. (see <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/110302-scientific-evidence-report-published/>).
19. Gray L. 'Climategate' scientists criticised for not using best statistical tools. *Telegraph* 2010: 14 April (see <http://www.telegraph.co.uk/earth/environment/climatechange/7589715/Climategate-scientists-criticised-for-not-using-best-statistical-tools.html> and <http://www.telegraph.co.uk/earth/environment/climatechange/7589897/Hockey-stick-graph-was-exaggerated.html>).
20. Leyland J. RPI versus CPI – The Definitive Account. *Significance Website* 2011 (see <http://www.significancemagazine.org/details/webexclusive/1314363/RPI-versus-CPI---The-Definitive-Account.html>).
21. Bird S. At war with statistics. *Straight Statistics* 2009; 16 July. (see <http://www.straightstatistics.org/article/war-statistics>).
22. Surveys, Design and Statistics Subcommittee. Statistical critique of 203 Home office press releases from February to September 2008+2009. Home Office, London: March 2010 (see <http://www.homeoffice.gov.uk/publications/about-us/hosac/sdssc/SDSSC-press-releases?view=Binary>).
23. Bird SM. Like-with-like comparisons? (Letter to Editor) *Lancet* 2010; 376: 684.
24. Bird SM. Febrile convulsions after seasonal influenza immunisation in UK (Letter to Editor). *Lancet* 2011; 378: 399 – 400.
25. Garnett GP, Cousens S, Hallett TB, Steketee R, Walker N. Mathematical models in evaluation of health programmes. *Lancet* 2011; 378: 515 – 525.
26. Bird SM. Real root of a data disaster. *Sunday Herald* 2007; 2 December: 30.
27. National Police Improvement Agency. *National DNA Database Annual Report 2007-09*. National Police Improvement Agency, London: 2009.

28. ESRC. ESRC research data policy changes; are you (and your data) prepared?
<http://www.esds.ac.uk/news/newsdetail.asp?id=2884>.
29. Thomas R, Walport M. *Data Sharing Review*. Information Commissioner's Office, London: July 2008. (ISBN 978-1-84099-204-5).
30. Anderson R, Brown I, Dowty T, Inglesant P, Heath W, Sasse A. *Database State*. Joseph Rowntree Reform Trust, York: March 2009. (ISBN 978-0-9548902-4-7).
31. Working Party of the Academy of Medical Sciences (chair: Professor Sir Michael Rawlins). *A new pathway for the regulation and governance of health research*. The Academy of Medical Sciences, London: January 2011. (ISBN No: 978 -1- 903401-31-6).
32. Walport M, Brest P. *Sharing research data to improve public health*. *Lancet* 2011; 377: 537 - 539. Published online January 7, 2011 as DOI:10.1016/S0140-6736(10)62234-9.
33. Press briefing: 2011 Census and Lockheed Martin UK
[.https://2011mc.census.gov.uk/index.php?module=documents&action=view&id=669](https://2011mc.census.gov.uk/index.php?module=documents&action=view&id=669). See also
<http://www.guardian.co.uk/uk/2011/feb/19/census-boycott-lockheed-martin>.