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The professionalization of the 'shoe clerk'

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1. Introduction

'One view of the shoe clerk's job is to please the customer well enough to earn his commission' (Bross, 1974).

It is a singular honour to be elected President of the Royal Statistical Society (RSS) and I am grateful to the Society for providing me with the opportunity to represent the discipline in this way.

Like no doubt many of my predecessors, I spent some time during my Presidency reading, in some cases for the first time, past Presidential addresses to the RSS searching for inspiration and guidance. Anyone doing this will be struck by the diversity of their style and content, but I hope that they would agree with me that underpinning them all is a single fundamental thread: a passion for the discipline.

Many of the addresses have tackled issues that are associated with widening the influence of statistics—essentially through outreach. One aspect of this laudable objective that is not always considered is the statisticians themselves. The discipline of statistics itself cannot influence, cannot persuade, cannot interact, cannot design, cannot analyse and cannot interpret. Statisticians can and do.

In his Presidential address Peter Armitage (1983) pointed to the many distinguished statisticians who had served as President before him and like him had defined their divergence from the unity of statistics by being active primarily in medical statistics. Although much of my professional activities over 30 years employed in the pharmaceutical industry are covered by medical statistics, I do not regard myself primarily as a medical statistician. I am a pharmaceutical statistician and many of the issues that are concerned with the development of the profession of statistics I see through eyes coloured by working in an environment that is governed by regulations.

In my address I want to delve into the professionalization of the pharmaceutical statistician against two backdrops. The first is the regulated world of drug development that I have referred to already and the second is the backdrop of the 20th century's professionalization project that was typified by Wilensky's (1964) seminal paper on the 'professionalization of everyone'—hence the 'shoe clerk' of the title. Why pick on the shoe clerk? I single out the shoe clerk because it has been used as a potential model for the statistician operating in public health by Bross (1974) in particular to illustrate the relationship to their customers.

Bross was intent on highlighting issues for statisticians working in 'collaborative clinical trials'. In particular he was interested in addressing the question of the primary responsibility of

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the statistician: is it to 'look after number one', is it to the discipline and the principles of 'good statistical practice' or is it to the funding agency and/or the general public? Bross argued that the responsibility of the individual statistician was personal and depends on how broadly he or she views their role. As a scientist the statistician has broad responsibilities; as a shoe clerk much narrower, indeed ultimately their responsibility may only be to 'please the customer well enough to earn his commission'. Bross concluded that the statistician functioning as a scientist was vulnerable unless, and until, they were protected by their status as a professional.

As importantly I want to address the question about whether a higher degree of recognition as a traditional profession would have benefit for pharmaceutical statisticians in terms of greater influence, increased trust and recognition.

2. Statistics and statisticians in the pharmaceutical industry

2.1. The establishment of statisticians in the pharmaceutical industry

In 1976 a small group of statisticians met to discuss the feasibility of establishing an organization for statisticians working within the UK-based pharmaceutical industry. The prime purpose of the formation of the organization that became known as PSI—or to give it its full name Statisticians in the Pharmaceutical Industry—was to provide a forum for pharmaceutical statisticians to discuss issues that were relevant to their work within a regulated industry. I think that it is true to say that at the time the formation of PSI was not viewed positively by the RSS, nor by the Institute of Statisticians nor by the British Region of the Biometrics Society. Formally established the following year, PSI has grown from a membership of 47 in 1977 to over 1200 in 2004.

In Grieve (2002) I argued that this rapid increase was largely due to the requirements of the regulatory environment. The primary guidance on good clinical practice requires that

> 'the sponsor should utilize qualified individuals (e.g. biostatisticians. . .) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trials reports'

(International Conference on Harmonisation, 1996). The development of this guideline and the related guideline on 'Statistical principles for clinical trials' (International Conference on Harmonisation, 1998) can be seen as the culmination of a natural development that had begun in 1969 when the US Food and Drug Administration mandated statistical analysis of clinical trials data to support drug licence applications. Within the pharmaceutical industry this requirement brought about a fundamental change in the work of statisticians in pharmaceutical companies.

2.2. Early statisticians in pharmaceutical research and development.

Quirke (2004) has described the increasing importance and use of statistical methodologies within the Pharmaceuticals Division of Imperial Chemical Industries (ICI) in the period 1955–1975 largely in support of drug discovery. O.L. Davies, who in the 1950s headed the Statistical Research Section within the Research Department of the Pharmaceuticals Division of ICI, had joined the Dyestuffs Division in 1936, the year that pharmaceutical research proper had begun in ICI with the establishment of the Medicines Section of the Dyestuffs Research Department. Davies was the first editor of *Statistical Methods in Research and Production*, which was produced by the ICI Mathematics and Statistics Panel, a panel that ran for many years until the biological divisions of ICI demerged to form Zeneca in the early 1990s. Members of this panel produced a series of monographs on statistical and mathematical themes including *Mathematical Trend Curves, Short Term Forecasting, Cumulative Sum Techniques* and *Non-linear Optimization Tech-*

niques. These books and monographs were very influential in research and development and production environments.

The experience of O.L. Davies in being drawn into the drug development side of the chemical industry was not unique. The pharmaceutical business of many chemical companies evolved from their dyestuffs divisions in the 1930s and 1940s and statisticians in many of these companies supported the work both here and in the USA. From 1943 Frank Wilcoxon worked for the American Cyanamid Company in the insecticide and fungicide laboratory where he developed his eponymous rank tests (Wilcoxon, 1945). When he transferred to the Lederle Laboratories Division of Cyanamid he established the Mathematical Analysis Department and was later joined by Charles Dunnett. Edgar Fieller joined the Boots Pure Drug Company in Nottingham in 1934 where he developed a fiducial approach to determining an interval estimate for the ratio of normal means (Fieller, 1940).

The Food and Drug Administration's mandating of statistical analysis to support drug licence applications saw a large scale shift of statisticians away from the type of work that O.L. Davies, Wilcoxon and Fieller were involved in to clinical research. This left a void with very few statisticians being employed in areas other than clinical research. This void would not be properly filled until the 1990s.

2.3. Development of the regulatory environment

After the formation of PSI, important developments for pharmaceutical statistics evolved out of a paper that was read to the Society by Lewis (1983). The purpose of the paper was to review issues and statistical developments that had led to an improvement in the design and analysis of industry-sponsored clinical trials. It was influential on three grounds.

First it placed before an academic audience the issues that are involved in the design, conduct and analysis of clinical trials in a regulated environment. Second, it highlighted the total lack of statisticians who were directly employed by regulatory authorities in Europe, a situation that was in contrast with that pertaining in the USA where statisticians in the Food and Drug Administration were available to discuss with their counterparts in industry issues of general principle as well as specific issues that are associated with individual drug development projects. This issue was taken up by the RSS and the report of its Working Party on Statistics in Drug Regulation (1991) led directly to the establishment of the Statistics Unit within the then Medicines Control Agency with John Lewis as its first appointed head. Similar developments were to follow in Europe. Thirdly the paper pointed to the need for the development of guidelines governing statistical principles in clinical research. As I have noted, these regulatory guidelines have directly led to an increase in the numbers of statisticians being employed within the industry.

2.4. The roles of statisticians within the industry

I prefaced my remarks by commenting that I regarded myself as pharmaceutical statistician, rather than a medical statistician. This may seem a narrow distinction, but I believe it to be important. There is a perception in some quarters that statisticians who are involved in the pharmaceutical industry are solely engaged in the design, analysis and interpretation of clinical trials, particularly large so-called phase III trials. Nothing could be further from the truth. The RSS Working Party on Statistics in Drug Regulation identified the following stages of drug development in which 'statistical issues arise and statistical methods are used':

(a) pharmacological screening and profiling;
(b) formulation and stability testing;

(c) preclinical toxicology;
(d) pharmacokinetics pharmacodynamics;
(e) early human pharmacology;
(f) phase II and phase III clinical trials;
(g) bioequivalence studies;
(h) post-marketing surveillance.

Many of these do not involve the design and analysis of clinical trials and yet they are of critical importance to drug development, which in many ways is in crisis.

The cost of developing new drugs from discovery to registration is ever increasing, currently estimated to be between $900 million and $1 billion whereas at the same time the approval rate of new drugs is, if not falling, no better than stationary. The prime concern is that the failure of drugs often occurs at stages of the development in which the majority of the research and development costs have already been incurred. Kola and Landis (2004) presented data from the largest 10 pharmaceutical companies over the period 1991–2000. During that period 23% of new drugs failed at the final regulatory stage thereby incurring the full research and development costs, but without generating any return on investment. The failure rates in phase III trials—by which stage about 80–90% of the full research and development costs will already have been incurred is 45%, whereas in phase II trials it is 62%. If the industry is to improve these figures it will require considerable investment at the front end of the development process. Kola and Landis (2004) suggested six initiatives that could help in tackling the attrition problem. The details of these approaches are not germane here; however, most are concerned with the development of predictive models for efficacy and/or toxicity to be used as early as possible in the drug development process. Their development will require statisticians to be involved and it can be argued that the return on investment of statistical expertise in this way will be at least as great as its use in the more traditional areas of phase II and phase III clinical trials.

This need to change the focus in drug development will open up many opportunities for statisticians within the industry to broaden the scope of their activities and these need not be restricted to applications in a scientific context. I believe that statisticians have a responsibility to branch out to any area of their organization where data are used to make decisions. Statistics is the science of uncertainty and variability, and an understanding of the importance of both in the decision-making processes within any organization is crucial to ensure that rational decisions are taken. I should add that I do not regard this argument as applying solely to the pharmaceutical industry.

3. Marquardt and the need for entrepreneurial statisticians

Donald Marquardt worked as an industrial statistician in the Engineering Department of the du Pont company. In his American Statistical Association Presidential address he noted that in many industrial settings statisticians were not as influential as they could be (Marquardt, 1987). The reasons for this he argued are due to internal and external perceptions about the importance and influence of statisticians.

3.1. How we are seen affects how we can influence

Marquardt (1987) contended that others see us in one of three ways. The narrow view of statisticians is that we are merely ‘compilers of data’ and although this is an important function it is neither difficult nor challenging. A second, broader, view is that statisticians are the specialists who can give support to the design of experiments and surveys, who can determine the

appropriate method of analysis and ensure its execution, and who can ensure that quantitative and reliable inferences can be drawn from the data that are collected. This view mirrors the description of the role of the statistician in International Conference on Harmonisation (1996) which was referred to previously—design, analysis and interpretation, and as Marquardt noted 'many statisticians today would be content if only the majority of their clients would operate from this middle view'! In Marquardt's view this is not sufficiently broad. Ideally he suggests that we should be seen as full participants in 'problem diagnosis and solution', we should be seen as unrestricted in the fields of application within our organizations and we should be seen as working at any level of detail from the simplest data presentation to the most abstract detail.

Marquardt (1987) argued that among statisticians there is also a difference in the way that we view ourselves. The narrow view, he argued, sees statistics as a branch of theoretical or applied mathematics with adherents to this view permitting only abstract problems to be included within the discipline and regarding only teaching and research as being honourable careers. This of course is a caricature. I suspect, however, that there is a significant minority of applied statisticians—many within the pharmaceutical industry—who would argue that there is truth in the caricature and we could surmise that this attitude was at least in part responsible for the establishment of PSI.

In a more consensual way Marquardt (1987) argued that most statisticians see statistics as a unique discipline using mathematics and probability theory as tools and providing careers not only as an academic discipline but also in a variety of practical applications in almost every sector of the economy and public service. I hope that such a consensual view resonates with the Fellowship of the RSS. We are a broad church and, as Peter Green argued in his presidential address, although there is considerable diversity there is also unity (Green, 2003).

According to Marquardt a consequence of this consensual view is the realization that there are clear market segmentations of the world in which statisticians operate. At a high level the market may segment into subject domains such as manufacturing and engineering sciences, health sciences, commerce and business, economics, education, social sciences etc. At a lower level there may be individual segments within each category. For example, we have already seen in the pharmaceutical context that there is differentiation between the research, clinical development and production functions.

Such a segmentation approach can lead to a realization that statisticians may be in competition with other professionals in the job market. Marquardt (1987) listed as natural competitors to the statisticians

(a) engineers (of all types),
(b) physicists,
(c) business professionals, including those with Master of Business Administration degrees,
(d) social scientists,
(e) computer specialists,
(f) mathematicians and operations researchers.

In the pharmaceutical context, for example, statisticians may need to compete with pharmacologists carrying out complex analysis of non-linear hierarchical models in the context of pharmacokinetic and pharmacodynamic investigations (Sheiner, 1984; Racine-Poon and Wakefield, 1998) or with health economists developing approaches to assessing cost-effectiveness (Van den Hout *et al.*, 1994; Grieve, 1998; O'Hagan *et al.*, 2000). These professionals are all using or 'doing' statistics for a large proportion of their time and yet the proportion of people fulfilling these roles who have a formal statistical qualification is negligible.

In many ways this competition between professions has been foreseen in research into the sociology of professions.

3.2. The sociology of professions

'All professions are conspiracies against the laity'—George Bernard Shaw, *The Doctor's Dilemma.*

Providing an answer to the question 'what is a profession?' has been at the heart of so-called 'taxonomic' approaches to the professions that dominated historical and sociological research up to the mid-1970s. Taxonomic research was primarily concerned to identify traits or attributes of professions with researchers (e.g. Carr-Saunders and Wilson (1933)) viewing the professions as special categories of occupation that have unique attributes that differentiated them in a qualitative way from other ('non-professional') occupations. Although there was no general agreement on what constituted an appropriate set of such attributes those characteristically identified of 'the professions' relate to the social organization of occupations, and the professional role or work activity. Millerson (1964) performed an analysis of attributes that had been put forward by a number of researchers and identified six essential features of a profession:

(a) a profession involves a skill based on theoretical knowledge;
(b) the skill requires training and education;
(c) the professional must demonstrate competence by passing a test;
(d) integrity is maintained by adherence to a code of conduct;
(e) the service is for the public good;
(f) the profession is organized.

I believe that most statisticians would argue that their profession meets these definitions.

Within the taxonomic tradition, a 'process' approach has been developed by many writers, the prime example being Wilensky (1964). The central tenet of this approach was the identification of a process of 'professionalization'. This approach aimed to identify events in the 'life-history' of occupations that constitute this 'process of professionalization' by which occupations develop into a profession by acquiring increasingly more traits or characteristics of a 'full' or 'pure' profession. Wilensky, for example, looked at the date that a 'first event' occurred in a number of American professions; these included

(a) the first training school,
(b) the first university course,
(c) the first local association,
(d) the first national association,
(e) the first state licensing law and
(f) the first code of ethics.

It is clear that this model does not provide an adequate description of the professionalization of statistics within the UK framework since arguably in that case the sequence should be

(a) the first local association,
(b) the first national association,
(c) the first university course,
(d) the first training school and
(e) the first code of ethics.

Abbott (1988) rejected both the taxonomic and the process versions of the development of the professions. For him paramount in understanding how a profession develops is the link between

a profession and its work—a link that he called the jurisdiction. The professions compete within an interacting system to expand and defend their respective jurisdictions. To illustrate, accountants and lawyers may compete over the accounting jurisdiction and this competition appears as 'skirmishes' between the two occupations over issues such as the determination of 'best' accounting practice and the interpretation of the law so far as it relates to accounting. On a more prosaic level solicitors and estate agents may compete to provide conveyancing services for house purchasers.

Abbott's (1988) model includes elements of disturbance, jurisdictional contest and transformation to describe the development of a system of professions in which professions compete with one another for control of the workplace. The sources of system disturbance can be external or internal to a profession. External sources may comprise the creation of new tasks due to technological advances or organizational change. Internal sources might take the form of developments in vocational knowledge or skill. Such changes may strengthen existing jurisdictions or facilitate the expansion of jurisdictional boundaries between professions. Disturbances result in jurisdictional contests between professions. Through a process of 'transformation' these disputes are settled. Abbott conceived of at least five types of settlement: conferment of full jurisdictional claims on one of the combatant professional groups; subordination of jurisdiction—an arrangement whereby two occupational groups occupy the jurisdictional space but one is superior to the other; division of jurisdiction into functionally interdependent but structurally equal parts; an arrangement whereby a second profession retains an advisory role in relation to certain aspects of the work performed by a principal profession; division of jurisdiction according to the nature of client.

In some cases statisticians make a virtue of this competition. In his Presidential address to the Biometrics Society Breslow (2003) questioned whether the statistical contributions to medicine are undervalued. He pointed out that whereas the 2000 Nobel prize for economics had been awarded to two econometricians, Daniel McFadden and James Heckman, for work on discrete choice models and selection bias, similar contributions by epidemiologists and statisticians in medicine had failed to attract recognition by the award of a Nobel prize for medicine. Since then Robert Engle and Clive Granger jointly received the 2003 Nobel prize for economics for their essentially statistical work on 'co-integration'—the analysis of economic time series with common trends.

Abbott (1988) used statistics as an illustration of some his ideas. He argued that the inferential revolution in statistics that took place at the beginning of the 20th century led to a split between an elite mathematically oriented group of statisticians and the 'traditional application-based mass'. The elite coalesced to form 'the modern profession of statistics' and created the Institute of Mathematical Statistics whereas the mass remained in other professions. From that point onwards

> '... statistics itself has always been a small, largely academic discipline that extends inferential jurisdiction by commodifying its techniques in texts, formulas, tables, and graphing tools. Although good statistical analysis takes great judgement and substantial expense, statisticians flood their techniques everywhere, let others use them badly, and make a living repairing bad applications and contracting their direct services to the elite clientele. This pattern, may of course, have been forced on the profession by the extreme commidifiability of most of its knowledge, which makes underselling extremely easy and conceals the loss of quality involved. But it may also reflect a chosen elitism.'

3.3. Enterpreneurial statistical practitioners and consulting

The solution that was proposed by Marquardt by which statisticians can reclaim those parts of the segmented market that are inhabited by other disciplines is to embrace a philosophy of entre-

preneurialism and consultancy (Marquardt, 1979). In Marquardt's terms the entrepreneurial practitioner is not reactive, waiting for problems to be identified by others and then merely to provide the solution. The entrepreneurial practitioner is proactive in identifying the needs of client groups, in convincing the clients that there are problems which are worthy of solution, in the development of appropriate solutions and in their implementation and monitoring. Much of this philosophy is common to the quality movement and in particular to the management revolution that was brought about in Japan by the four statisticians Shewhart, Deming, Juran and Ishikawa. As Tribus (1989) put it,

> 'You, as statisticians, need to learn to go out and find problems before the problems find you and your company and your country'.

Although this may seem simple it requires recognition that entrepreneurial statisticians need not only be excellent technical statisticians; they need to be good communicators, and they need to be good marketers of their skills. This includes an appreciation that selling the statistician's skills requires different approaches to different audiences. In Grieve (2001) I argued that in many circumstances it will be simpler to convince managers to implement new methodologies or solutions by appealing to the bottom line, than by arguing that the solution to a problem is the most technically sophisticated that is available. A recent example which I was involved with is described in Berry *et al.* (2001), involving a Bayesian response-adaptive dose–response design in patients who had suffered an acute stroke. The design involved some unique features for a multinational clinical trial, not the least of which was that there were 16 dose groups and that it used predictive models of outcome that allowed early updating of the dose–response model, and all of this controlled by a self-contained computer system. The decision to implement this approach was based not on the fact that the design was statistically advanced, but because simulations of the performance of the design showed that in most scenarios the sample size would be considerably reduced. In the event the drug did not work (Krams *et al.*, 2003). None-the-less the approach was regarded as a success because a clear-cut decision was made as early as possible, freeing resources to be invested in investigating other potentially valuable new treatments. An earlier example was reported in Racine *et al.* (1986) and Racine-Poon *et al.* (1987) in which by using a Bayesian two-stage approach to bioequivalence studies we could increase the flow of successful studies through a clinical pharmacology unit.

Unfortunately Marquardt's solution is not immediately implementable for the reason that there is a shortage of effective 'consulting statisticians' (Meyer *et al.*, 1998):

> 'Our field has not been wildly successful in attracting individuals who innately have the characteristics it takes to be effective. Statisticians, as a group, tend to be introverted. It is not likely that an introvert can be trained to be an extrovert. Therefore the statistical profession should step up efforts to recruit more dynamic individuals to the field. Unfortunately, there is much competition, and such individuals are likely to be attracted to fields that appear to be more exciting or have better pay.'

I cannot pretend that we can hope to transform extroverts to introverts, so we may need to tackle the issues through the mechanisms of the market. The successful marketing of the skills and wares of statisticians and their market value are linked. The more success that a group of statisticians has in solving difficult problems cost-effectively the easier it is to argue for both an increase in head count and, when necessary, increased salaries to attract the appropriately experienced and qualified statisticians.

4. Professionalization, statisticians and the pharmaceutical industry

The earliest 'professional' organization of statisticians in the UK was not as might be supposed

the Association of Incorporated Statisticians that was established in 1948, which later became the Institute of Statisticians. The following notice appeared on November 5th 1927, in the *Accountant* magazine under the heading of 'Statisticians and Accountants':

> 'The registration is announced as a company limited by guarantee of a body called the Society of Statisticians and Accountants Ltd, with a maximum of 500 members, each liable for 5s in the event of winding up. The object is stated to be to provide an organisation whereby persons engaged in statistical and/or accountancy work, commerce, the public services or otherwise, may secure a definite professional status. The sponsors of the company appear to be certain local government officials in Lancashire. The statisticians can no doubt speak for themselves, but we are clearly of the opinion that the formation of societies of accountants, unless under the aegis either of the Institute or the Society, is to be discouraged. The public has with difficulty been educated as to the organisation of the profession, and the multiplication of bodies which include under one form or another the word "accountant" can only lead to confusion bad for the profession and the public alike.'

There is no reference to this Society in the minutes of the RSS Council for this period, so it is not possible to say what the statisticians would have said 'for themselves'. The purpose of the Society was to provide a home for those whose work in local government involved some aspects of accountancy, but who were ineligible for entry to the Institute of Municipal Treasurers and Accountants which had originally been established in 1885. They looked also to attract 'accountants' in public or semipublic service, e.g. hospitals or social service. Whatever it thought, the Council of the RSS need not have worried for long, as the Society survived for only 11 years (Stacey, 1954); indeed as Edwards (2003) noted it is the only accounting organization that is 'known for certain to have failed'.

In 1930, the Society of Statisticians and Accountants provided evidence to a Board of Trade committee investigating the desirability of the registration of accountants, reporting that its members

> 'show an overwhelming body of opinion in favour of setting up a Register and restricting the practice of accountancy to those whose names are or would be inscribed on such a register.'

The following exchange is taken from minutes of the Committee's examination of the Secretary of the Society.

> *Question*: 'Is any proportion of your membership recruited from the Fellows of the Royal Statistical Society? Have you any knowledge of that?'
>
> *Answer*: 'I am not a Member. I have not a list of their Members that I am aware of. I recall that I have seen their list of Members, but I could not possibly say that any of our Members were Members of that body. I should be surprised to find that any appreciable number were, because, particularly in the North, the work of the Royal Statistical Society is not well known, and in fact the methods of admission to the body are not well known.'

From 1948 the Institute of Statisticians provided a means of producing qualified statisticians to work in Britain but also abroad, primarily in countries that were to form the Commonwealth. Statisticians were awarded Graduate membership of the Institute for passing the Institute's examinations, or equivalent, and Membership and Fellowship when they had accumulated sufficient appropriate practical experience. When these qualifications were first awarded in 1949, 61 statisticians were awarded Membership and 67 Fellowship. In the first 20 years these numbers had risen to 405 and 230 respectively, reaching 607 and 437 at the end of 1992 when the merger with the RSS took place and the title of Chartered Statistician was awarded for the first time.

During the succeeding 10 years the RSS has been progressing changes to the Royal Charter to enable it to be designated by the Department of Trade and Industry as the authority regulating

the profession of statisticians in the UK. This would allow recognition of Chartered Statisticians within the European Union under Directive 89/48/EEC. To date among the 719 'professions' that are recognized and regulated in Europe, statistics is still notable by its absence.

Among pharmaceutical statisticians there has been much debate over the precise meaning of the phrase 'an appropriately qualified and experienced statistician' (International Conference on Harmonisation, 1998). The European Federation of Statisticians in the Pharmaceutical Industry published a review of the position in the 10 European countries that it represents (European Federation of Statisticians in the Pharmaceutical Industry, 1999). This included a consensual understanding of what is an 'appropriately experienced and qualified statistician'. Such an understanding was expected to bring benefits for individual statisticians by gaining a 'professional identity' and an incentive to undertake further training. Individual companies could benefit through standardized recruitment practices and in particular an easier assessment of the capabilities of commercial organizations providing statistical services. This is particularly important for small biotechnology companies who are not sufficiently large to support the employment of their own statisticians, and therefore lack the expertise to judge the abilities of contract staff. As the regulations are written it is the responsibility of the drug sponsor to validate the experience and qualifications of the statisticians designing and analysing their trials.

The agreed definition is that a qualified statistician

> 'is expected to have a university degree in statistics or equivalent, plus more than 3 years practical experience in medical statistics.'

This definition is not designed to support a formal accreditation scheme, whether quasi-legal or statutory. It is consistent with the requirements of being a Chartered Statistician. The obvious question arises: would it be beneficial if the requirements were established on a statutory basis?

There is no consensus among statisticians in Europe or, for that matter, the USA supporting a legal framework for the 'certification' or 'accreditation' of statisticians in general. For example, Smith (1995) said that he would not wish 'to restrict the scope of statistics by subjecting it to an arbitrary legal definition'. Of course drug development takes place in a regulated environment, established by statute, and it can be argued that it therefore provides the appropriate setting for the establishment of a legalized framework for the statistics profession. There are other areas where this may also be true. The recent interest in the establishment of a statutory framework for official statistics by the RSS, the Statistics Commission and the Conservative Party in its recent manifesto, might also provide the opportunity to define legally the qualifications, and experience, of statisticians who are involved in the production and reporting of national statistics. It has been argued by many that a providing a statutory basis for national statistics would contribute to increasing the public's trust and confidence in official statistics.

However, there may be downsides to a legalized framework. As O'Neill (2002) has noted there is a 'crisis of trust' in the Government, the public services, corporations and schools. Many of these crises have involved professionals and professional organizations who until now have been responsible for the policing of themselves. The events surrounding the Shipman inquiry have led to recommendations for a change in the regulatory environment governing the medical profession (Shipman Inquiry, 2004). There have been similar recommendations covering the legal profession (Clementi Review, 2004), actuaries in the light of the Equitable Life affair (Morris Review, 2005) and accountancy following the well-publicized Enron, World-Com cases. Each of these cases will result, to some extent, in a loss of control of the profession by the professional organizations. Establishing a statutory framework for specific groups of statisticians may ultimately therefore have the perverse consequence that the RSS may need to cede aspects of the control of the profession to a 'regulatory' body.

5. Discussion

What is the future for the professional statistician whether within the pharmaceutical industry and beyond? It should be healthy. Although the difficulties in the pharmaceutical industry have resulted in a contraction in the number of employers (for example, of the 10 largest companies in the period 1991–2000 that was referred to by Kola and Landis (2004), two have ceased to enjoy independent status) the demand for statistical expertise within the industry will continue to be high. This will be particularly true if statisticians take up the challenge to broaden the scope of the application of statistical ideas.

Fig. 1 is based on projections that were provided by Warwick University's Institute for Employment Research for the National Skills Task Force that was funded by the Department for Education and Employment (Wilson and Green, 2001). The projections are based on the use of a multisectoral, regional macroeconomic model combined with occupational and qualifications modules. The main projection period is 1999–2010. The model can be used at different levels of granularity with respect to the occupations, whose hierarchical classification is based on the standard occupational classification 2000 that was published by the Office for National Statistics (2000). At the highest level occupations are classified into nine major groups:

1, managers and senior officials;
2, professional occupations;
3, associate professional and technical occupations;
4, administrative and secretarial occupations;
5, skilled trades occupations;
6, personal service occupations;
7, sales and customer service occupations;
8, process, plant and machine operatives;
9, elementary occupations.

There are three more levels in the hierarchy. For example statisticians are to be found at the lowest level of the hierarchy within 'professional occupations':

Major group: 2—Professional Occupations
Sub-Major Group: 24—Business and Public Service Professionals
Minor Group: 242—Business and Statistical Professions
Unit group: 2423—Statisticians.

Among the professional occupations, minor group 242 covering business and statistical professions is projected to experience the third highest *per annum* growth rate of any minor group over the period 1999–2010 at 4.2%.

At face value Fig. 1 indicates that the future for the employment of statisticians is healthy. However, these figures need to be interpreted with care. First, from a purely statistical perspective the reliability of the projections at this level of detail is such that they should be taken to be indicative rather than providing a precise picture, as they are based on extrapolations over a relatively short and possibly atypical period. Second, the grouping of business and statistical professions includes not only statisticians but also accountants—of all types: management, chartered cost, management and works—auditors, actuaries, business analysts, economists and management consultants. Thirdly the projections focus on the total numbers of individuals who are expected to be employed in such jobs in the future; they may give a misleading impression of job opportunities and career prospects because they fail to reflect the 'replacement demand' that is caused by retirement, career moves etc. Although in the case of projected employment decline such replacement demand can outweigh negative changes in the context of an increased

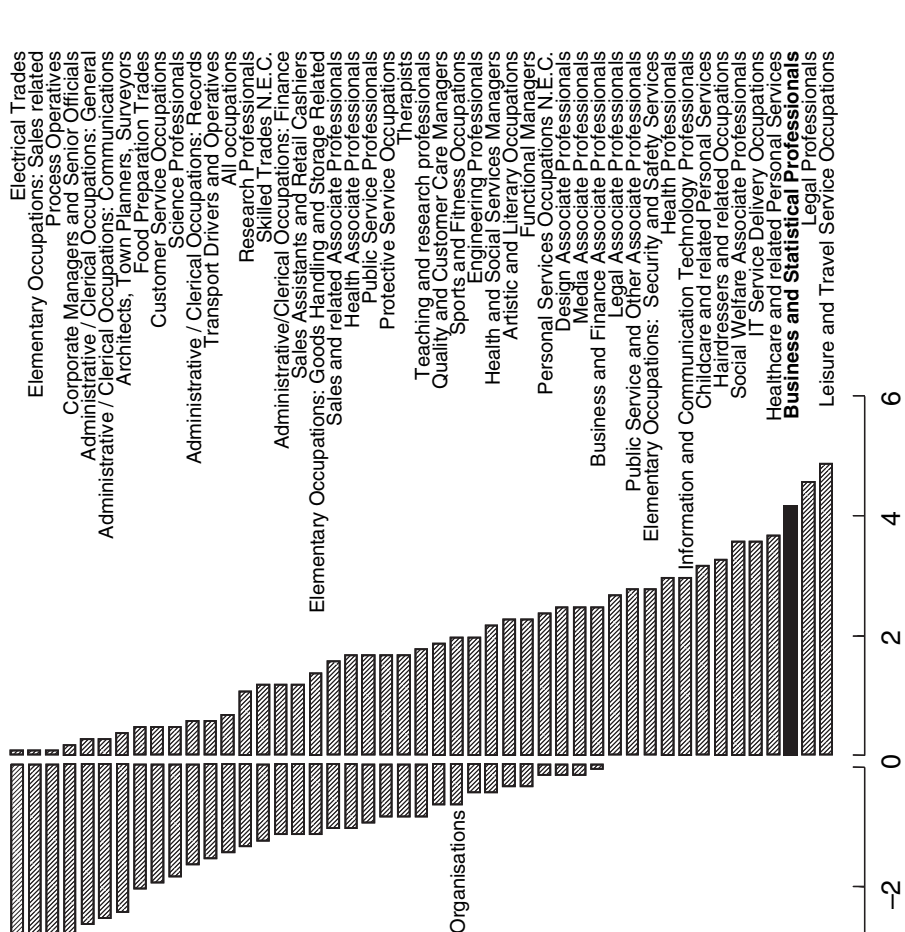

Fig. 1. Detailed occupational projections by standard occupational classification 2000 three-digit categories, ranked by growth (1999–2010) (Wilson and Green, 2001)

demand, the production of a particular occupation may not keep pace with demand. This is a distinct possibility for statisticians.

There is a suggestion that in some parts of the profession insufficient statisticians are being produced to maintain the required level. The recent 'International review of UK research in mathematics' (IRM) (Engineering and Physical Sciences Research Council and Council for the Mathematical Sciences, 2004) concluded that

> 'the future holds very significant dangers for UK Statistics, which is failing to produce enough young research leaders to fill even currently available Chairs, let alone those which will become vacant in the near future. The seriousness of this problem is exacerbated by the rapidly escalating demand for Statistics and statisticians outside the university sector.'

The problem here is that, if the university sector is not regenerating itself, in the future there will not be sufficient university teachers to produce the required number of statisticians to meet the 'rapidly escalating demand'; indeed the international review of mathematics indicates that this is already occurring:

> 'There is a serious concern that now the UK is not producing a sufficient number of Ph.D. graduates in statistics to satisfy the demand from industry and at the same time to maintain the level of excellence in universities'.

A second danger concerns the perverse consequences of the continuing use of blunt tools such as the research assessment exercise to manage output and quality of research in the university sector. The following example illustrates the point. During the last year a work colleague of mine approached me and asked whether I could help their partner who worked at a teaching hospital. It was a simple request, requiring only help in responding to a referee's comments arising from the submission of a paper to a medical journal. I was surprised by the request because I knew that the hospital has medical statistics group. When I pointed this out, I was disappointed to learn that the group no longer provided support to clinical researchers because they needed to spend more time preparing single-author papers for submission to biostatistical journals as their contribution to the research assessment exercise. This is not an isolated case and I believe that it constitutes a real danger for the statistics profession. If we turn away clinical researchers and scientists sufficiently often they will either find other ways or other professions to help them.

Although statistics as an academic discipline may survive on its own without reference to practical problems, it will be weakened. The history of statistical development in the last century teaches us that statistical developments in answer to real scientific problems are more likely to stand the test of time than academic development for its own sake. I have argued in the past that that is a parasitic science. I now agree strongly with Hill (1962) that as statisticians it is a 'symbiosis that we must seek'. In the medical field, the combination of the statistician's knowledge of statistical principles and the scientific method and the clinical researcher's basic knowledge of the disease must be harnessed for the greater good of both sides. To achieve this there are two critical elements—communication and partnership. It is essential that each side has an understanding of the language and concepts of the other and an acknowledgement that, although it may not always be an equal partnership, it is a partnership none-the-less. Of course partnership is inimical with the concept of the shoe clerk, but I trust that it was a concept that we never really took seriously.

If we accept that we are aiming for partnership where do we stand on the issue of competition with other professions? My own view is that as statisticians we need to accept that there will always be competition, and that there will always be scientists and other professionals who use statistical ideas and develop new statistical methods. We should support them. We should

help them to improve whatever they have developed. We should encourage them to consider becoming associate members of the RSS. By being open we are more likely to have greater influence than if we attempt to restrict, in a professional sense, access to statistical methodologies. Abbott (2001) used the actuarial profession to argue that professions which protect themselves by tightly controlling access are less influential than more open professions. He argued that the actuaries have developed a tightly organized, rigidly controlled and a relatively small profession. Entry into the profession is strictly controlled; the career opportunities for actuaries are limited and the area for the application of their expertise is small. The accountants in contrast have developed a large profession 'porous to the point of absurdity' in which their careers can lead in many diverse directions and whose applications included auditing, tax law and management consultancy. Abbott argued that the influence of the accountants is far greater than that of actuaries because they can bring their ideas to bear in many different arenas. The statisticians should aim to emulate the accountants. Indeed I have often pointed out to graduate statisticians wishing to join the pharmaceutical industry that, of the more than 100 professions which are involved in the drug development process from chemical synthesis to post-approval marketing, only two professions are involved in all stages—the accountants and the statisticians.

In a paper that was read to the Society at the height of World War II Kendall (1942) looked to the future and in particular to what statisticians would be doing in the following decades. He noted that

> 'Beginning as a small sect concerned only with political economy, they have already overrun every branch of science with a rapidity of conquest rivalled only by Attila, Mohammed and the Colorado beetle. They have ousted mathematics from its position as the matrix of the sciences, and they are beginning to appear among the arts. They have obtained a foothold in commerce; several big firms run their own statistical departments, and others consult statisticians for guidance in their affairs, as they consult lawyers or chartered accountants. The scope of their activities thus ranges from the day-to-day operations of ordinary business to the most abstract branches of pure mathematics, and, enormous as it already is, must, I think, extend even farther. We may look forward to the time when statistics is taught in schools; when it is an honourable and populous profession, with perhaps a Trade Union; when professors of statistics outnumber professors of divinity; when every sizeable business firm includes a statistician among its retinue, much as every notable family in the eighteenth century had its own chaplain; when the man in the train who begins his remarks with "Of course, I am not a statistician" does so with a sense of humility and not, as at present, with an air of quiet satisfaction at freedom from a serious mental disfigurement.'

We still have a considerable way to go down the path that was described by Kendall but we are well on the way. We shall nevertheless still need to fight the prejudices about statisticians and their work. Recently the film of the life of Alfred Kinsey has reignited interest in his work, largely statistical, into human sexual behaviour. In 1948 *The Lancet* published a poem by 'a peripatetic correspondent' which was inspired by reading Kinsey's survey of the 'Sexual behaviour in the human male':

> O cupid! Cast away your bow and quiver—
> Statistics prove your method inexact.
> O Donne! Go take a jump into the river:
> You hymned the essence, but ignored the fact.
>
> Locked in some cool aseptic heaven above,
> Trained statisticians painlessly inquire
> Into the quaint geometry of love,
> The quantitative aspects of desire:
> Observe the conduct of the lovesick male
> (Not passionate, not noble, not obscene),

And plot it on a logarithmic scale,
Noting a random scatter round the mean.

O monumental volume, smug and fat!
Did man, who wrote the Song of Songs, write that?
O God! O Kinsey! O Jehosaphat.

The professional life of the pharmaceutical statistician I believe can be, and should be, as varied as is possible. To close I can do no better than to quote Austin Bradford Hill:

> 'To those who would thus seek their pleasures in "producing order out of chaos" I can confidently recommend the life of the Statistician in Medicine' (Hill, 1962).

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