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Protecting the People?

Risk Communication and the Chequered History and Performance of Bureaucracy

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Abstract

The history and characteristics of bureaucracy[1] are examined with a view to understanding the impact of the bureaucratic mindset on medicines' regulation, the pharmaceutical industry and healthcare delivery with a focus on risk communication, pharmacovigilance and patient safety. Controversies and allegations relating to common, negative effects of bureaucratic regulatory and management systems are reviewed and examples of creative and effective practice provided. Strategic directions and specific actions for reform are proposed.[2]

> *"A Vogon would not lift a finger to save his own grandmother from the Ravenous Bugblatter Beast of Traal without orders signed in triplicate, sent in, sent back, lost, found, queried, subjected to public inquiry, lost again, and finally buried in soft peat for three months and recycled as firelighter."*[1]

Risk assessment, risk management and risk communication are among the most important elements of the relationship between public authorities and their populations and between healthcare personnel and their patients. Whether it is hurricanes, tsunamis, chemicals, food, road safety, smoking, binge drinking, epidemics, infection control, surgical procedures or specific medications, there is an overriding responsibility to protect people from harm as far as is reasonably possible or to provide them with options that allow them to protect themselves. The heart of risk management in healthcare is the rapid and transparent recognition and assessment of risk and the early provision of sound, relevant, intelligible information about benefits and harms, empowering:

- professionals to offer the safest best possible options and guidance;
- patients and consumers to make discriminating, informed choices.

The risk management enterprise is almost always mediated through political and bureaucratic processes and is, therefore, vulnerable to agendas and pressures that compete or interfere with the primary goal of protecting and enlightening populations and individuals. This article, first outlining the history and nature of bureaucracy (literally, 'the rule of people at desks'), examines how the bureaucratic mindset affects the communication of risk in pharmacovigilance and patient safety and how some of the manifest flaws can be addressed.

1 *Bureau* comes from an old French word meaning *baize* – the material used for covering desks; *bureau* later came to mean *desk* or *office*; the *-cracy* suffix is from the Greek for *rule of*, hence *'rule by people in offices'*.

2 In preparing this article, the author consulted colleagues and health workers in several countries for their opinions and experience. Their contributions, as opinions or anecdotes, some of which appear in the text of this article, are summarized in an Appendix, which is available online at http://links.adisonline.com/DSZ/A76.

1. History

All complex societies, from ancient Babylon to the present day (including, for example, Egypt, Greece, Rome, Byzantium, India, China and the medieval Papal administration which was one of the most sophisticated in the world), have had more or less elaborate systems for the execution of government or clerical policy and functions. In the modern world, the term 'public administration,' is a more neutral label for the high-level activity, and while 'bureaucracy' in its academic form is a neutral, descriptive term of a particular method of administration, it has been forever tainted by its original and continuing negative associations.[3][2,3]

Our concern is with three principal manifestations of bureaucracy: both medicines regulation and pharmaceutical manufacturing, with their large audiences of public, patients and professionals; and healthcare delivery systems (hospitals, clinics, pharmacies, for example) with individual patients as their primary concern. Although no bureaucracy operates perfectly, and some are manifestly inefficient or corrupt, the system itself, in principle, is probably the best hope we have for the just and equitable provision of services and resources, as we shall see later.

2. Reputation

The machinery and officers of religion and the state had been subject to the satire and intense critical commentary of major thinkers and writers since ancient times, long before the word bureaucracy existed.[4][4] Open mocking of officaldom and previously taboo subjects flourished in the 20th century: films such as the Marx Brothers' Duck Soup; hugely popular shows such as MASH, Oh! What a lovely war, Beyond the Fringe, That was the Week that Was and The Men from the Ministry; and, more recently, popular cartoon strips, not least in the exploits of Dilbert[5] and the great Asterix.[6]

If some of the major figures in literary history railed against bureaucracy, they were not alone, for the last two centuries also saw an upsurge of popular, professional and academic hostility to many of its manifestations, in healthcare and many other fields. This attitude, the reality underlying it, and its implications for risk communication and patient safety are discussed after an examination of just what bureaucracy is.

3 Bureaucracy, in its French form, *bureaucratie*, was probably first used by Jean Claude Marie Vincent de Gournay in the mid-18th century. Appointed as France's administrator of commerce, in 1751 Gournay was outraged by what Louis IX's Comptroller General Colbert had put in place the previous century and railed against the multitude of government regulations he believed were suppressing business activity. His famous protest: ''We have an illness in France which bids fair to play havoc with us; this illness is called bureaumania,'' was echoed in other contemporary writings. For example, letters from Friedrich Melchior, Baron von Grimm: ''We are obsessed by the idea of regulation, and our Masters of Requests refuse to understand that there is infinity of things in a great state with which a government should not concern itself.'' (1 July 1764); and: ''The real spirit of the laws in France is that bureaucracy of which the late Monsieur de Gournay used to complain so greatly; here the offices, clerks, secretaries, inspectors, and *intendants* are not appointed to benefit the public interest, indeed the public interest appears to have been established so that offices might exist.'' (15 July 1765). The word was coined in a spirit of protest against complex and self-serving systems, and has hardly recovered since. One of the earliest uses in English was by Lady Sydney Morgan[2] in her then-celebrated novel of 1806, *The Wild Irish Girl*, in which she wrote of, ''the *Bureaucratie*, or office tyranny, by which Ireland has so long been governed,'' adding a deep implication of political oppression to the concept.

4 Some of the great names include Horace, Juvenal and Aristophanes in classical times; through Persian poetry around the 10th century, to Chaucer, Boccaccio, Shakespeare, Rabelais and Erasmus; Hall and Donne in the 17th century; then the great writers of the 18th and 19th centuries, including Pope, Swift, Defoe, Dryden, Mark Twain, Molière, Dickens, Tolstoy, Balzac, Gogol, and on to Kafka, Orwell, Huxley and Joseph Heller and many more in the last century.

Dickens: Little Dorrit: Chapter 10 – Containing the Whole Science of Government

The Circumlocution Office was (as everybody knows without being told) the most important Department under Government. No public business of any kind could possibly be done at any time without the acquiescence of the Circumlocution Office. Its finger was in the largest public pie, and in the smallest public tart ...

... This glorious establishment had been early in the field, when the one sublime principle involving the difficult art of governing a country, was first distinctly revealed to statesmen ...Whatever was required to be done, the Circumlocution Office was beforehand with all the public departments in the art of perceiving – HOW NOT TO DO IT.

Charles Dickens, *Little Dorrit* (published in serial form December 1855–June 1857)

Weber's Seven Principles of Bureaucracy

1. Official business is conducted on a continuous basis.
2. Official business is conducted with strict accordance to the following rules:
   - the duty of each official to do certain types of work is delimited in terms of impersonal criteria;
   - the official is given the authority necessary to carry out his assigned functions;
   - the means of coercion at his disposal are strictly limited and conditions of their use strictly defined.
3. Every official's responsibilities and authority are part of a vertical hierarchy of authority, with respective rights of supervision and appeal.
4. Officials do not own the resources necessary for the performance of their assigned functions but are accountable for their use of these resources.
5. Official and private business and income are strictly separated.
6. Offices cannot be appropriated by their incumbents (inherited, sold, etc.).
7. Official business is conducted on the basis of written documents.

3. Meaning

The writings of Max Weber[5] have had the greatest influence on our modern conceptualization of bureaucracy, primarily in democracies, at least in its ideal, rational, 'scientific' form. He identified seven core principles[7] for a system that delivered the most rational and efficient administration of a society. They included the rule-following nature of specific roles and the division of labour within a vertical hierarchy of authority and reliance on written documents.

He described the bureaucratic official as having specific characteristics, including appointment on the basis of conduct and technical qualifications,[6] the exercise of authority following impersonal rules, and the rewards of salary and the prospect of advancement in a lifetime career. Officials are responsible only for the impartial execution of assigned tasks and must sacrifice personal judgement[7] if it runs counter to official duties.[3]

Weber recognized that such a system, rational and efficient in principle, could be abused and diverted in many ways, not least by becoming a political oligarchy, unaccountable and hostile to democracy and service to the people.[8][8]

Robert Merton[9] was another important commentator on social structures who identified the phenomenon of red tape and other inefficiencies in real-world bureaucracies. He suggested that, if the predominance of rational rules, and their close control of all actions, favour the reliability and predictability of the bureaucrat's behaviour, as Weber believed, it could equally lead to lack of flexibility and a tendency to turn means into ends and produce 'goal displacement.' Meier and O'Toole,[10] for example, assert that

5 1864–1920; notable German sociologist, political economist and administrative scholar whose seminal work was *Economy and Society*, published posthumously in 1922, arguably one of the greatest sociological treatises of the 20th century.

6 The Chinese Imperial Examination System, established 1500 years ago, was the first to elevate merit above patronage as the criterion for appointment.

7 This has the occasional inevitable consequence of ethical dilemmas for employees and conflict with the concept of 'professional autonomy'. This issue recurs later in this article.

8 This idea had been earlier developed in Robert Michels' *Iron Law of Oligarchy* in his 1911 book, *Political Parties*. It states that all forms of organization, regardless of how democratic they may be at the start, will eventually and inevitably develop into oligarchies.

"... bureaucracies can and will implement policies in ways unintended by the political principals".[11] This kind of corruption was succinctly described by Dame Janet Smith in her damning assessment of the UK General Medical Council (GMC) in her 2004 report on the Shipman murders:

> *The GMC focussed too much on the interests of its members, rather than safeguarding the interests of patients.*[9][12,13]

Amongst other important contributions to popular thinking (and ironical judgement) about bureaucracy were:

- *Parkinson's Law*:[10][14] "Work expands so as to fill the time available for its completion."
- *The Peter Principle*:[11][15] "In a hierarchy every employee tends to rise to his level of incompetence."
- *Putt's Law*:[16] "Technology is dominated by two types of people: those who understand what they do not manage, and those who manage what they do not understand."
- *Pournelle's Iron Law of Bureaucracy*:[17] "In any bureaucracy, the people devoted to the benefit of the bureaucracy itself always get in control and those dedicated to the goals the bureaucracy is supposed to accomplish have less and less influence, and sometimes are eliminated entirely."

The ideal model has some latent and apparent flaws – self-containment and inflexibility being the most serious. Ponderous responses can be seen vividly in the extreme circumstances of crisis, when rigid organizations are shown to be incapable of fleet-footed reaction to fast-moving events and of responding effectively to the urgent communications, emotional and other needs of multiple audiences. Even when crisis plans exist, disasters almost always require improvization and creativity which no bureaucratic Standard Operating Procedure (SOP) can provide for.

"Poor fellow, he suffers from files[a]."

Aneurin Bevan (1897–1960), British Labour politician. Quoted in Michael Foot, Aneurin Bevan, Vol. 1, Chapter 5 (1962). Referring to the administrator and trade unionist Sir Walter Citrine. Citrine, Foot claimed, had a "card-index mind."

a This is a play on the common UK English word 'piles' otherwise known as haemorrhoids, an affliction treated somewhat jocularly in some circles.

It is also credibly argued that bureaucracies favour men and stereotypical male values (rule- and control-based management), often to the exclusion of women and female values (principle- and trust-based approaches).[18] The style and ethos of a bureaucracy are matters of choice, entirely in the hands of those in charge.

Bureaucracy, however, in spite of its variable manifestations, is probably the best hope we have for serving the purposes of democratic administration and the equitable distribution of services and resources in the public sector (Gonçalo Sousa Pinto, private correspondence).[12] It is the dominant administrative model in the private sector, where profit and market penetration are

9 The following comment on the GMC from another source represents a devastating analysis of an organization, with ostensibly benign purposes, which has become a kind of monster: "The GMC displays the hallmarks of a paranoid Third World dictatorship in how it seeks out (usually non-existent) problems; indeed, Shipman appears to have been a timely pretext to pursuing a pre-existing authoritarian agenda. It has turned its attention to medical students, joining forces with the Medical Schools Council to target what they consider inappropriate behaviour at an early stage."

10 Parkinson's argument was based on statistical analysis of the substantial growth of the UK civil service bureaucracy at times when national commitments were declining, when, for example, the British navy was dramatically reducing its fleet and manpower after World War 1, and when the Empire was being dismantled after World War 2.

11 A humorous treatise, which also introduced the 'salutary science of hierarchiology'.

12 Here is an eloquent statement of the case for the defence: "... a bureaucratic system is essential to ensure democratic and universal access to healthcare or any service provided by the State... Bureaucracy is in place to ensure that the State relates to all citizens in such a just and egalitarian way, and that individuals in positions of power ... do not take priority in that relationship... Bureaucracy also helps organize the logistics of the State or organization in the spirit of creating SOPs, in order for the system to learn from itself while purging any errors from its activities." (Gonçalo Sousa Pinto, private correspondence).

the driving forces.[13] It is only one of several organizational types (see boxed text below) and is far from being the best for all situations.[19,20]

Types of Organizations

Henry Mintzberg, one of several influential thinkers in this field in the 1980s and 1990s, identified five types:

- The entrepreneurial organization (often a young outfit with minimum structure and formality).
- The machine organization (bureaucracy, highly structured and formalized, Weber's model).
- The professional organization (development of professional standards and support of professional membership).
- The divisional (diversified) organization (often a constellation of specialized sub-units, which may become bureaucracies in their own right).
- 'Adhocracy' (all kinds of innovative, one-off, dynamic projects outside line-management and other formal structures).

Bureaucracy itself may have several different styles and cultures, including innovative, supportive, pure bureaucratic, acquisitive and monopolistic,[21] autocratic and democratic, none of which is appropriate for all situations, and some of which are actively hostile to effective organizational functioning in the fields of health and public service. (For one diatribe on this issue, see Charlton.[22]) Rational bureaucracy in a democracy (Weber's model) may be incompatible with other types of legitimate authority, such as traditional and charismatic leadership (in developing countries, for example). We should note that all systems, however well-intentioned, live under the constant threat of subversion by corruption and patronage, and by the impact of the short-term tenure of political masters and the shuffling of staff.

In summary, 'bureaucracy' is the name of a formal system for public administration which, in its ideal, theoretical form, can serve democracy and groups or individuals by delivering services that are efficient, equitable and reliable; it can also serve the very different purposes of the private sector. It is a system, however, vulnerable to a host of corruptions and diversions that can blunt or undermine its core aims and objectives. The word itself is frequently used as a critical, often satirical encapsulation of these weaknesses.

4. Performance

Death of compassion: how managed care and bureaucracy are strangling the heart of medicine[23]

USA wastes more on healthcare bureaucracy than it would cost to provide healthcare to all of the uninsured[24]

Unnecessary bureaucracy is crippling NHS research[25]

Bureaucracy run amok: can checklists kill?[14][26]

India's bureaucracy is 'the most stifling in the world'[27]

Drug industry scandal a 'crisis'[28]

It is all too easy to find headlines and titles such as these in the media, academic journals, published books and blogs. The prevailing opinion seems to be of universally burgeoning and bloated bureaucracies and of complex and disabling regulation, which both have a dire effect on research, innovation, service delivery, risk communication and patient safety.[15][12]

We have to be cautious about taking all this hostility at face value: bureaucracy, including regulation, is one of the arenas of bitter political and professional debate, with left and right, bureaucrats and their publics, amongst many other often warring parties, having very different view of its benefits and harms.

The position of the 'right' is indicated by this remarkable opinion from a conservative blogger:

> "*But the reality is that market discipline is far more effective than any law when it comes to making you safe ... An airline doesn't need Federal regulations to get them to keep their*

13 How the exclusive obsession with profit exposes the vulnerability of management bureaucracies to questionable, even outrageous, practices is evident from Enron to Vioxx, from selective serotonin reuptake inhibitors to Olympus (cameras) and, of course, banks.

14 This headline was provoked by a decision of the US Office of Human Research Protections which was later reversed as the result of massive professional protest.

15 For a passionate and heart-rending account of the multiple failings of healthcare policy and bureaucracy as they affect general practice, see Lakasing and Francis.[12]

fleet of aircraft in tip-top condition ... The big government types would be apoplectic at the suggestion, but the reality is that if all FAA regulations were repealed, it would likely have no measurable effect on airline safety.''

This writer also applies the same prediction with regard to the abolition of the FDA and food safety in the US.[29]

A quite contrary view is expressed by a professor of politics:

''*Ironically, the real problem with many public bureaucracies today is not that they are bloated institutions who are over-staffed and spend too much money, but that they are understaffed and don't have the funds to do their jobs*.''[30]

An example of one extreme position, which demands very thoughtful assessment, is the colourful, popular and controversial 'Natural Health' website of Dr Joseph Mercola, whose hostility to the standards of drug regulation (and pharmaceuticals in general) spawns a daily exposition of what he describes as fraud, corruption, distortion of evidence and threats to health. A recent and typical example is 'Systemic Corruption within the FDA Threatens Your Health'.[31] (Anti-immunization campaigners use similarly inflammatory language, see section 5.)

5. Information and Risk Communication

Major issues in bureaucratic communications are the ethics of public communications (transparency and full disclosure, especially); the integrity of the information on which risk messages are based (who generates the information and on what basis with what assumptions or prejudices); and the social context in which they are delivered (knowledge, trust, societal beliefs, and so on):

''*The prevailing context of risk communication is fear, or something to be dreaded, avoided and even intervened against in order to keep us safe. Moreover, the information models of risk assessment are built on quantitative platforms with measurable results. This means that they are also built on official information bases that have been constructed by agencies with rather narrow agendas, much of which are self-serving and reflective of their own institutional narratives about efficiency, reliability and validity. Ultimately, then, risk assessment models are subject to all the pitfalls and critiques of official information*.''[32]

The potential institutional distortions implied in this comment will already be familiar to readers, as will the preference for data over information and exegesis. They form the basis of many of the controversies about regulatory and commercial practices in risk assessment and communication. A further important related issue is attitude to risk: many commentators refer to a prevailing risk-averse culture which they believe is hampering medical and pharmaceutical research and risk communication without demonstrable contributions to safety.

This is from one pan-European vested perspective:

''*Clinically initiated medical research has become suffocated by excessive, complex regulation, adding many months of delay. The directives have not prevented poorly designed or unethical studies, nor have they made studies safer. Rather, they have frustrated clinicians, delayed progress, and impeded the completion of essential trials*.''[33]

Risk aversion has a profound effect on action and communication associated with risk: with most publicly-managed risks, even those of exceptionally low probability, such as the terrifying Shipman[16][13] and Allitt[17][34] cases, there is often a public outcry and call for radical action, followed by panicky ('knee-jerk') legislation, maybe new regulations, and declarations by politicians or business people that they will ensure 'this never happens again' (a doomed hostage to fortune). This approach exacerbates several serious prob-

16 Shipman was convicted of killing 15 patients and thought to have maybe killed a further 200.

17 The official enquiry into the attacks on 13 children was held in private, giving rise to some very negative assessments about the intentions of the Secretary of State for Health, Virginia Bottomley, and raising the old question of the public's right to know.

lems: it reinforces the public's nervy, precautionary attitudes to risk they do not choose (unlike their reactions to voluntary risks such as smoking, driving, extreme sports and so on); it implies that all risks (even of very low probability) can be regulated and removed; it implies that tolerance of risk is not a necessary aspect of rational social life or medical therapy; it villifies uncertainty. It suppresses open investigation, dissemination and acceptance of good information about risks and harms. It also underlies expensive and wasteful defensive clinical practice.[35,36]

Drug safety scares (for example, cerivastatin (Baycol®), rofecoxib (Vioxx®), tegaserod (Zelmac®), rosiglitazone (Avandia®) and, most recently, rimonabant (Acomplia®) have caused widespread outrage, not least because the commercial and regulatory bureaucracies and manufacturers often gave the impression (whatever the reality) of being self-servingly less than honest in their communications, and slow to reveal or react to evidence of significant harm. Such incidents, along with a common perception that the drug trial and approval systems are themselves flawed, have done much to damage public confidence in regulation and provoked deep scepticism about the integrity and credibility of the authorities' risk communication practices.[37] The rise and rise of the influential and deeply damaging anti-immunization lobby (with nearly 3 centuries of history[18][38,39]) has been generously helped on its way by official risk communication failures to manage the storm of religious, political, ethnic and superstitious assertions and myths that dog the science. Compounded by actual incidents of error and damage, such as the Rotarix® contamination controversy and infant death from measles vaccine in Tamil Nadu,[40,41] the authorities remain distant from achieving the credibility and trust that would bring some hope of influencing public belief and behaviour.[42] This exposes core weaknesses of big administrations: their only partial grasp of the ineffable complexity of human nature and motivation and the limitations of their traditional tools for meaningful engagement.

In responding to a review of Health and Safety regulation, commissioned by the UK Government from Professor Ragnar Löfstedt,[43] The Foundation for Law, Justice and Society published a policy brief[44] that encouraged regulators " *... to take measured risks and adopt a more lenient, evidence-based approach to risk management in health and safety regulation.*"

6. Patients Not Prototypes

Although their focus is different, this is a view shared by many health professionals who believe that many regulatory shibboleths do not protect patients[45] and that the lack of transparency about risk (principally a failure to share comprehensive and intelligible information, including early concerns about emerging problems), especially in drug development and regulation, expose professionals and patients to serious subsidiary risk.[46-48] 'Confidentiality' is one of the big bureaucratic guns in the war for control, repelling all boarders: does it really serve the public interest, for example, that current issues of concern on the desks of regulators are protected from view like battlefield intelligence? The double-barrelled assault of 'commercial confidentiality' defeats all hopes for progress and the sharing of information. In a field that should be ripe with partnership and collaboration, this vocabulary is often put to surprisingly hostile use by regulators and industry alike.

There is also the conundrum that approval safety-hurdles placed too high, especially where patients vary greatly in tolerance and response, as with atypical antipsychotic drugs, may deprive potentially large populations of useful therapy. Jerome Groopman[49] points out the folly of relying on guidelines that are inevitably based on prototypes:

> "*They are no substitutes for individual thinking. And they break down when cases are atypical or complex. It's critical to factor in that human*

18 In 1722, Reverend Edmund Massey denounced inoculation as interference with the will of God to punish sinners through disease, it "usurps God's providential authority", he proclaimed.

biology is highly variable, that diseases have multiple presentations, that symptoms exist with a range of intensity and frequency, while algorithms and treatment guidelines are, of necessity, simplifications. It is impossible to standardize all care.''

There is not, and never can be, an SOP for thinking, for judgement, for discriminating choices, for empathy and humanity, for creative solutions, in drug safety, in regulation, in clinical practice, risk communication or signal detection (or any other field of human endeavour), although many behave as if there could be. 'Due diligence' cannot be SOPed: the belief that it can is one of the failures of the bureaucratic mindset. The only alternative is open public discourse about complexity, uncertainty and the evolving nature of science.

Dale H. Gieringer[50] characterizes a central problem, which has huge implications for risk assessment and communication and rational patient choice:

''*A fundamental problem of the present approval system for new drugs [is] the assumption that new drugs be approved as 'safe and effective' on a collective, society-wide basis. The problem is that safety and efficacy are inherently subjective concepts, whose meaning inevitably varies from individual to individual ... No one has yet defined safety and efficacy.*[19] *Nevertheless, distinguished panels attempt to make what are termed 'scientific assessments' in the absence of objective basing points. In practice, safety and efficacy depend strongly on individual circumstances such as age, sex, genetic makeup, and a host of other medical and personal factors that are often difficult for regulators to know. Even more important, the meaning of safety and efficacy depends crucially on personal values and attitudes toward risk: what seems safe to one person may well seem unsafe to another in similar circumstances. By imposing collective choice in drug risk, the present system is therefore inherently controversial, requiring the arbitrary imposition of values by technocratic authority.*''

This truth is most crudely obvious when a drug is withdrawn from the market to protect people (we do not know how many), at the same time as it deprives a sometimes vocal minority of those whom the drug had helped, sometimes uniquely so. Risk management is the alternative approach, when, as with high-risk drugs such as isotretinoin or thalidomide, elaborate paperwork and counselling safety mechanisms may be put in place to allow access to the drug while protecting patients at serious risk (in these cases, particularly pregnant women). Sadly, experience suggests that such methods often fail, when prescribers or dispensers ignore warnings (as in the notorious case of contraindications for the use of cisapride, for example,[20][51],[21][52] or the more recent case of kinase inhibitors and contraindicated drugs[53]), or unauthorized supplies are available (as with isotretinoin all over the world). Users of black market, Internet or under-the-counter drugs are unlikely to benefit from any of the traditional risk communication activities of the responsible authorities (and are largely invisible to them). Occasionally, a drug fails to gain approval because of lack of evidence of benefit within narrow regulatory criteria, even when clinicians and patients assert its effectiveness and evidence demonstrates it; such was the case in the UK with glyceryl trinitrate ointment for the healing of anal fissure, for example (Andrew Herxheimer, personal communication). Patient needs can be trumped by other considerations and voices

19 While the substantial point is well taken, 'safety and efficacy' do have prescribed legal and regulatory meanings; the problem is that those meanings do not necessarily align with variable and ill-defined meanings of the terms in the public mind, or with public choices or priorities.

20 Research on the impact of the FDA's 1998 campaign about the contraindicated use of cisapride came to the conclusion: ''The FDA's 1998 regulatory action regarding cisapride use had no material effect on contraindicated cisapride use. More effective ways to communicate new information about drug safety are needed.''

21 Similar ineffectiveness of high-profile safety protocols has been found in many environments, for example in operating theatres where wrong-patient, wrong-site surgery remain serious problems.

(although it is sometimes unclear as to who or what they are).

The Perils of Passively Following Routines

Visiting a seriously ill intensive care unit (ICU) patient, a lifetime senior nurse (author's relative, personal communication) was disturbed to see ward staff regularly and correctly reading and recording data from multiple monitoring machines, but without scanning previous data entries to detect trends, therefore putting the patient at risk in the event of deterioration which, on occasion, the visitor had to point out and insist on action.

An elderly man is bathed every morning in his home by visiting carers, but they will not put cream on his bedsores because this is not on their list of duties (Sainsbury E, personal communication).

The issues of judgement and professional autonomy and the contradictory impact of comprehensive rules, SOPs and regulation are the subjects of passionate debate in the literature. For example: 'Writing hospital policy in the discourse of procedural directives reduces nurses' ability to act as autonomous, critically thinking professionals, with implications for patient safety, nurse autonomy and the professional status of nursing.'[54]

7. Routines and Professional Judgement

In a Chartered Institute of Management Accounts report on retail and local government risk management practice,[55] a key finding was:

> "*Bureaucratic processes and systems can hamper good risk management – either as a result of a 'box-ticking mentality' or because managers and staff believe they do not need to consider risk themselves.*"

The 'box-ticking mentality' has been the source of much criticism and is a typical symptom of bureaucratic thinking and processes. In a 'damning' report about the UK Care Quality Commission's IT-based approach to spotting problems in healthcare providers' services,[56] their 'light-touch', electronic box-ticking system for collecting data is alleged to be 'putting patients at risk'.[22] In a review of the radical market reforms to the UK National Health Service (NHS),[57] a commentator notes the risks:

> "*... we must be concerned about how quality and performance are measured – healthcare may become a box-ticking exercise, with services offered because of their tariff or their amenability to measurement. Corners may be cut with essential parts of the service that are not directly reflected in targets, resulting in healthcare that performs well on paper, but which does not meet patients' needs.*"

But these risks are not new. The reforms themselves arise from a health service that had, in some respects, already lost its way through the displacement of the goal of public service with institutional, bureaucratic (and cost-cutting) priorities. In a radio interview about patient care and bureaucracy, Prime Minister David Cameron, described the process exactly:[58]

> "*It's not one problem in particular. It's the stifling bureaucracy. The lack of consequence for failing to treat people with dignity. Even, at times – as we saw with Mid Staffordshire*[23][59,60] *– the pursuit of cost-cutting or management targets without sufficient regard for quality of care.*"

This identifies a common bureaucratic corruption: a hermetic administrative ethos that is unconcerned about, ignorant of, or unreceptive to evidence of the impact of decisions on staff, users or outsiders. The naive bureaucratic view of risk communication (provide 'one size fits all' information, for example tick boxes or complex and time-consuming forms) illustrates this implacable deficiency of technocratic management of problems with profound human and social dimensions. The big players in regulation have no understanding of or concern about the inevitable powerful impact of their decisions on politicians, scientists, journalists and patients in countries outside the exclusive frontiers of their domains. They provide nothing in the way of insight or guidance for foreign fellow professionals who may be cast into controversy and

22 According to Margaret Hodge, Chair of the Public Accounts Committee, "The Care Quality Commission has come under fire in recent months following press exposure of problems at the Winterbourne View Hospital, the latest inquiry into the scandal at Mid Staffordshire NHS Foundation Trust, and its own report on dignity and nutrition at NHS hospitals."

23 A scandal of patient neglect and abuse which rocked the UK in 2009.

doubt by actions taken thousands of kilometres away.[24][61,62]

The conflict between procedure and meaning is a serious concern in the issue of informed consent – a critical risk communication process – where the ticked box and the signature represent fulfillment of the bureaucratic requirements but may, at their worst, be no more than an empty gesture by a confused but submissive subject or patient.[25][63] When there is overwhelming and detailed information, especially where the consequences may be complex and/or uncertain, the precautionary bureaucratic and legalistic provision of dense and lengthy documentation contributes little to ethical practice in reality. This applies to clinical trial protocols, patient information leaflets and (as we all know) to those endless software and banking agreements whose terms and conditions boxes we tick without any idea what we are consenting to; specifically, what risks we are accepting, which may or may not have been communicated intelligibly, along with the assumed benefits. Industry compliance with countable regulatory communications requirements may be audited on timescales (the 15-day rule, for example) rather than the quality, completeness and meaning of data.

Those who deplore regulation assert the benign intentions and ethical principles of professionals and business people,[26] but we know, in medicine (and business) that not only can some people not be trusted to behave well, but that they are downright dangerous (see 'Fatal heart drugs in Pakistan' in boxed text above). The medical research horrors that gave rise to the Nuremberg Code and the Declaration of Helsinki are sufficient evidence of the depravity of some scientists in the unregulated pursuit of knowledge, but even those measures did not clean up the scene (the Willowbrook scandal, for example[27][64]) and there are those who believe all the Belmont Reports,

Fatal Heart Drugs in Pakistan

Media reports (25–27 January 2012; for example, BBC News Asia[66]) tell of more than 100 deaths and 250 seriously ill patients in Lahore after an estimated 40 000 patients were given free cardiac medication at the government-run Punjab Institute of Cardiology. Contamination with fatal doses of pyrimethamine (an antimalarial) was initially suspected as the cause. A number of arrests have been made.

Points of interest:

- The first deaths occurred some 3 weeks before the story broke: reactions to identifying and communicating the risk were very slow
- Government-run hospitals are required by law to buy the cheapest available medication

Across the Pacific

Such incidents are not confined to emerging countries. In February 2012, the FDA sent out an alert: "The FDA is warning healthcare professionals and patients about a counterfeit version of Avastin 400 mg/16 mL, which may have been purchased and used by some medical practices in the United States. The counterfeit version is labeled as Avastin, manufactured by Roche and does not contain the medicine's active ingredient, bevacizumab."[67] Unapproved medicines were purchased, presumably, because they were cheaper: no amount of regulation and bureaucracy stops these things happening.

24 There is doubt even about the reliability of communications at home: recent research suggests that out of 91 Class I recalls (drugs with the potential for serious adverse consequences or death) since 2004, one in five were absent from the US FDA's customary notification processes, leaving all audiences ignorant of information about them. During 2004–11, the FDA issued 2900 announcements through its Recall Alert system, 1700 of which were drug recalls listed in enforcement reports.

25 An eloquent discussion of the intrinsic complexity of informed consent is provided by Corrigan. This is a particularly valuable study because it includes extensive quotations from interviews with research subjects whose experience challenges many taken-for-granted assumptions about the process.

26 See RedState quotation above,[29] (section 4).

27 "From 1956 through 1971, residents at the Willowbrook State School for Children with Mental Retardation were infected with live hepatitis in order to develop a vaccine. Parents gave permission for their children to participate in this study, often because it guaranteed acceptance into the overcrowded facility."

Institutional Review Committees, Ethics Committees and paraphernalia of regulatory control have still not ensured intrinsically ethical practice or the safety of patients and research subjects.[28][65] (They also believe there have been other serious adverse effects on the progress of science, as mentioned in section 5; see Osanto et al.[33])

Bureaucracies have a tendency to foster managerialism[68] with its emphasis on efficiency, cost minimization, hierarchy, centralization, control and reliance on technical fixes. Scientific and professional leadership, sometimes local or regional, is replaced by centralized managerial and administrative direction, local intimacy is destroyed and core skills are neglected or devalued. These processes can be seen in the loss of clinicians from the ideally broad mix of staff in national pharmacovigilance management, for example; the abolition of regional pharmacovigilance centres; and the pretentions of nursing degree qualifications at the expense of core nursing skills.[69] Such shifts have profound implications for the quality, integrity and focus of what happens within systems and to their external customers.[29][70]

8. Time-Wasting Loss to Patients

Much of the agitation about the impact of bureaucracy on pharmacovigilance and patient care and safety comes from a range of startling statistics from around the world about the amount of time health professionals spend on paperwork;[71-74] collectively, *millions* of hours per week (see following boxed text).

Time spent on paperwork and allied activities is time stolen from time with patients, either in terms of total numbers served or in terms of time spent with individuals; the resulting pressure and stress may lead to errors of all kinds, inadequate communication (including difficult and time-consuming risk communication) and a decline in positive, interactive care, adherence and safety.

Bogged Down in Paperwork: Research Findings[71-74]

In 2008 nursing staff across England spent more than a million hours a week on paperwork The Royal College of Nursing found; time it said could be better spent tending to patients.

The Australian Medical Association Red Tape survey of 2011 found that almost 10% of general practitioners (GPs) are spending more than 9 hours of their working week dealing with government red tape, and more than 20% are spending up to nine hours ... The average red tape burden was 4.62 hours a week.

In the survey, which had more than 1650 responses, one in three pharmacists said increased paperwork and problems with stress had affected the service they provided to patients in the last 12 months ... More than three in five admitted the issues had resulted in increased medication errors or near misses, and over half said they had led to poor quality counselling or advice to patients.

A Stunning Example of Complexity

The author has a copy of the patient assessment form for NHS Continuing Health Care, EH/ML/018/10; Welsh Assembly Government Circular, 015/2010.[75]

The objectives are admirable, and include: ''... to put much greater effort into developing models of service which help to prevent or delay the need for more intensive health and social care services or facilitate a return to lower level support.'' The assessment is for patients who might require continuous nursing or respite care for 1–6 weeks.

The entire document is 119 pages long, with 67 pages of complex details about the history and rationale of the regulations, with the content from page 68 to the end being the form itself. A senior health worker completing the form, reported that it took her 7 hours (personal communication [anonymity requested]), about the time expected even after the full day's training specified for users. No risk of box-ticking superficiality here, but is this really a reasonable and proportionate alternative?

28 For example: ''... rising nurse workloads and introduction of barcode medication administration technologies are creating a human-technology interaction that can cause risky compensatory behaviours – namely, shortcuts and workarounds. When the Institute for Safe Medication Practices surveyed nurses' opinions and experiences in trying to meet the 30-minute rule, it received an overwhelming response from more than 17 500 nurses. Without question, nurses said they believed complying with the requirement can cause more harm than good.''

29 One of the most bizarre, if minor, manifestations of this control-based approach emerged in the UK in 2011, when nurses in the county of Kent appeared on the wards wearing red tabards bearing the words ''Do not disturb; drug round in progress.'' Reassuringly, this preposterous insult to patients provoked widespread outrage.

Bureaucracies love meetings. Meetings consume vast numbers of staff hours and burn stacks of cash. They often have similarly demotivating and stress-inducing effects as paperwork in pursuit of productivity gains which range from substantial to zero. Anecdotal evidence gathered by this author across several training pharmacovigilance courses in several countries suggests a weekly total of anything between 4 and 12 hours spent in meetings, with one far-Eastern colleague reporting a staggering weekly total of between 20 and 30 hours. Few people regard more than a small percentage of this meeting time as productive, yet it is an area in which huge improvements can be made when the dead hand of unimaginative bureaucratic control and inertia is lifted. Unproductive time in useless meetings is an insult to staff dignity and a further obstacle to patient safety. Too few meetings are problem-solving partnerships; too many are manifestations of paternalistic management and process-driven obsessions.

9. Reporting Adverse Drug Reactions: The Labyrinth

Good risk communication is dependent on having good risk information available; pharmacovigilance is one of the important methods of gathering risk data. The question of adverse drug reaction reporting forms is one that I have addressed previously[76] and it continues to be a matter for concern: is vital safety information best collected by the mechanism of filling in complex and time-consuming forms? The answer is a resounding 'no!' but the pressures to maintain the established system are great and, it must be said, regrettably plausible, particularly in the light of limited resources. One observer (McEwen J, personal communication) notes that ADR reporting by hospitals and family doctors in Australia has been falling in recent years, almost certainly as a result of its low priority and the pressure of other forms and administrative duties.[30] We must find ways of reducing the burden of reporting for busy professionals.[31]

The communication of risks identified through the non-systematic, 'spontaneous' process of pharmacovigilance is a further issue of concern at every stage of the long chain from patient, reporter, through local and national pharmacovigilance centres, assessors, regulators, manufacturers, and ultimately to physicians, pharmacists and patients. Is the end result useful, credible, reliable and timely? There are serious questions, not least about the speed with which emerging risks are recognized, assessed and communicated through the bureaucratic processes.

Sadly many of these deficient systems are used as the default model for export to developing countries, where culture and practices make them unsuitable and inefficient, and preclude the search for more creative and relevant solutions.[32][77] This leads to sub-optimal performance and sometimes failure (Gonçalo Sousa Pinto, personal communication).[33]

30 This is against a recent rising trend of reporting from companies and 'others', particularly resulting from campaigns to encourage reporting of adverse events following immunization for H1N1 and seasonal influenza.

31 Poison centres all over the world have for years collected data on millions of cases without a single form being completed by reporters.

32 The use of government bureaucratic domination as well as ecclesiastic bureaucratic domination was highly effective in the overtaking of colonial properties. However, bureaucratization was an ineffective tool for the reformation of decolonized states ... the bureaucratic form is unnatural in societies where charismatic or traditional authority still dominates.

33 An example of the difficulties of the implementation of international projects developed in Europe was the decline of the useful and well-intended hypertension initiative managed by the Pharmaceutical Forum of the Americas. This withered in the field, partly at least, from the imposition of very complex protocols and data collection which healthcare workers and patients could not cope with.

The Case of Antimicrobial Resistance

In the field of risk communication, there are few larger failures than the long-term, continuing, extravagant and irrational use of antibiotics in humans and animals (for example, see Lalvani et al.[78]). This enormous threat to the future of worldwide public health appears not to have been grasped by politicians, healthcare workers, patients or the public at large, and this can be attributed only to a comprehensive failure of risk communication throughout the world. While some admirable efforts have been made (for example, the annual European Antibiotic Awareness Day[79]) ignorance, laziness and misguided animal husbandry conspire to threaten us all. In many developing countries antibiotics are promiscuously available in pharmacies and on the streets, and doctors and pharmacists, often under pressure to prescribe or dispense at least something, collude with patient demands on a vast scale. In other areas of public health (smoking and safe sex, for example), we have seen that only vivid campaigns over years (decades, in fact) are likely to affect attitudes and behaviour. Nothing less will reduce the irrational use of antibiotics while enforcement at borders and on the streets is so ineffective.

10. Benefits

It would be perverse to suggest that bureaucracy has no beneficial effects; like democracy and capitalism, we do not currently have any convincingly superior models, and abolition would have more negative than positive effects, however flawed we feel current practice is. In experiencing the benign effects of bureaucracy, as we all do from time to time, the mechanisms are often invisible or have a very low profile: efficient and seamless service does not draw attention to itself, except inasmuch as it is experienced as exceptional. It is the problems which stand out and are recorded. When we can go online and make an appointment with our GP; when we receive a short message alert for our next blood test; when our hospital admission is a simple and fluid process; when the pharmacist dispenses our medicine with careful explanation and good supporting information; when adequate stocks of vaccines are available at times of need; when we can make well informed, voluntary choices about our therapy and its risks – we are experiencing the benefits of an effective bureaucratic infrastructure to healthcare. But there are still enormous problems and real threats to our safety and welfare through the very bureaucracies that can serve us so well. The model itself may not be the greatest risk, but the irrationalities and absurdities to which it is so amenable under short-sighted or self-seeking management threaten us all.

Summary of Potential Benefits of Bureaucracy

1. *Policies, rules, standardization, uniformity:* predictability, clarity, objectivity, equity, continuity.
2. *Technical qualification and division of labour:* enhanced economies of scale, specialization and control.
3. *Chain of command:* control, enhanced decision making and efficiency; reduced conflict.
4. *Accountability:* upwards to political or commercial masters and outwards to patients, customers, shareholders, the public at large.
5. *Employee commitment:* career path, employment safeguards, security; contribution.
6. *Outcomes:* effective and equitable delivery of services and resources in line with organizational mission and with political and public expectations, within budget.

11. Reform

Charles Landry writes very well about 'Creative Bureaucracy' in his blog of that name.[80] Some of his ideas help us to conceptualize how bureaucracy can evolve for the 21st century and how some of the weaknesses of past models can be addressed.

He says that bureaucracies need "*... a shift to involving users more and co-creating policies, products or solutions; a shift from hierarchical to network thinking, a breakdown in traditional disciplinary boundaries, and cultural cross-fertilization. The creative bureaucracy thesis seeks to marry two seemingly incompatible concepts – creativity and bureaucracy – in order to do this. Creativity focuses on resourcefulness, imagination and flexibility ... Many people who work in bureaucracies are not expressing their full talents. Can we create conditions to better harness their imaginations, creativity and competences?*"

Al Gore's National Performance Review[81] set a demanding reform agenda with these goals:

- Cut 'red tape' and rules by half.
- Establish 'customer service' standards for every department, agency and bureau.
- Give bureaucrats at the 'street-level,' where they interact with the people, more discretion to respond to particular needs and circumstances.
- Eliminate waste, overlap and duplication.

The UK Customer Service Excellence project[82] (arising out of the old Charter Mark) aims to provide 'a practical tool for driving customer-focused change' and is a positive, even radical instrument for improving service delivery through realigning organizational priorities and relationships. The UK regulatory agency, the Medicines and Healthcare products Regulatory Agency (MHRA), has been involved in the Government's 'Red Tape Challenge'[83] asking the public to comment on regulatory practice, pressurizing the organization to take serious account of public opinion and to engage with it.

'One size fits all' as the approach to communication is one of the prevailing bureaucratic deficiencies, nowhere more so than in risk communication. It is only recently that medicines risk communication (in package inserts, for example) has started to take account, amongst the multitude of other individual variables, of the particular languages of its multiple audiences and of health literacy (the FDA's Strategic Plan for Risk Communication identified this as a primary area for reform[84]). Pictograms,[34][85,86] and other graphical methods are starting to make inroads into the dominance of the printed word and there is greater understanding of the critical part played by expert one-to-one counselling, explanation and discussion (a role in which pharmacists need to have a much higher profile). Both, however, remain threatened by bureaucratic preferences and pressure on time. Considerable progress has been made in establishing the principle of close consultation with patients and patient groups[87-89] in producing intelligible patient information, and some radical new materials have been published. One of the lessons of the Twitter/Facebook age is that a myriad of micro improvements can be generated by thoughtful mass audiences; openness to this kind of progressive change is the characteristic of nimble organizations,[80] few of which are yet in the field of regulation. The doors, however, are open.

Bureaucracies are not, by and large, good educators or communicators, although there have been some stunning public health campaigns from time to time in various parts of the world, notably for HIV prevention, smoking and road safety. Among the characteristics of successful campaigns are persistence and repetition, often over many years, decades even. These are not the natural characteristics of bureaucracies,[35][90] but they are critical to influencing public perception of risk and changing behaviour. Some regulatory authorities, ministries of health, organizations such as the US Centres for Disease Control and Prevention (CDC), hospitals and others have embraced new technology and media and are producing attractive, intelligible information and access and brilliant tools, such as the FDA's Medwatcher[91] ADR reporting and safety alert app for iPhone and iPad, and the use of smart phones in Kenya for infection control data reporting.[92] *mobile*PDR®,[93] the National Institute for Health and Clinical Excellence (NICE) Guidance app[94] and the Diabetes UK Tracker app[95] are examples of the effective use of technology to put information, guidance and the latest risk information in the hands of physicians and patients *at the precise moment they are needed*. There are many other examples.

Online patient communities and campaigns have broken down the official monopoly on the – traditionally lumbering – provision of safety and other medicines information and the discourse associated with therapy and safety. Some official

34 An excellent study in South Africa demonstrated how much patients liked pictograms and were able to interpret their meaning accurately. Local adaptations of international sets were found to be much more reliable in their interpretation than the international originals, reinforcing again the intimate knowledge of local audiences which effective communication requires.

35 The tyranny of annual budgets and the ostensible achievement of preliminary targets (indicators of change, for example) tend to lead to short-term commitment. Such was the case in Thailand with the brilliant safe sex campaign of the early 1990s – as a result of which rates of condom use and HIV infections showed enormous improvements (increase and decrease, respectively), but the campaign was abandoned in the belief that its aims had been achieved. Since then condom use has dramatically declined, and the rates of HIV infection have soared.

efforts have recognized and embraced the opportunity. Although the shop window of many authorities is bright and engaging, it is unclear as to whether the inner life of regulation and pharmacovigilance has been infected by the new dynamism, allegedly 'putting patients first' – a slogan touted universally in the last decade or so, but still a profound and unmet challenge to bureaucratic arrogance and inertia in many places in many respects.

Subversion of bureaucratic protocols and routines is one way in which negative organizational impact on clients may be moderated: there is a wonderful study of 30 nurse advisors in one NHS Direct site who were interviewed, with observation of the call centre and analysis of routine monitoring data also carried out.[96]

> ''*The data revealed that respondents' behaviour was deceptive, giving the appearance of being controlled and standardized but in reality representing that of a professional working autonomously. By casting the encoded knowledge as a source of risk, respondents were able to invoke the use of professional judgement to manage the risks it posed. Informal risk management strategies and a focus on individual rather than organizational needs enabled respondents to subvert managerial control*.''

The championing of individual needs against the grain of bureaucratic priorities is sometimes an ethical imperative and one is tempted to cheer this finding to the rafters. However, enthusiasm is somewhat dampened by the knowledge that, more often than not, those in oppressively managed organizations, identified as defying the rules quietly or loudly (even with demonstrable, ethical benefit), are likely to suffer serious consequences. A considerable literature records the extent to which open communication about risk in healthcare is suppressed (in operating theatres, for example, where even with high profile protocols to anticipate and prevent error, lack of critical engagement with the process undermines its effectiveness[52]) and that fear of speaking up, even amongst senior people, in all kinds of organizations, threatens safety and ethics in many human activities.[97] This is a high priority for reform.

Summary of Potential Flaws and Failures in Bureaucracy

1. *Goal displacement:* loss of mission and purpose; defensive stance; organizational self-enhancement; survival.
2. *Rigidity:* routinization; failure to change with changing needs; incapacity to address complex variables and needs and exceptions; box-ticking mentality; oversimplification of messages; downplaying of risk and uncertainty; risk of scams and workarounds.
3. *Red tape:* over-reliance on complex and burdensome paperwork or electronic equivalents; delays and barriers to access.
4. *Employee alienation:* devaluation of individuality; autocratic management; powerlessness; individual discretion proscribed.
5. *Internal conflict and territoriality:* 'silo' mentality and conflict; diversion of energy and resources; threat to organizational mission.
6. *Accountability:* limited to all but inescapable legislative requirements and crises; non- or anti-democratic.
7. *Waste:* time, materials, resources, opportunities in meetings, diversions, pet projects, irrelevances.
7. *Vulnerability:* patronage, nepotism, corruption, short-termism (political appointments).
6. *Outcomes:* highly variable; often ponderous and slow; reflect managerial or technocratic perspectives rather than market-focused values; may offend standards of equity, transparency, social justice.

In bureaucracies, policy is usually imposed from the top, whether it originates from ministerial directives, legislation or the board room, with all the risks of flaws arising from autocratic, managerial, paternalistic or hierarchical prejudices, except in those organizations with more dynamic and participative cultures. Such top-down imposition inevitably meets a range of significant obstacles to smooth implementation, especially when it challenges 'the way we do things round here,' is unpopular, is under-resourced, appears out of touch with the demands of day-to-day operation or is practically unenforceable. Such has been the fate of spontaneous reporting and regulatory warnings in many parts of the world. The reverse process is also evident: accurate and transparent information generated at lower levels of an organization (in relation, for example, to an emerging new risk) may be watered down or distorted as it rises up a hierarchy and emerges, in public, as something quite different. The most powerful and enduring changes tend to come from the grassroots, where the passion and commitment generated by real-life

challenges are fostered. Officialdom does not always respond favourably to such initiatives although they may demonstrate the kind of genius that policy makers sometimes lack and can offer immense improvements.

> *"Government proposes, bureaucracy disposes. And the bureaucracy must dispose of government proposals by dumping them on us."*
>
> P.J. O'Rourke

There are many stories of the success of this upward pressure for change, either from inspired local initiatives,[36][26,98] (which may improve on official policy[37][33]) or the adoption of radical new thinking such as that found in TeamSTEPPS[99] or the CDC's 'Speak Up' campaign[100] (where the purpose is to encourage patients to exert constructive inward or upward pressure). These often address a range of risks to patient safety which large organizations tend to generate: low staff morale and high turnover; poor communications and a suppression of divergent views or reporting of errors; a lack of shared sense of urgency; inhibited, fearful or alienated patients or customers, for example. It is clear that critical thinking and action at ground level are often essential to correct the deficiencies or unethical drift of bureaucractic organizations from their primary aims and duties. This, as a wellspring of inspiration and improvement, is often under threat and a deeply neglected resource.

Computer-based patient records (CPR) represent another very important advance to mitigate the problems and risks of bureaucratic paper-based systems[101] for patient safety, dispersed, as they often are, around multiple departments and health organizations, giving rise to all kinds of risks of duplication, adverse events, missed information and physical loss. (The risks of CPR, however, are not to be underestimated, especially when systems are hurriedly planned and implemented.)[102]

One final gift of technology for the benefit of patient safety, and a heads-up for action by regulators and academics, is the processing of risk information in ways which make complex statistics comprehensible and meaningful. One such example (among many) is a beautiful, animated visualization of a Cochrane Summary of Findings table,[103] presenting the benefits and harms of adjuvant radiotherapy after cervical cancer surgery. (This is from a splendid website 'Understanding Uncertainty' full of great ways of presenting risk and uncertainty visually and intelligibly.) Here is an imaginative and vivid tool for health professionals and patients to understand exactly what is known and what is not known, in ways that will facilitate clinical decision making and authentic, informed, individual choice. At last, the static, cherished, printed word of bureaucracies may be in retreat!

12. A Model System

Sparkling evidence that healthcare can be sustainable, compassionate, relatively safe and effective can be found all over the world. We will end with one example of an award-winning system which appears to have avoided all the potential traps of large, bureaucratic organizations,

36 In 2006, researchers at Johns Hopkins University published results of a 'programme that instituted in nearly every ICU in Michigan a simple five-step checklist designed to prevent certain hospital infections ... The results were stunning. Within 3 months, the rate of bloodstream infections from ... intravenous lines fell by two-thirds. The average ICU cut its infection rate from 4% to zero. Over 18 months, the programme saved more than 1500 lives and nearly $200 million.' The Office for Human Research Protections (OHRP) claimed that the programme was unethical and closed it down. The New York Times commented that the OHRP are "in danger of putting ethics bureaucracy in the way of actual ethical medical care." Hearteningly, local and Internet protest got the decision overturned, but one blogger commented: "as more and more regulations – many sensible but some asinine – are promulgated in the name of safety and quality, I hope the OHRP story kickstarts a process in which the regulators and the regulated collaborate to ensure that the ultimate goal of better patient care is being served."

37 "While the American College of Surgeons National Surgical Quality Improvement Program juggernaut rolls out across the continent, Dr Goldfarb has developed a quality-tracking system that is much less expensive and resource-intensive. It also appears to yield significant and reproducible reductions in mortality and morbidity."

and to have genuinely improved the health and welfare of its constituents. Southcentral Foundation[104] in Anchorage, Alaska, provides comprehensive care to nearly 60 000 Alaska Natives and American Indian people, many of whom live in areas accessible only by plane. Southcentral's customers own, manage, direct and design the system of care. Their President says: "... we intentionally design everything from our buildings and facilities, to our services and systems, to be responsive to the needs and values of the Native Community. Our customers drive everything." And the claim seems to be substantiated by the Foundation's local reputation and by receiving one of the prestigious Malcolm Baldridge National Quality Awards, 'the nation's highest Presidential honor for performance excellence through innovation, improvement and visionary leadership.'[105] The Southcentral story gives us hope that big organizations can be nimble, imaginative and responsive, and can meet the complex demands of healthcare with vision and humanity. The US Department of Veterans Affairs[106] is another organization belonging to this category of excellence.

13. Conclusions

It is clear that rational, lean, ethical bureaucracies focused on their primary service objectives, intimately in touch with their constituencies, can deliver effective results and value for money in the interest of individual users and society as a whole. This includes the rapid and effective assessment of risk and the delivery of comprehensive, intelligible and useful risk information. It is also clear that there are a thousand ways in which bureaucratic processes and bureaucratized organizations can put enormous obstacles in the path of effective, humane, safe practice, and transparent risk communication, and can squander huge resources of time, money and human motivation.

If the ultimate aims of all administration in healthcare (and no less in pharmacovigilance) are the intelligent reduction or management of risk and the safety and welfare of patients, then much has yet to be done to reform the attitudes, values and behaviour of bureaucrats, in government, industry, regulation and management. When, as for the nurse counsellors in the NHS, the intrinsic characteristics of the system itself can be judged to pose risks to safety, we can be in no doubt as to how much sweeping reform is needed. At the heart of reform is the simple question: 'What are we here for? How can we be sure that everything we do, every resource we employ, every procedure and communication we instigate, contributes to that single, ethical, core purpose?'

Summary of Major Areas for Reform in Underperforming Bureaucracies in Healthcare

1. Renewed clarity (or redefinition) and public declaration of primary organizational service, commercial or mixed purpose/mission, with staff and end-user engagement as integral elements.

2. Assessment and reform of all processes and relationships to align with the mission, eliminate distractions and create a dynamic, networked, inter-disciplinary (rather than rigidly hierarchical, departmentalized) culture; standards by which performance will be measured.

3. Declaration of standards relating to all activities, e.g. transparency, urgency, quality, humanity, flexibility, innovation, creativity, openness, internal and external engagement, minimal red tape, error reporting, and how performance will be assessed, including user opinion.

4 Staff development and training (including senior managers) in values, attitudes and behaviour which support the mission and a dynamic organizational culture; appraisal tools for assessment.

5. Strengthening the resources and authority of front-line presence for active and persistent engagement with users and audiences, including individuals, to discover their opinions and needs and to communicate with them in ways that meet their needs and support and enhance their health, performance or morale.

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