Expert Patients and the New Healthcare Paradigm

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A rapid escalation of the ongoing global power struggle in the US$3 trillion health sector [1] is challenging the status quo between global pharmcos, pharmacy industries and guilds, the all powerful fiefdoms of clinicians, government agencies, politicians and the health insurance industry.

This perfect storm is due to a unique combination of interconnecting drivers that collectively offer the winner, in this high stakes game, to take all. This would be achieved by acquiring control of the supply and cost of all medications and complementary products, as well as controlling the knowledge of what actually works for each and every patient according to their own genetic profile.

Informed consumers and expert patients are challenging the existing industry and government power blocs by taking control of their own health and demanding access to proven natural foods and products.

This contest of strength is showing all the characteristics of a dirty war as all sides start to realise the ramifications of winning and ramp up their efforts to grab the high ground and the knowledge asset acquired via the new electronic health records (EHR), by harvesting information from the data provided by the support services associated with it.

The primary driver for this power shift is the inability by Western governments to meet the direct costs of escalating health bills due to an explosion of modern day non-contagious epidemics with associated rising costs of products and services, plus the indirect costs to the economy due to loss of income from decreased productivity (days off work) and future income lost by premature death. For example, the annual cost of obesity (and its related conditions, diabetes, heart disease and stroke) contributes US$93 billion to the nation's yearly medical bill, [2] while in Britain, the financial impact of obesity is estimated to reach £45.5 billion per year by 2050. [3]

When the indirect costs of welfare and income tax reduction are factored into the equation, along with meeting the costs of a rapidly increasing ageing population (the over 65s are set to comprise 20% of the population in the USA by 2030), it becomes apparent that all Western governments, whether welfare or private healthcare orientated, will need to implement dramatic cost saving strategies if they are to survive the projected rate of increase in chronic disease and stay abreast of the next wave in "predictive and preventive medicine" – the new designer drugs tailored for genetically distinct groups that will tackle disease before you get it, ripening the market for long-term drug dependency.

Navigating the Third Healthcare Revolution

According to Sir Muir Gray, Director of Clinical Knowledge of the UK's National Health Service (NHS), we're moving into a 3rd healthcare revolution which will be knowledge-based, where the "knowledge [of what works] will become the enemy of disease". [4]

The first revolution was the discovery that dirty water produced disease; the second revolution was the discovery that chemicals could influence the course of disease, and this third revolution will be driven the new-found ability of knowing what actually works (of today's medications and procedures) for each and every individual and, more importantly, which emerging medical breakthroughs could work. Governments and insurers will take the lead of Sir Muir Gray, who says "the application of the knowledge we already

possess will have a bigger impact on health and disease than any drug or technology likely to be introduced in the next decade". [5]

In a bid to control the knowledge, governments, insurance companies, clinicians and pharmaceuticals are building their own electronic health databases to plug in everyone's medical records (and eventually every genome) in order to harvest the knowledge of which clinical procedures deliver the best outcome, the risks and benefits of drugs within given populations, environmental factors and geographic variations in disease and, most importantly, the cost-saving benefits or revenue generating capacity that this knowledge will bring.

The capacity to enter information into a database in real-time has far-reaching implications for all involved. The sharing of data across multiple parties, including general practitioners, specialists, clinics, hospitals and support services (pathology, radiology), not only provides the clinician with all the information relating to the medical events of the patient, but the benefits and risks of any new drug, product or procedure will be realized in a comparatively short time which will release those that pay and those that prescribe from the bondage of the pharmcos and manufacturers of new technology and enable more cost-effective treatments that achieve better outcome for patients. The UK government's expected cost of running the NHS's new IT systems could cost £40 billion by 2014, a huge increase on the budgeted cost in 2002 of £6.2 billion.[6] Where are the tangible benefits for patients?

To date most of these repository projects have run into problems due to the resistance of clinicians, who traditionally collect and effectively "own" patient information, to enter this data and share it with the owners of the new repository systems or, in many cases, even the patients themselves. However, this is not hindering the funding of these systems by governments as without access to this type of knowledge they have nothing to combat spiralling healthcare costs.

The insurance industry is also taking a keen interest in accessing the knowledge from these harvested repositories. In the US, health insurers Kaiser Permanente, which has 8.7 million members, employs over 13,700 physicians and runs more than 30 medical centres[7], has already established its own repository and through the harvesting of data can now offer treatment to members whose data indicate that they may be heading towards an adverse event, such as a heart attack, so producing large savings for the organization.

With the pharmaceuticals taking a keen interest in acquiring the harvested knowledge from these massive data repositories the battle for control is also touching on a range of issues regarding ownership of individual and collective data.

Each country seems to be tackling the issue of identity verification along similar lines using either national identity cards, welfare or tax numbers, whilst, at the same time, arguing for a national ID card or exchanges that can link multiple existing ID systems together for health and welfare. Much confusion exists around ownership and privacy where most governments and corporations seem to use privacy legislation as a reason not to provide information to citizens.

In order to avoid this tricky issue of ownership, a common approach is to allow personal information within a health record (including the DNA profile) to be sold without permission so long as the person's name is not included. This "de-identified" rationale falls down on two points: firstly, it is possible to reconstruct identities from these databases using new probability software; and secondly, current practices allow de-identified information to be sold by a third party, without the owner's permission, to multinational insurance companies, which, in effect, challenges the whole principle of ownership and legalises theft by corporate bodies.

Unless ownership of individual data and the range of issues surrounding the rights of access and use of aggregated data are established for the citizen and the common good, then the likely default position will be a few powerful multinationals controlling the knowledge in collaboration with governments.

In order to put the endpoint of this power game into context it's necessary to recognize not only the US$3 trillion industry that's up for grabs, but also the value of this new knowledge-based commercial asset. Although no reliable figures have been published of this knowledge asset, it's easy to estimate what the asset-value would be, and therefore the share value of a small group of multinationals controlling the very heart of this knowledge-based revolution.

This asset would contain the majority of individual medical records (including the knowledge of their DNA profile) within the Western world and, in particular, those individuals who either have the ability to pay for extended treatment or who can access the appropriate insurance.

The real asset value increases dramatically as it becomes possible to then match these findings with emerging genomic products. This provides the owner with the ability to offer personalized treatment for the existing chronic population of the Western world and the targeted market referred to as the "worried well" that would effectively become drug-dependent for the rest of their lives in the belief that they are taking preventive medicine.

Power Bloc Dynamics

To gain an understanding of these forces and to work out the implications of what happens if any particular party wins the high ground we need to understand the politics of power. Only then do the tactics and strategies of the dirty war become apparent and the darker implications for us all become blatantly obvious.

The three power blocks who currently vie for control are those who control the manufacture and dispensing of drug-related products, those who are authorised to diagnose and prescribe product-based treatments and those who pay which, in most western countries, tend to be government and/or insurance companies rather than consumers.

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The fourth emerging force represents the communities of common interest whose concern is to obtain knowledge of what actually clinically works for them in their specific condition. As the aggregation of this eco-group occurs it will gain the consumer power to counter the pharmaceutical industries, it will accrue the knowledge to challenge the diagnostic powers of healthcare providers and it will exert political power to either dictate policy change or even remove governments.

Most commentators are aware of the general dynamics between the three power blocks, but few have factored in the destabilising fourth power. Aside from any obvious outcomes of shift in power, such as a rise in prescription costs and insurance or a tightening of restrictions on the products we buy or the services we are granted access to, very little is said about the true ramifications for us, and even less thought is given to the not so passive emerging fourth power. Let's examine the potential for each group.

Manufacturers and dispensers

The stated goal of these players is absolute control of product supply and, if possible, the extended use of drug products for all which would include the chronic (33 per cent of Western populations[8]) and the "worried well". The most worrying aspect is that a strategy of dependency usually ends up as being multi-product based, often using pills to counter the effects of the original treatment.

All's fair in a corporate orientated world, some may say, where the share value is king, but a "sickness" industry singularly profits from increased drug-dependency and targets large markets with blockbuster drugs that generate 40%-45% of their revenue. Traditionally pharmcos ignore any innovative research into drugs that prevent, treat or cure, instead ploughing funds into a small range of blockbuster drugs which can generate revenues of over US$20 billion during the life-spans of their patents. [9]

As the bubble bursts, it is finally acknowledged by the pharmcos that beneficial outcomes are limited to only 33 per cent of users, and up to 50 per cent may not respond. They focus the blame for this failure on the variations in genetic make-up of individuals, where some people, for example, may metabolise the drug before it has time to act. However, the real cause of failure is that the clinical trials, funded by the drug companies themselves, use only carefully selected individuals that do not reflect the population for whom these drugs are aimed, such as those suffering from one or more chronic degenerative diseases, or the elderly. In addition, the studies may inaccurately reflect the true results of findings due to the vested interests of the authors or to a failure of reporting negative findings. [10]

Because scientific proof of effectiveness and safety in the broad community is not required for drug approval, the testing only truly begins when they enter the market place and are foisted onto a trusting public. With a meaningless reporting regime of adverse reactions in real-time, which provides absolutely no contribution to any evidence-based research that can be accessed by other clinicians, the consequences of adverse reactions have time to reap many casualties as was seen in the cases of both Thalidomide and Vioxx.

Also under the spotlight is the effectiveness of older, generic drugs (whose patents have expired) against newer drugs. Approval for a new drug is dependent upon achieving superior results than the drug it is replacing, or improved clinical outcomes when added to an accepted protocol. Pressure to replenish revenue streams with new patents as the old patents expire has led to inflated claims, and with no requirement to test the added-value of a drug in a real-life setting, it is difficult to prove these claims.

However, in 2002 when ALLHAT (Antihypertensive and Lipid Lowering treatment to prevent Heart Attack Trial) published its findings from a five-year trial involving 30,000 patients, no difference was found in the clinical outcome between using cheaper diuretics (thiazides) over the more expensive angiotensin converting enzyme inhibitors (ACEIs) and calcium channel blockers (CCBs). There was no difference in mortality but a greater incidence of adverse events was seen with the ACEIs and increased occurrence of heart failure with the CCBs, while the thiazides reduced the incidence of stroke and had better effects on lowering blood pressure. In spite of the negatives for the thiazides, such as reduced potassium and increased glucose and cholesterol levels, these did not lead to any difference in clinical outcomes and they appeared to modestly improve the outcome for most. As with most generic drugs, the cost for thiazides was only US$0.05 - $0.30 daily, while the other medications ranged from $1.15 - $1.50 daily. [11]

Although future negotiations between health care payers and the pharmcos will likely be based on clinical outcome, the pharmcos are looking to the emerging market of "predictive and preventive" medicine – the industry's definition of the "wellness industry" - where they will be able to predict predisposition through genetic screening and then prevent the disease with drugs before we become sick (this will also include mandatory vaccination programs). [12] Steve Burrill (of Burrill & Co, biotechnology company), predicts that when everyone's genome and medical records are plugged into the system that "in the future babies could be given a smart card when they are born and we'll add to that as they go through life." [13]

With new technology that can decode the human genome and identify the key signalling molecules (targets) linked with disease, and the capacity to make, test and screen 1,000s of new chemical compounds day in, day out, through building a library of millions of chemicals, it will be possible to match a drug with each new target as it is identified. By linking genetic variance to drug response, scientists will be able to determine which drugs will work best with each genetically distinct group. Peter Goodfellow of GlaxoSmithKline (GSK) says "We'd like to create a drug for every target in the human genome, so you could start with drugs, not the target." [14]

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However, supporting a strategy in the absence of research to understand the full implications of altering gene expression, that leads us down a route of greater drug-dependency is hardly intelligent, particularly as the WHO has stated that 80per cent of heart, stroke and diabetes and 40 per cent of cancer is preventable and that it is cheaper to prevent disease among healthy populations than to treat sick populations. Currently only 3 per cent of health care spending is used for prevention. [15]

Global pharmcos are also looking to capture the lucrative alternative health industry to annihilate competition and control product supply and consumer choice. Dirty tactics have so far involved government regulatory bodies and the Codex Alimentarius Commission, an international organisation that sets international standards and codes for foods, establishes upper limits for over the counter (OTC) vitamin and mineral supplement dosages, and reclassifies all products that have therapeutic action as medicines regulated under the various drugs acts.

The next stage will involve the patenting of new products based on natural products. Natural products cannot be patented, but what can be patented is the technology that isolates and measures the bioactivity of each discovered active compound of a natural health product and then replicates this in a laboratory. Hence we see the emergence of pharmaceutical versions of herbs (PharmaPrinting), nutritional products (Nutraceuticals) and functional foods based on a person's genetic make-up (Nutrigenomics). For investors to invest, market

exclusivity must be assured. We are already beginning to witness the banning of natural health products under the guise of consumer protection, and there are already indications that we are heading towards a situation where it would be illegal to grow herbs in your own back yard on the basis that they are dangerous. The endpoint for the pharmcos is to capture all the indigenous markets (Chinese, Ayurvedic, South American, African etc.) who have used traditional herbs for centuries and convert them to patented products that have passed all the testing, standardization and scientific proof required for all drugs. [16]

Clinicians and prescribers

Often referred to as the priesthood, this highly fragmented group of clinicians seek to control the ownership of the relationship with the patient, the prescribing of drugs, the procedures that are used and the acquired knowledge of their application. Their collective stance of non-collaboration (although not shared by all clinicians) in government health initiatives to establish an EHR not only reflects this desire to control the ownership or copyright of patient records, but also an unwillingness to be accountable for decisions made on the patient's behalf. EHRs will enable the auditing of all decisions and trace major mistakes in general practice and hospital management.

An additional pressure will come from patients who will expect to have access to, or be advised on, the latest clinical evidence when making choices in treatment. Sir Muir Gray states that whereas "the clinician was the driving force in the 20th century, the patient will be the driving force in the 21st century." [17]

At this turning point, clinicians can either submit and become glorified pill dispensers (as described by the then British Prime minister, Mrs Thatcher) or they can take up the challenge and use what's left of their credibility and trust to help patients as advocates and assist them in harvesting the knowledge of what works. As attitudes to the profession change, the intimidating paternalistic stance that was once their hallmark will no longer be acceptable as patients demand the respect they deserve when making critical health decisions.

Governments and insurers

With health insurance costs set to rise by 6.5 per cent annually (an estimated US$1.00 of every US$5.00 spent in the US on healthcare), with statistics indicating that more people in the USA per annum are dying from medical errors (approx. 195,000 in 2000-2002[18]) than from breast cancer, AIDS or motor vehicle accidents, [19] and with the predicted rise in chronic disease set to affect 50 per cent of populations in developed countries,[20] governments and insurance companies are looking to drive the costs down, increase their profits and get better patient outcome.

Reducing costs means extricating the industry from the stranglehold of those that control prescribing - the pharmocs and clinicians. A rapid deviation from the scientifically-based model of healthcare to one that is clinically-based will demote the "scientific evidence" mantra that governed healthcare policy in favour of what actually works, whether scientifically proven or not. With the EHR initiative, governments and insurers will be able to accelerate the diffusion of clinical research information to sponsors, researchers, regulatory bodies and the medical community at large, systemise healthcare by defining and controlling procedures including the rules on what can be prescribed for any condition, and control what products can be used accordingly. They will then be able to aggregate the demand and negotiate cheaper prices.

The UK government has also tapped into the frequent flyer market of patients with chronic conditions who make the most visits to GPs and hospitals. The Expert Patient Programme [21], an NHS health initiative where a certificate of competence is issued after a 6-week course of 2.5 hours per week, simply replicates the self-management advice that self-help or support groups have been offering for decades, but through the formalisation and adoption of the program (20,000 people have already taken part) has been able to show measurable benefits both on improved quality of life and cost-savings for the health budget. Tangible results demonstrate a reduction in visits to GPs and other health professionals by 44-80 per cent by various groups, and a 31 per cent reduction in hospitalisation for asthma sufferers. [22]

The expert patient - Pandora's box

Although there are short-term benefits of shifting management of chronic conditions back to the consumer, the long-term implications of endorsing groups of highly motivated people have not been factored into the health equation.

Under the government and pharmco model, the "expert patient" is drug-compliant and therefore more cost effective and profitable. However, virtual community groups in increasing numbers are communicating their views and their own knowledge of what works for them over the Internet, and with the availability of the new, free, open source software and tools, these groups will be able to gather, store, harvest and share knowledge themselves, and become better informed and more responsible for their health – a threat to the system, indeed. With the new emphasis on clinical outcome, as opposed to scientific evidence, comparison studies between mainstream and complementary medicine may be published and present new challenges to conventional healthcare.

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The driver for this wave in consumer power is the cost of treatment, the reduction of disposable income, a loss of confidence and trust in the medical industry and, more importantly, the realisation that health is spiralling downwards and not a cent is being spent on addressing the causes. This group does not want to be drug-dependent, does not want to see their children suffering chronic conditions: they want to own the right to be healthy and any move by governments or pharmcos to inhibit access to natural food and health products or therapies that have proven benefit will be met with fierce and co-ordinated opposition. Likewise, this group will strongly resist and fight for the power to deny consent to any group – government, pharmco or clinician - or even any IT company such as Microsoft or Google which stores health records to data-mine or de-identify these records for the on-selling to corporations who seek to control and influence the market.

With a growing consensus that failure to address the key causes of our decline - environmental pollution and nutritional depletion - will drive us deeper into a cul-de-sac, this fourth consumer power will succeed in destabilising the current balance of power. When the core message from the three power blocks – "We think we can help you manage and take responsibility for your condition that we created and, if able, to have you pay for it" - finally dawns on the majority then the wave towards true preventive medicine, to manage your own health before you become sick, will become the new mantra.

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