Enabling Technologies
Mobile Helps to Successfully Integrate Patient Engagement into Global Clinical Trials

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The Case of Schizophrenia Patients

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Global leaders in patient adherence solutions. Running 80+ programmes in multiple markets.
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Dr Kate Perry of Atlantis Healthcare discusses why medication non-adherence is something which must be addressed, and why the responsibility to improve adherence sits across all healthcare stakeholders.

16 Symptom Checker – The Pivotal Tool for Patient Engagement
It is becoming increasingly obvious that patients are a vast, untapped resource for healthcare professionals. Provided with the appropriate tools, patients could be doing a lot of useful work before they even arrive at their consultation. Rather than complaining about patients coming in with lists or printouts, doctors should be channelling their patients’ energy and motivation into saving them time and making the consultation more productive and, therefore, satisfying.

Jason Maude of Isabel Healthcare Ltd. explains why the proponents of patient engagement should realise that an engaged patient must also be an informed and empowered patient, and tools must be provided to the patient to help them make sense of the information.
Issue of patient adherence is complex and involves interacting dimensions of patient-related factors, social/economic factors, condition-related factors, therapy-related factors, and health system/healthcare team factors. In other words, the nature of the adherence beast is multi-faceted and inherently interdisciplinary. Expert advice informing best practices to improve patient adherence is needed from healthcare-related clinicians, mental health experts, sociologists, social workers, epidemiologists, health-related researchers, and policy-makers. Miki Peer of MEMOTEXT Corporation argues that a more appropriate term for how adherence should be properly viewed then may be transdisciplinary, i.e. adherence requires a holistic approach, one that seeks to integrate knowledge from all related disciplines into a coherent whole.

Evolving Shifts in Patient Adherence Through a Digital Society

With about 80 per cent of chronic patients online in a global digitally networked society, new paradigms and methods evolve when talking about patient adherence programmes. The tailoring of content, the wisdom of the crowd effect, or the online community of practice phenomena are examples of new qualities of the mass medium called “internet”. Alexander Schachinger of healthcare42.com analyses that what the media and FMCG economies already use on a daily basis has not even been understood in the healthcare sector, as regards the huge potential which rests here in improving patient adherence.

Enabling Technologies: Mobile Helps to Successfully Integrate Patient Engagement into Global Clinical Trials

Increasingly, all phases of clinical research rely on patient-reported outcomes to provide accurate information on the status of a patient’s health condition and how they are being affected by certain treatments. Used widely to support post-marketing labelling claims, PROs give researchers invaluable information on the effects of a drug. Electronic data collection facilitates secure, instantaneous monitoring, as well as providing the ability to track and trace trials in real time, allowing sponsors to identify and respond to any concerns as they occur. This article by Tim Davis of Exco InTouch and Tony Kane of Vodafone Global Enterprise focuses on the rise of mobile technology in the ePRO arena. It looks at how its deployment can aid cost-efficiency and secure patient adherence to medication regimes, particularly within global clinical trials.

Cognitive Behavioural Hypnosis for Sleep

Sleep disorders may range from the familiar insomnia, to the less frequent narcolepsy, with many other types in between, identified for their medical and psychological morbidity. Inasmuch as hypnosis employs the power that may be exerted by the mind to influence the actions of the body, a skilfully prepared hypnosis can be an effective therapeutic treatment for those variations of sleep disorder that respond to such. For disorders of a more organic nature, medicinal preparations or procedures may prove to be the desired treatment, or a combination of treatments may be called for. Richard A. Blumenthal, a New York State Licensed Mental Health Counsellor focuses on the use of hypnosis capable of helping a patient who is experiencing difficulty with some aspects of what one would expect to be healthy sleeping habits.

Effecting Change, Affecting Lives: The Case of Schizophrenia Patients

Patients with psychosis, such as schizophrenia, often suffer from poor life quality, deteriorated functional capacity, and the burden of social stigma and other socioeconomic pressures. Even though pharmacological treatment may provide psychotic patients relief from disturbing symptoms and enable them to gain greater control over and satisfaction with their lives, a huge percentage of them fail to comply with it during part or all of the process. Zoe Tziakou and Constantina Georgaki of PCC HELLAS explain why now is the time to turn to a multidisciplinary approach through coordinated action by health professionals, researchers and policy-makers to achieve better benefits for all concerned.
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MODERN TECHNOLOGY
36 Harnessing Technology to Improve Patient Outcomes Through Engagement
Changing the focus of how healthcare is delivered has become an imperative for developed economies. These changes are exemplified by the pace of reform that is happening in both the US and the UK. With ever greater proportions of national gross domestic product being spent on healthcare, and an ageing population, it is clear the status quo is no longer an option if we are to remain economically viable nations. Legislation through the Patient Protection and Affordable Care Act in America, and the Health and Social Care Bill in the UK, both have at their heart a fundamental shift in how providers of care need to operate. Peter Mills of nGage Health explains that the central tenet of reform is the migration away from an episodic, transactional approach to healthcare delivery, to one where greater emphasis is placed on total population cost containment and demonstrable outcomes.

40 Challenges and Opportunities from Worldwide Serialisation Initiatives
What if there was an ethical way to engage with individual patients using tools they are already comfortable with and processes that will in any case be mandatory in pharmacies and production plants? It would certainly be a great place to look for new gains in compliance and persistence. Mark Davison of Blue Sphere Health argues in this article that one of these new processes - pack-level serialisation - will have multiple benefits for health outcomes as well as for product security.

44 Paperless NHS Timescales are Meaningless
That smart technology could save the NHS £billions is not disputed. The very real danger is that the recommendations being made today (and being budgeted for out of our taxes, now) simply won’t be relevant by the time they are implemented. And there lies the challenge for the public sector, and the NHS specifically. Many commentators have previously identified that Government projects follow Parliamentary timescales and agendas, yet few have the ideas, the solutions and the conviction to propose tangible actions that will make a difference to us all in the short and medium term. Edward Shropshire of Aquarium Software looks at the NHS vision and how to best implement it.

DRUG DELIVERY, DRUG PACKAGING, LABELLING & DISPENSING
50 Compliance Against the Odds: Keeping Pace with the Complexities of an Ageing Population
In spite of MDS becoming common parlance in caring circles, myths about what monitored dosage systems can and can’t do continue to muddy the waters among decision-makers. As technology continues to progress apace, the creator of the first ever monitored dosage system, Norman Niven of Protomed, brings us up to speed on the truths and myths of MDS and the relationship between compliance and dementia care.
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Adherence Stats
Studies show 50% of U.S. patients do not take their medicines as prescribed. Non-compliance has been associated with as many as 125,000 deaths per year.

- 10% of older adult hospital admission
- 40% of admissions to nursing homes
- 20% of cases of preventable adverse drug events
- 33-63% of medication-related hospital administrations
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Quality healthcare outcomes depend upon patients’ adherence to recommended treatment regimens. Patient non-adherence can be a pervasive threat to health and wellbeing, and carry an appreciable economic burden as well. In some disease conditions, more than 40% of patients sustain significant risks by misunderstanding, forgetting, or ignoring healthcare advice. While no single intervention strategy can improve the adherence of all patients, decades of research studies agree that successful attempts to improve patient adherence depend upon a set of key factors. These include realistic assessment of patients’ knowledge and understanding of the regimen, clear and effective communication between health professionals and their patients, and the nurturance of trust in the therapeutic relationship. Patients must be given the opportunity to tell the story of their unique illness experiences. Knowing the patient as a person allows the health professional to understand elements that are crucial to the patient’s adherence: beliefs, attitudes, subjective norms, cultural context, social supports, and emotional health challenges, particularly depression. Physician–patient partnerships are essential when choosing amongst various therapeutic options to maximise adherence. Mutual collaboration fosters greater patient satisfaction, reduces the risks of non-adherence, and improves patients’ healthcare outcomes. It goes without saying, perhaps, that patients must understand what they are supposed to do before they can follow medical recommendations. Thus, patients’ health literacy is central to their ability to adhere. According to Healthy People 2010, health literacy involves the “degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (US DHHS, 2000, p.20). Studies show that the risk of non-adherence is very high when patients cannot read and understand basic written medical instructions. Misunderstanding of this type is not as uncommon as one might imagine. One large study of over 2500 patients found that nearly one-third had marginal or inadequate health literacy. Of these, 42% misunderstood directions for taking medications on an empty stomach, 25% misunderstood the scheduling of their next appointment, and nearly 60% were unable to read and understand a typical informed consent document (Williams et al., 1995). Language barriers contributed somewhat to these limitations, but even when patients could understand the language of their medical instructions, many could not comprehend the medical information. Further, older patients in this study had significantly more problems understanding their medical regimens than did younger patients. Other studies confirm these trends and indicate that our current interventions aimed at increasing health literacy to improve patient adherence have, so far, been disturbingly ineffective.

Journal for Patient Compliance has accumulated a fantastic array of methodologies and best practice guidelines in this issue, which will help you to understand the evolving shifts in patient adherence in today’s digital world. Carole North, Managing Director of 90TEN Healthcare, kicks off this issue with lessons in behavioural change - shaping the brain’s responses. Peter Mills of nGage Health explains harnessing technology to improve patient outcomes through engagement. Zoe Tziakou and Constantina Georgaki of PCC HELLAS look into affecting change and affecting lives of schizophrenia patients.

I hope you all enjoy this issue of JPC, and acquire some insightful knowledge from the many experts in adherence management.

Mark A. Barker
the art of

behavioural change

There's no one-size-fits-all solution to address the complexities of medication adherence.

To change patient behaviour for better health outcomes, it is imperative to understand the evidence base for patients who are intentionally and unintentionally, non-adherent. It is then vital to connect them with personalised interventions that are relevant, timely and will motivate them to change their individual health and treatment beliefs.

As recognised industry thought leaders, 9OTEN Healthcare has over 10 years’ experience designing and delivering award-winning patient adherence programmes.

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Lessons in Behavioural Change

A client recently asked me how long it takes to form a habit and how we can affect real behavioural change through a patient support programme. When you consider how many people give up on their New Year resolutions before the end of January, which are often health-based (to drink less, quit smoking, lose weight, do more exercise), the explanation could be applied to our personal agenda as well as to supporting patients to take their medications at the right time, in the right dosage.

Shaping the Brain’s Responses
In order to understand how habits are formed, a basic knowledge of neuroplasticity is useful. Put simply, neuroplasticity is the brain’s ability to restructure itself after a period of training and practice. The scientific principle is that when neurons in the brain activate at the same time as a response to an event, they become associated with one another and form stronger connections. The more we repeat something and use that portion of the brain in a focused way, the more new neural pathways develop in the brain.

If, for example, you view a functional MRI of the brain of a pianist who frequently practises, it will appear that he or she has a larger area of their brain devoted to mapping their fingers. This change is directly related to the volume and quality of their practice schedule. Conversely, if a skill or habit is not practised, the space is used by other pathways that need to grow, for example for memorising routes, or learning new skills or facts.

66 Days to Form a Habit
Studies with 96 volunteers monitored over 84 days concluded that it can take anything from 18 to 254 days, depending on the individual, to form a habit. As habit can be characterised as a form of automaticity that involves the association of a cue and a response, the point at which the automaticity was highest and, therefore, the habit formed, was on average 66 days. ¹

A study using neuroplasticity-based cognitive training on schizophrenia patients, showed that 50 hours of training improved verbal learning/memory and cognitive control that endured for six months after the training.²

Behaviour Change Techniques to Form a Medication Adherence Habit
Because patients have their own views and experiences regarding their disease and treatment, they require support to adopt new behaviours and habits.

To effect real behaviour change you need to understand three basic things about your patient:
- **Barriers**: What is stopping them from adopting the new behaviour?
- **Triggers**: How can you get them to start a new behaviour?
- **Motivators**: What will help them continue with the new behaviour?

Once you have this information you will need to follow a process that supports the adoption of the new habit:
- **Step 1**: To raise awareness and encourage acceptance of the behaviour the patient needs to adopt, they will first of all need to understand why this is relevant to them. At this point the patient will need information about their condition, their medication and what it can do to improve their condition, and details of how they can self-manage by making lifestyle changes.
- **Step 2**: Making it appear to be easy is the next step. Does your patient understand and feel confident...
So the next time you wonder why you haven’t managed to keep to your gym schedule, you might find applying these behaviour change processes helps you form your new habit!


Step 3: Make the behaviour change desirable. In order to do this, you need to consider how it fits with patients’ self-image and how they relate to others (or want to). Because we are social animals, we tend to emulate the lifestyles and habits of people we respect and follow societal norms. Patients often feel isolated, and this is why they seek out online groups where they can share their experiences with others in similar situations. It’s important that the information you provide to patients illustrates the adherence behaviour as the norm.

Step 4: Trigger an element of payoff by making the new behaviour rewarding. Reassure them that they are doing the right thing even if they don’t see any change. This is particularly relevant if the patient has an asymptomatic condition such as osteoporosis, hypertension or hyperlipidemia.

Step 5: Reinforce the benefits of the behaviour by reminding patients why it is important. This will help them form a habit that they’ll want to keep doing. Adherence programmes targeting children often include games and stickers for milestones, while more sophisticated techniques can be utilised with adults.

So the next time you wonder why you haven’t managed to keep to your gym schedule, you might find applying these behaviour change processes helps you form your new habit!

References

Carole North is co-founder and Managing Director of 90TEN Healthcare. She has over 11 years’ experience delivering programmes that increase adherence to treatment by empowering patients to change their health beliefs and behaviours, supporting HCPs to manage those patients, and developing initiatives that help reduce acute hospital admissions. 90TEN Healthcare consistently wins awards for its adherence, concordance, experiential and social marketing campaigns, and is currently delivering patient adherence programmes in 23 countries. Email: carole.north@90ten.co.uk
Turkey is emerging as one of the new consumer markets in the global healthcare arena. One of the biggest changes to create the push in the Turkish healthcare market is the stability of the political environment, with a new government making its greatest focus on healthcare. With its 74.7 million-strong young population, Turkey is expected to be transformed to a huge health consumer market after 2015, whereas developed western markets are aging and saturated.

Turkey has gone through various stages in the last 30 years of its history, transforming from a closed economy and unsettled democracy to a significant global actor with rapid socio-economic development prospects and a highly urbanised society. The country’s GDP achieved 780 billion USD in 2012, as opposed to 200 billion USD in 1990, and it is among the fastest-growing economies in the world. Per capita income is expected to see a 2.5-fold increase to $25,000 by 2025, from $10,000 in 2010. Healthcare has been the greatest focus of the current Turkish government which came to power in 2002. Right after this, the government launched the health transformation programme, with the aim of providing extensive healthcare services to the Turkish citizens right from birth to old age, to enhance regional healthcare policies, and to upgrade healthcare services to modern standards.

Driven by the healthcare reform and private investments, healthcare spending of the country is expected to achieve 62.7 billion dollars in 2015, which is double the amount of its spending back in 2006.

Turkey has a 74.7 million-strong population, young but aging. By 2020, the number of working-age people from 35 to 64 years old will reach 30 million in the country, and 76% of its population is expected to live in urban areas. Today’s Generation Y will be the key target healthcare consumer in the next decades, and they will redefine the healthcare market in Turkey, with their techno-savvy behaviour, consumerism and high awareness of health.

In parallel with its economic growth, after the 2000s, Turkey has gone through a significant socio-economic transformation, especially felt in its largest cities such as Istanbul. To give an example of the impact of this socio-economic transformation in the country; by 2013 there are 67 million mobile owners and 40 million 3G subscribers in Turkey, which is one of the highest figures in the world. According to telco operators’ forecasts, by 2015, 5 million personal health monitor and mobile phone devices are expected to be connected to each other through the mobile health services systems, and the biggest telco operators are investing heavily in this currently.

However, despite the growth of the middle class in the country, Turkey is a country with a very high income gap and socio-economic diversity. By 2011, 44% of the population were classified in the poor class, but this is expected to drop to below 25% in the next two decades. While there is vast consumer potential in cities like Istanbul, the buying power and awareness is still very low among non-urbanised regions, and they are totally dependent on government insurance. However, along with the development of the economy, the income gap is also expected to lessen in the future.

Although the key health indicators improved significantly in Turkey in the last 10 years, as in every other developing country, the prevalence of lifestyle diseases is increasing as well in Turkey. By 2015, it is estimated that there will be almost 9 million diabetes patients in Turkey, and 24 million hypertension patients. The key health indicators of Turkey improved within the healthcare reform period, whereas rapid socio-economic
Another significant outcome of the health transformation programme of Turkey consists of nine components to cover the healthcare system with all its dimensions. The basic component of the programme is a general health insurance scheme covering the entire society under one umbrella. While the government’s healthcare budget doubled during the reform period, the coverage of public insurance increased to 90% of the society by 2012, from 50% prior to 2003, whereas penetration of private insurance in Turkey remained at 3% of the population, which is much lower than its western counterparts. Increasing coverage of public insurance, on the other hand, created a heavy burden on the government budget, which was reflected as huge price pressures on pharmaceuticals and medical device companies.

Another significant outcome of the health transformation programme has been the increasing quality of healthcare services in the country. Between 2006 and 2010, the number of private hospitals increased by 86%, and public hospitals by 9%. Encouraged by the hospital modernisations under healthcare reform, the rate of qualified beds increased from 12% in 2002 to 40% in 2011, whereas the installed base number of MRI units increased 12-fold from 58 to 781, and CT units 2.5-fold from 323 to 1088.

Despite its gaps and challenges, the health transformation programme in Turkey has achieved its objectives and led to huge changes in the Turkish healthcare system. Many of the current applications, like a national health information system, would seem quite utopic only a decade ago. Healthcare will definitely continue to be the greatest focus of the government in the next decades. Currently, a very active health promotion programme is being implemented by the government in Turkey against obesity, smoking and inactivity. The government aims to reduce obesity from the current 32% to less than 20% by 2023, and smoking from 27% to 15%, and is launching strong national programmes to implement preventive services against cancer, diabetes and cardiovascular diseases.

Another project in the government’s current agenda is the establishment of huge health campuses. To enhance regional development, the government identified 29 key regions and, in the form of a public-private partnership, huge and ultra-modern health complexes will be built in those regions, with around 3000 bed-facilities containing every element from R&D centres to recreation sites. The tender process is expected to finalise this year, and this project will reshape the healthcare industry in Turkey, starting a totally new era of services in public hospitals.

Along with the ongoing healthcare reform, as the emerging hotspot in the global healthcare market, the country received significant global investment in various healthcare segments such as private healthcare services, medical devices and pharmaceuticals. After 2010, many companies like GE and Siemens Healthcare converted Turkey into their CEEMENA headquarters, whereas Turkey’s biggest private hospital groups - Acıbadem Health Group and Medical - were acquired by Malaysian Integrated Healthcare Holdings and Caryle Group respectively. The total healthcare market in Turkey, covering private health services, pharmaceuticals, medical devices, medical imaging and clinical diagnostic segments, is expected to arrive at 29.6 billion dollars revenue, at a compound annual growth rate of 8.2% by 2015. In 2011, the top ten private hospital chains in Turkey comprised 30% of the private healthcare services revenues of 10 billion dollars in Turkey, whereas the Turkish pharmaceuticals market was the sixth largest in Europe, with its 13.5 billion USD revenues.

Turkey has a lot of potential for all types of companies across the spectrum. Turkey has always been regarded as a research and development hub in the healthcare industry and now, for everyone it is time to see Turkey as a huge and mostly unsaturated consumer market with a significant amount of opportunities in providing healthcare services, innovative healthcare technology devices, as well as significant opportunities for pharma and clinical diagnostics companies.

Ms Hilal Cura attained an MBA from Bilgi University (Istanbul, Turkey) and BS in Business Administration Bilkent University (Ankara, Turkey). With 9 years of sales and market research expertise in cross industries such as Healthcare, her particular expertise and interest are Marketing & Sales Development Strategies, Market Intelligence, Market Research and Qualitative Analysis. Her career highlights are; conducting market research reports/ grown consulting studies in healthcare (across industries) and several years of sales/ marketing experience in retail business.

Email: hilal.cura@frost.com

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Journal For Patient Compliance: Strategies to enhance Adherence and Health Outcomes 11
The Adherence Groundswell – Why Healthcare Professionals are Taking Notice

“As the global population ages and more people take a growing number of treatments for their long-term conditions, healthcare professionals (HCPs) are taking the issue of medications non-adherence increasingly seriously,” said Atlantis Healthcare lead health psychology specialist, Dr Kate Perry.

“Between a third and a half of prescribed medications for long-term conditions are not used as recommended, resulting in a high cost to both the patient and the healthcare system,” said Dr Perry, speaking to an audience of healthcare professionals and academics at the Australasian Society for Behavioural Health and Medicine Conference recently.

In New Zealand alone, the cost of medication non-adherence has been estimated to be between NZ$550 and NZ$720 million per year, said Dr Perry in her talk, entitled: “Understanding Medication Non-adherence: Summarising 50 Years of Research.”

In the UK, NICE estimated that around £4 billion of medicines supplied on prescription through the NHS are not used correctly, and a total of 4.6% of global total health expenditure (THE) or $269bn worldwide, can be avoided from better adherence to medicines1,2.

Such are the rates of medication non-adherence around the world, the World Health Organization describes medication non-adherence as a global epidemic.

Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments, it has said.

An alarming percentage of people discontinue their medication for chronic conditions after just six months, ranging between 34 and 72 per cent, according to a collection of studies, says Dr Perry.

Dr Perry discussed the reasons why patients may not take their medication as prescribed. Intriguingly, patients not only forget to take their medication, but also choose not to take it for a variety of reasons. “Taking medication means different things to different people. For some, it serves as an unwanted reminder of poor health,” said Dr Perry. Often when taking a number of treatments, the process can be quite complex, or perceived by the patient as quite intrusive, she explained. “Patients might not take the right dose at the right time or under the right conditions, with a meal for instance.”

A dislike or fear of side-effects was another important reason for non-adherence.

“There is a general wariness about side-effects, whether real or perceived,” said Dr Perry.

“If a patient experiences a side-effect, they may think: “Is this treatment worth it for me?” And evaluate whether or not to stay on the treatment.”

Then there are those patients who don’t think their condition is serious enough to warrant regular medication. Those suffering from largely asymptomatic conditions such as high cholesterol are often in this group.

“You don’t see or feel this condition, so you don’t see or feel the medication working” said Dr Perry. “You see it with osteoporosis too, another largely asymptomatic condition.

“These types of chronic conditions can be hard for people to conceptualise. Some people believe they can solve their health problems wholly through a change in lifestyle.

“People think if they can just manage their lifestyle better through exercise and diet, they can cure their conditions by themselves,” said Dr Perry.

When people opt out of taking their medication as prescribed, it is an individual decision, often made without consulting a healthcare professional. The patient may be researching their condition online or talking with their friends about it.

“Patients are choosing not to take their medicine for whatever reason, and from the patients’ point of view these reasons are logical and make sense. These patient beliefs are important and are a big part of the reason why health psychologists have made the field of treatment adherence their own,” she said.

The term adherence, said Dr Perry, which more HCPs are moving toward, refers to a much more collaborative method where the doctor and patient agree on how to treat the illness together. And if there is failure to
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adhere to the medication, there is a joint responsibility. “The patient has often done their own research on their situation and has their own ideas about what can be done. You could argue, they have been living with this condition, that they are experts in their condition,” said Dr Perry. “Adherence is about the coming together of doctor and patient – it is much more respectful, and it empowers the patient to take responsibility of their condition and their treatment,” she said.

With this in mind, there is a multitude of patient-directed, evidence-based ways to help improve medication adherence. Electronic and mobile health solutions can be delivered by email or smartphone, for doctors who are time-poor, she said. Pharmacists are also playing an increasingly important role in picking up on non-adherence, especially with patients who are living with long-term conditions.

If patients are not managing to pick up their script, pharmacists can help by sending it out and they can also talk through any concerns the patient may have about taking the medication. Meanwhile HCPs looking to solve the situation must be aware that they cannot offer a “one size fits all” approach, warned Dr Perry.

Each patient must be treated on an individual basis. Atlantis Healthcare develops and delivers patient support programmes that are truly patient-centric, she said. “Patients’ reasons for non-adherence are elicited and then addressed through the provision of individualised interventions. More than this, interventions are delivered across multiple channels, depending on the preferences of the patient. A patient might receive something in the post or receive a call from a nurse, or the nurse may deliver the intervention in their home. “This personalised approach to both the intervention content and the delivery channel is quite exciting; there are big opportunities,” she said.

Dr Perry said there is now a real acknowledgment that medication non-adherence is something which must be addressed, and the responsibility to improve adherence sits across all healthcare stakeholders.

Pharmac, the New Zealand government’s drug-buying agency, is recognising the issue of medication non-adherence, having put out a request for more information around adherence services in January this year. Momentum is also gathering in the UK. The NHS is facing unprecedented resourcing pressures; by 2050, 40 million people in England are expected to suffer from non-curable long-term conditions that require management through medication. Better patient adherence is heralded as the way forward to ensure patients can get maximum value from their treatments.

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2. IMS (2012).

Dr Kate Perry, Lead Health Psychology Specialist (full-time). Kate is a registered psychologist with over 10 years of experience working within the healthcare sector. Kate obtained her MSC in Health Psychology from the University of Auckland and completed her doctoral qualification in Clinical Psychology at the University of Surrey. Prior to her work with Atlantis, Kate worked in NZ and the UK as a clinical psychologist specialising in neuropsychology assessment and intervention. Kate is particularly interested in the application of psychological strategies to help patients manage specific difficulties including pain, fatigue and stress.

Email: Kate.perry@atlantishealthcare.com
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Symptom Checker - The Pivotal Tool for Patient Engagement

Some years ago I asked a primary care doctor in Chicago what he thought about making our company’s diagnosis decision support system available to patients. He simultaneously made a gun out of his hand and growled, “patients coming in with lists!” We have moved on since then, but most doctors still do not actively embrace patients doing their own research, particularly on diagnosis, and ‘coming in with lists’. My view is that, in an era of a shortage of medical resources and time, patients are a vast untapped resource, and engaged patients are a valuable asset that overburdened doctors should make use of. It’s time to make a virtue out of a perceived vice, and the symptom checker is one of the key tools to effect this.

As the patient engagement juggernaut gathers pace across many developed countries, the National eHealth Collaborative in the US has recently weighed in with a Patient Engagement Framework. This is set out in a very simple and useful tabular format, and highlights the symptom checker as a key tool to engage the patient. Significantly, it includes the tool under the “Engage Me” column supporting “engage and attract” and “retain and interact” activities.

This really shows how the movement has matured from believing that the patient could be informed by just providing a depository of information but no real means of making sense of it. Now, the proponents of patient engagement realise that an engaged patient must also be an informed and empowered patient, and tools must be provided to the patient to help them make sense of the information. Personally, I have always believed that helping the patient to research their own diagnosis with tools, like a powerful symptom checker, elevates the whole patient engagement movement another few notches. It really is crossing the Rubicon, as it encourages patients to engage in the crucial but rarefied domain of formulating a differential diagnosis and clinical reasoning. Since the patient is an expert on their symptoms, why shouldn’t they be actively encouraged to do this?

In addition, the US Bipartisan Policy Center’s recent report, Improving Quality and Reducing Costs in Health Care: Engaging Consumers Using Electronic Tools, found that engaging consumers more fully in their own health and healthcare not only improves the experience of care for patients and their families, but also improves the quality and cost-effectiveness of care.

There is now an increasing body of evidence to show that more informed patients cost less, and recently the journal ‘Health Affairs’ ran a study entitled ‘Patients With Lower Activation Associated With Higher Costs; Delivery Systems Should Know Their Patients’ Scores’, which showed how well-informed patients cost significantly less.

“This fact is noteworthy from both a clinical and a policy standpoint. Patients who have more knowledge, skill, and confidence in managing their health, and who are more adept at navigating and using the healthcare system, appear to incur lower costs.”

The new Accountable Care Organisations in the US and Clinical Commissioning Groups in the UK would be well advised to read these documents and make sure that they are offering these tools to their patients.

Lastly, some fascinating results from the latest Pew Research survey, “Health Online 2013”. They now call those who search online for health information “online diagnosers”.

“When asked if the information found online led them to think they needed the attention of a medical professional, 46% of online diagnosers say that was the case. Thirty eight percent of online diagnosers say it was something they could take care of at home and 11% say it was both or in between.

“When we asked respondents about the accuracy of their initial diagnosis, they reported:

• 41% of online diagnosers say a medical professional confirmed their diagnosis. An additional 2% say a medical professional partially confirmed it.
• 35% say they did not visit a clinician to get a professional opinion.
• 18% say they consulted a medical professional and the clinician either did not agree or offered a different opinion about the condition.
• 1% say their conversation with a clinician was inconclusive.”
It seems that patients are using tools like the symptom checker sensibly and going to see their doctor in almost half the occasions that they do search. Also very impressive is their accuracy rate of 41% - not bad for totally untrained lay people! The research on the diagnostic accuracy of doctors does not show a much better picture and, in complex cases, is often much worse!

My company has developed and marketed a diagnosis decision aid system to healthcare professionals for many years, and we recently released a patient version of the system. This new system has been adapted and modified for use by patients, but is still a highly sophisticated tool compared to the symptom checkers that have been available up to now for patients. We were apprehensive about doing this, mainly due to people saying how the patients would become unnecessarily alarmed when they entered ‘headache’, for example, and saw brain tumour listed as a possibility. What has been interesting, looking at the several thousand queries that have been entered since it’s been available, is the complexity of the symptoms entered. In only about 5% of cases do the patients just enter a simple one-word symptom. In the vast majority of cases they are entering four to six well-described symptoms. There were no patterns to the queries, as they were all very different. Contrary to expectations, it seems that many patients are sophisticated users of these tools and doctors should be using them as motivated partners in their care.

It seems increasingly obvious that the patients are a vast, untapped resource for healthcare professionals. Provided with the appropriate tools, like a symptom checker, the patients could be doing a lot of useful work before they even arrive at the consultation. Rather than complaining about patients coming in with lists or printouts, doctors should be channelling their patients’ energy and motivation into saving them time and making the consultation more productive and, therefore, satisfying.

On a final note, USA Today covered the Pew Research and asked their readers whether they “turn to the internet for medical diagnoses”; 87% answered yes!
Adherence is Transdisciplinary, Perhaps Even its Own ‘Discipline’

The issue of patient adherence is complex and involves interacting dimensions of patient-related factors, social/economic factors, condition-related factors, therapy-related factors, and health system/healthcare team factors. In other words, the nature of the adherence beast is multi-faceted and inherently interdisciplinary. Expert advice informing best practices to improve patient adherence is needed from healthcare-related clinicians (doctors, nurses, pharmacists), mental health experts (psychologists, psychiatrists), sociologists, social workers, epidemiologists, health-related researchers, and policy-makers (among others). A more appropriate term for how adherence should be properly viewed then may be transdisciplinary. That is, adherence requires a holistic approach, one that seeks to integrate knowledge from all related disciplines into a coherent whole.

Perhaps this points to the need for a shift in perspective. Specifically, a shift from a solutions-oriented approach to an understanding and acceptance of adherence as its own discipline. Adherence is not a science; it is not an art. It is an alchemy of disciplines including medical science, behavioural science, communications, demographics, psychographics, organisational management, systems-oriented thinking, and economics. One argument for considering adherence as a discipline is that it would be subject to the same methodological rigour as other disciplines, including the establishment of an evidence base and organised, systematic dissemination of knowledge that incorporates structured training. These processes are clearly in motion with the publication of adherence-specific journals such as this one, and adherence-related toolkits from reputable sources that are aimed at clinicians (e.g., the one published recently by the American College of Preventive Medicine titled ‘Medication Adherence – Improving Health Outcomes’, available at: http://www.acpm.org/?MedAdherTT_ClinRef). Of note, these efforts move the field closer to top-quality practices by addressing the key features of evidence-based practice, namely finding, applying, and appraising the evidence (see Figure 1).

Like Adherence, mHealth is Interdisciplinary and in Need of an Evidence Base

Similar arguments can be (and have been) made for the field of mHealth, defined as “the delivery of healthcare services via mobile communication devices”. Like adherence, mHealth is by its very nature an interdisciplinary field comprised of elements of both science and art. Again, it requires a team of experts from various fields such as information technology, healthcare, sales and marketing, business management, business development, etc... As in adherence, an evidence base within the field of mHealth is sorely needed, as noted in a recent World Health Organization document summarising global mHealth initiatives:

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“Competing health system priorities was consistently rated as the greatest barrier to mHealth adoption by responding countries. Health systems worldwide are under increasing pressure to perform under multiple health challenges, chronic staff shortages, and limited budgets, all of which makes choosing interventions difficult. In order to be considered among other priorities, mHealth programmes require evaluation. This is the foundation from which mHealth (and eHealth) can be measured: solid evidence on which policy-makers, administrators, and other actors can base their decisions.”

“Despite the need for evaluation, the survey found that results-based evaluation of mHealth implementations is not routinely conducted. Only 12% of Member States reported evaluating mHealth services. A concerted effort needs to be made to promote the importance of evaluation and the sharing of results with all Member States.”

Establishing an Evidence Base for mHealth Adherence Programmes

Given the state of each field/discipline separately, one might expect that mHealth programmes and interventions targeting patient adherence are completely lacking in evidence – however this is not the case. Free et al. (2013) recently conducted a systematic review on the effectiveness of consumer-directed mHealth interventions aimed at behaviour change or disease management. They concluded that there was good evidence of increased adherence for some behaviours and suggestive evidence for others, but that “high quality adequately powered trials of optimised interventions are required to evaluate effects on objective outcomes”. There have been other, more narrowly-focused reviews published within this area as well. For example, text messaging (also known as short-message service or SMS), the most accessible and frequently used mHealth feature, has been the focus of two recent reviews highlighting its potential for improved health. The earlier of the two reviews identified 33 studies of text messaging interventions, but only closely examined 14 of these studies. The authors found that 13 out of 14 studies reported positive behaviour outcomes, a 93% rate of success, although the amount of success varied across studies. The second review was more rigorous in the criteria used to evaluate the published studies, focusing only on studies with a higher calibre of research. This review identified 12 studies but looked more closely at the best nine studies and found that eight out of nine “found evidence to support text messaging as a tool for behavior change” (an 89% success rate).

These reviews, along with other summary papers, are helpful in identifying key points for moving forward in this area. Specifically, they highlight what has worked well in the past and what areas need improvement. Aspects of text messaging interventions that make them more successful include: i) tailoring to the individual patient’s needs and ii) interactivity. An area needing particular improvement is that of the length of time that patients are followed up, ranging from three to 12 months in past studies. In order to understand how far-reaching the intervention effects may truly be, however, future studies need to extend beyond 12 months. It is important to note, however, that this problem is not unique to studies of text messaging in health, or to mHealth interventions. Long-term follow-up of patients is extremely time-consuming and expensive, and is therefore a limitation in research of many other health-related interventions as well.

Overall then the research to date shows that text messaging and other mHealth adherence interventions are successful in promoting healthy behaviours and behaviour change.

Considering the widespread ownership and use of cellular phones and the cost-effectiveness of these kinds of interventions, this is clearly an extremely promising and exciting area of mHealth. However, the field of mHealth (and eHealth) is growing and changing at a rapid pace, with new adherence-related interventions/applications constantly coming to market. New mHealth technologies are emerging and being applied as adherence interventions without use of available evidence and/or without proper monitoring for effectiveness. Tomlinson et al. (2013) summarised this issue concisely:

“Similar strategies are being experimented with for a range of topics, delivery strategies (web, phone, videos, social media sites), and populations. There are a set of principles that could potentially be established to identify the optimal strategies for delivering mHealth interventions. However, our current research is not aimed at identifying these principles and strategies. Each pilot study is examining whether their particular style of a black box application works better than not having any black box application. It is time to start funding randomized controlled trials of interventions that are based on researchers’ best guesses about optimal implementation.”

In order to establish an evidence base for mHealth adherence programmes, a proper understanding of evidence-based practice is needed followed by a consensus on its definition and measurement.
Definition of Evidence-based Practice

Several competing definitions for evidence-based practice have been proposed over the last 15 years. The simplest definition was put forth by Sackett et al. (1996) as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients”. A broader, more inclusive definition was given by McKibbon et al. (1995) who highlight the need to collect, interpret and integrate “valid, important and applicable patient-reported, clinically-observed, and research-derived evidence.” Furthermore, they specified that evidence-based practice encompasses a process whereby “The best available evidence, moderated by patient circumstances and preferences, is applied to improve the quality of clinical judgements.” This definition is particularly attractive for its emphasis on two components: 1) the importance of patient-reported and clinically-observed evidence alongside evidence derived from classical research, and 2) the fact that practice must be moderated by patient circumstances. Typically, “evidence” is regarded as that which has been published in peer-reviewed journals with the highest ranking given to randomised control trials (RCTs). The major problem with discounting qualitative, theoretical and case studies is that quantitative data is not the only form of meaningful information (especially in the field of healthcare). Furthermore, published data is biased in a number of subtle ways (e.g., publication bias, reporting bias, focus on statistical significance rather than clinical significance), only some of which can be corrected in systematic reviews. The fact that contemporary definitions of evidence-based practice incorporate patient circumstances and patient preferences highlights the growing acceptance that “Evidence does not make decisions, people do”.

Increasingly clinicians and practitioners acknowledge that the most effective decisions are those made with the patient, and this can go a long way in improving healthcare practice, especially with respect to improving treatment adherence.

The exclusion of theoretical evidence has major implications for the field of mHealth adherence-related interventions. The most obvious and significant consequence of this omission is that interventions employed to date fail to draw upon theories of behaviour change and motivation. Again, Tomlinson et al. (2013) sum this up nicely: “There are well validated theories of behaviour change common to many evidence-based interventions for prevention, diagnoses, and care, but none of the mHealth initiatives appear to be grounded in such theories”. This is an area that deserves particular attention in the design and implementation of future mHealth adherence programmes if the goal is to foster evidence-based practice.

Summary and Conclusions

The opportunity therefore exists to integrate the transdisciplinary needs of adherence with the newly intersecting fields of technology and healthcare communications. There is a clear need for the development of an evidence base in adherence and in mHealth as separate fields, and the same can be said for mHealth adherence-related interventions.

A primary issue that must be addressed within this topic as we move forward is the use and integration of theories of behaviour change and motivation. Ideally, establishment of an evidence base will facilitate the creation of evidence-based practice within the field of mHealth adherence interventions. These efforts are needed in order to legitimise an area which has already shown significant potential for improved health and reduced healthcare costs, and which clearly sparks major interest from healthcare-related clinicians, policy-makers, patients and consumers.

References


Miki Peer, Medical Science Liaison at MEMOTEXT®, has been involved in many biomedical, psychological and psychiatric health-related research studies over the past decade. Miki is currently finalising her PhD in Medical Science at the Institute of Medical Science (University of Toronto). Prior to graduate studies, Mrs. Peer worked as a project manager and research assistant for neuroscientists, occupational therapists and psychologists. Miki holds a Hon. BSc from Trent University, with a joint-major in Biology and Psychology.

Email: mpeer@memotext.com
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Evolving Shifts in Patient Adherence Through a Digital Society

With about 80 per cent of chronic patients online in a global digitally networked society, new paradigms and methods evolve when talking about patient adherence programmes. The tailoring of content, the wisdom of the crowd effect, or the online community of practice phenomena are examples of new qualities of the mass medium called “internet”. What the media and FMCG economies already use on a daily basis has not yet even been fully understood in the healthcare sector, in terms of what huge potential rests here in improving patient adherence.

An uninvolved observer may see two separate and not mutually connected realities colliding here. On the one side we have an average of about 80 per cent of a western country’s population online. Four out of five of them use the internet for healthcare issues. For the German-speaking countries we are talking about roughly 50 million people. The impact of the internet on these so called e-patients affects their disease-related knowledge, their attitude, and their behaviour in the healthcare market and with their healthcare providers on an iterative proven base. If a patient posts a question in an open online patient forum, on average within half a day between three and six answers will be received from patients with similar indications, similar problems, similar experiences, different solutions. They will answer the patient’s question in the same language based on a trusted and sharing socially-based motivation. And guess what, it is not about different substances from different medications, but it is about hands-on real-world coping with problems that a human in everyday life has as a patient with a dedicated and mostly chronic disease.

E-Patients and State-of-the-art Patient Tools
E-patients use online a plethora of patient social networks and “patients like me” forums, interactive tools, customisable applications and similar. This digital and health-related supply side is mostly offered online from non-traditional healthcare players, like media and publishing houses, start-ups, patients themselves and similar. The scientifically proven reasons for the need, usability and effectiveness of these online tools are the following:

a) they are radically patient-centric and show thorough real usability,

b) they are tailorable and personalisable,

c) they deliver through the quality of “relevance” for a dedicated patient, getting the right information in the right form onto the device of choice.

On the other side we have the patient compliance brochures from the healthcare provider and industry, in a 1980s aesthetic written by industry medicals, with over-long sentences, no real-world relevance to patients, in a content form delivered as for a medical undergrad, with usually no co-creation or co-development together with patients, in a one-size-fits-all approach leading to a single final brochure for millions of patients within a dedicated indication. This existing 20th-century brochure-paradigm is copy-pasted though onto a website, a Facebook site or a mobile smartphone app. The result is that the industry does not know why their content doesn’t work and patients do not know why they should use it. The situation is roughly condensed so far.

Missing Ingredients?
The evolving paradigms and new qualities connected with digital patient adherence can mostly be found outside the typical world of the healthcare sector:

• leading books describing the new economic and social rules of an internet society (see for example: Manuel Castells, Clay Shirky, Yochai Benkler, Peter Kragh)

• innovative approaches for how consumer brands use the digital world to cooperate with their customers and target groups (see for example the quite often-quoted open idea campaign from Starbucks, under mystarbucksidea.force.com)

• and especially the globally leading medical internet and e-patient research publication institution, “Journal of Medical Internet Research” (see the plethora of globally collected e-patient studies under www.jmir.org)

The many new patient and medicare approaches that evolve with those new digital paradigms are also described under the term “health 2.0”. For a brief introduction to some of the relevant new qualities within the field of digital patient adherence, see the following.

What is Usability?
Usability is a product quality that is neither known nor needed in the healthcare industry, because the economic paradigm is not consumer-centric but payer-centric. So user- or patient-centric product qualities are, in most products and services, not relevant for the providers. This leads to a culture of user communication as described in the following - for didactical reasons provocative - example:

Market Researcher: “We found out that the majority of asthma patients prefer a white and blue color on our websites, mobile apps and e-learning videos.”

Brand Manager: “I don’t care. I like green. Make it green.”
In an disruptive contrast: in the digital world there is only one commandment: user-centricity rules.

Usability (or synonyms such as customary, feasible, conventional, having a use-case, ease-of-use, user-centricity) describes qualities of products and services that make the user able to use the product quickly, easily, repetitively, with additional motivation, even fun - and with a user lock-in effect.

This quality is in many industries achieved by usability experts, market research investments, focus group observations, ethnographic observations and even the participation of the end user together with the product development team.

Usability is the trigger point of the success of a website, a forum or a mobile application, but in the reality of digital healthcare products it receives the least investment because its relevance is not known.

**Learn and Listen from the Patient’s World**

Never before in the history of medicare has such a plethora of patient questions, answers, relevant agendas per indication, real-world coping issues, successful new strategies, shared experiences and many other aspects been totally open in the net - observable, collectable and usable. The social-empirical approach of a structured analysis and social network analysis derived from social science delivers the main real-world and medicare agendas of dedicated patients within a dedicated indication, which can be used to optimise and adopt patient-centric services and adherence tools.

This approach gives the content a user- and patient-relevance and a demand-orientated quality.

**Tailored Content leads to Information Therapy**

The concept of Information Therapy that Kemper and Mettler describe in their book, “Information Therapy”, is nothing more than delivering the right information to the right patient at the right time. The generic benefit and use case is always the same: a dedicated chronic patient passes during his patient journey through different therapy and medication regimes; diagnostic, operative or conservative treatments; rehabilitation and similar. Imagine content software that knows the actual journey status of the patient, what he knows already, what he has to learn based on actual or upcoming treatment changes, and that can be interactively personalised by the patient. Additionally, the patient can rearrange the content and evaluate the content via “understand vs. don’t understand”, “can cope with vs. can’t cope with” or similar.

This tailored content leads to patient-centric relevance and personalisation which are based on global e-patient research results, one of the two highly-relevant patient content and service qualities, which in turn leads to an increase in digital patient adherence.

**Co-creation and Co-development**

This approach can’t be stated directly enough. It may even define the first commandment of developing digital patient content or adherence approaches. Whenever you develop a digital service, tool or content for chronic patients, put those patients together with you on the developer’s table. We may call it design thinking, user innovation or ethnographic approaches; they all express the same quality: the co-creation and co-development of digital patient tools together with some of those patients increase usability and relevance on a highly cost-effective and health-effective level. From the usability evaluation research of the software industry it is known that the earlier the final users, their usage environment and their needs assesments are implemented in the first concepts, the higher the chance of success and the lower the costs of later update and rearrangement works.

The implementation of those exemplary digital adherence qualities described needs pilot and trial-and-error phases. Pharma and med tech companies, clinics and payers are all just observable in the stage of learning and adapting these new paradigms and approaches in the field of digital healthcare and medicare products.

**Alexander Schachinger**, an Austrian in Berlin, is founder and CEO of healthcare42, a digital healthcare research and consulting agency. After working as a physical therapist he studied media economy in Berlin and Toronto, followed by a career in the pharma and digital agency world. Since 2009 Alexander has been analysing the global online and digital healthcare landscape and consulting the healthcare industry on patient-centric digital approaches. This spring he finalises his Ph.D at the Humboldt University of Berlin, focusing on the e-patient phenomenon in Germany and Central Europe.

Email: alexander.schachinger@googlemail.com
Enabling Technologies: Mobile Helps to Successfully Integrate Patient Engagement into Global Clinical Trials

**Introduction**
Increasingly, all phases of clinical research rely on patient-reported outcomes (PRO) to provide accurate information on the status of a patient’s health condition and how they are being affected by certain treatments. Used widely to support post-marketing labelling claims, PROs give researchers invaluable information on the effects of a drug. However, a variety of concerns associated with traditional, paper-based PRO tools have arisen due to the inaccuracy in reporting and translation, lack of adherence and low levels of control. In addition, paper methods can prove slow and prevent vital information being identified immediately in trials. Electronic data collection overcomes these challenges by facilitating secure, instantaneous monitoring, as well as providing the ability to track and trace trials in real time, allowing sponsors to identify and respond to any concerns as they occur. Many pharmaceutical companies are now replacing paper diaries with electronic patient diaries in clinical research. Used to generate real-time, unbiased data from patients, electronic patient-reported outcome (ePRO) tools are being adopted and developed widely. Notably, mobile technology is being recognised as an ideal medium to collect accurate clinical data and is increasingly used in the global clinical trials market. This article focuses on the rise of mobile technology in the ePRO arena. It looks at how its deployment can aid cost-efficiency and secure patient adherence to medication regimes, particularly within global clinical trials.

**The Evolution of ePRO and the Importance of Mobile Technology**
The advent of ePRO solutions has been spurred largely by the growing importance of the patient voice in clinical research. As companies become more open to using electronic means of data collection and reporting, a number of businesses are now embracing ePRO solutions, using mobile devices to facilitate their data collection needs. With mobile device penetration reaching 86% of the global population by 2011, totalling almost 6 billion connections, the mobile phone is perfectly placed as a ubiquitous tool for the most reliable data collection possible. The reach of mobile networks, the multiple connectivity options, and the appealing user experience and processing capabilities of contemporary mobile technology enable a flexible and familiar platform that can be tailored to a broad range of study needs to produce reliable real-time data. Simplifying the electronic data collection process considerably, mobile
technology is now being recognised in the industry as a way of effectively engaging with patients globally and providing more sophisticated, reliable patient diary capabilities.

Allowing mobile device data capture by either the mobile web or through an installed mobile application not only facilitates patient engagement, but also offers sponsors and CROs a cost-effective, secure and customisable solution which is adaptable to specific trial requirements. Clinical questionnaires can be delivered regardless of age or demographics, meaning that those who were previously unable to participate in trials are now able to take part remotely anytime, anywhere, removing patient-to-site burden and, as a result, increasing the likelihood of adherence.

The Challenges of Engagement in Global Clinical Trials
Patient adherence to a medication regime is a major concern when conducting healthcare studies, especially in long-term, late-phase programmes. Non-adherence can negatively impact treatment outcomes and also disease management as a whole. It can also lead to further healthcare problems down the line and complications which could easily be avoided through effective medication adherence. The cost of non-adherence is estimated to be $290 billion each year in the US alone.2

The prevalence of chronic conditions is set to grow year-on-year as a result of an ageing global population and an increased likelihood of early diagnosis of conditions. Consequently, the growing emphasis on patient self-management has resulted in approaches that encourage patient engagement becoming more prevalent.

The growing number of clinical trials implemented globally, often in developing countries, teamed with the lack of access to healthcare in these regions, is a significant factor in overall patient non-adherence in trials. Conducting clinical trials overseas is becoming increasingly common as a result of the associated cost savings due to reduced resource costs. By outsourcing trials to other countries, sponsors can benefit from more rapid subject enrolment, increased numbers of available participants and access to chronic conditions, genetic diversity, high subject retention and less stringent regulatory constraints. Along with the challenges associated with accessing healthcare, when delivering patient care and therapy-associated questions via mobile devices, differences in local networks and mobile internet providers in other geographies have historically posed potential problems. These issues, teamed with language and translation barriers are often documented as shortcomings of conducting trials on a global scale. As a result, mobile solutions which streamline processes are welcomed by pharmaceutical companies and CROs alike.

For the engagement process in global clinical trials to be effective, working with a technology partner with a global footprint is essential. This not only enables local services to be customised to requirements, but also offers expert knowledge of how best to engage with patients in a variety of different languages and cultures.

The Value of Mobile Technology in Expanding Markets
The versatility and reach of mobile technology is continuously opening up new opportunities for innovation in a number of industry sectors. From emerging markets where mobile technology allows banking without infrastructure, to developed markets where mobile connectivity allows utilities to gain efficiencies by remotely monitoring energy usage, the transformational capacity of mobile technology is clear.

The unrivalled prevalence of mobile devices and networks has prompted increasing adoption in healthcare, which is often referred to as mobile health or mHealth. It is viewed by many as the perfect vehicle to encourage and support patient self-management for those with long-term, chronic conditions. This same rationale can be applied to generate successful outcomes in clinical research.

In light of the growing number of global trials conducted, mobile penetration is invaluable, allowing the provision of direct communication between patients and research organisations regardless of their location. For this to happen, global communication is essential, and this can be enabled through access to a global network that supports the integration of mobile devices. By providing adaptable and customisable data collection solutions which can be deployed onto a patient’s own mobile device for convenience and ease of use, the globalisation of clinical trials is made much more streamlined. The patient engagement strategy can be defined and tailored in-line with both devices used and what works best for patients. With clinical trials often being criticised for using unrealistic settings and attracting patient populations which are not always representative of the actual patients, marrying clinical trials and real-time mobile data collection can be the answer to capturing more accurate data.

By providing patients with a mobile device specific to programme needs, or even utilising the patients’
own device, the cost and complexity of coordinating a study can be significantly reduced. Local in-country provisioning can simplify the process of managing and distributing devices and, when utilising the patient’s own device, the cost and logistics of provisioning are removed entirely. The use of familiar mobile interfaces also reduces the reliance upon device-specific training, thereby offering a much more engaging experience. The recent advances in best practice for mobile data security and privacy in other industries (as exemplified by the widespread adoption of mobile banking) offer peace of mind for patients and solid vindication that solution providers are able to address all the necessary regulatory requirements.

**Mobile PRO Solutions Facilitate Improved Patient Adherence in Global Clinical Trials**

One of the main reasons often cited for low or non-adherence, in addition to forgetfulness, is poor communication with healthcare professionals due to lack of access, especially in remote locations. Providing a solution to this problem, communication through mobile technology not only enables remote access to healthcare, but also allows tailored reminders to be sent out to patients via their own mobile device in order to encourage them to take their medication. Another prevalent reason for non-adherence is cited as patients not taking their medication due to the absence of symptoms, teamed with patients not sharing their doctor’s belief on the severity of their condition. With a number of chronic conditions not displaying any symptoms, a significant number of deaths occur yearly as a result of patients not recognising disease indicators. Here, a mobile application which not only prompts adherence, but also educates on symptoms and the condition itself would prove highly beneficial.

In global clinical trials, patient compliance can be drastically affected if trial subjects do not fully understand what they are being asked to report on, or if the translation through the electronic device is not correct. Removing language barriers by offering mobile solutions tailored to meet specific language requirements means that sponsors are able to communicate seamlessly with a wide range of patients. In addition, the availability of real-time, accurate data means that pharmaceutical companies and CROs are able to access data immediately and as a result, be alerted to any errors or shortcomings which occur during a trial, saving cost and time.

Offering patients a quick and convenient way to record information on their medication regime, while at the same time improving adherence, mobile PRO solutions enable sponsors to generate the most reliable data possible. By providing ease of use and customisable solutions which can easily integrate into everyday life, the use of mobile technology across all stages of clinical research is able to facilitate improved patient adherence, while reducing trial preparation time and streamlining data management.

**Mobile Technology Holds Potential to Improve Clinical Outcomes in Global Clinical Trials**

It is clear that ePRO, and in particular, mobile technology solutions, have a huge role to play in the collection of real-time and unbiased data, particularly in the ever-growing global clinical trials field. In addition, the prevalence of mHealth in the wider healthcare industry is becoming ever more apparent, with these tools seen as a key way to reduce both economic and staff burdens in the healthcare industry.

Mobile PRO solutions will play an increasingly vital role in providing accurate and sustained reporting on the benefits and impact of a treatment, as well as improving patient adherence. The accessibility and familiarity of mobile technology in particular will help pharmaceutical organisations and CROs enhance the clinical trials data capture process in a cost-effective and secure manner, engaging patients with an enriched user experience. With a variety of recent reports suggesting that mobile technology will revolutionise clinical research and the healthcare industry as a whole, sponsors, CROs and global health organisations are actively looking for ways to adopt mobile technology and mHealth solutions into their clinical trials and healthcare programmes.

**References**


**Tim Davis** is CEO and co-founder of Exco InTouch, the leading provider of mobile and digital patient engagement solutions to support Clinical, Late Phase and mHealth. As a well-regarded speaker and subject matter expert in the clinical technology arena he is best known for championing mobile innovation in clinical and healthcare programmes. Email: info@excointouch.com

**Tony Kane** is responsible for Vodafone’s mHealth Solutions unit within their global Machine to Machine business. After graduating from Cambridge University, Tony has spent all of his career in the ICT solutions industry, occupying senior roles at IBM, BT and now Vodafone. Much of that time has been spent working with clients in the medical arena and these days focussed on helping those clients turn the concept of mHealth into reality. Email: tony.kane@vodafone.com
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Cognitive Behavioural Hypnosis for Sleep

Sleep disorders may range from the familiar insomnia, to the less frequent narcolepsy, with many other types in between, identified for their medical and psychological morbidity. Inasmuch as hypnosis employs the power that may be exerted by the mind to influence the actions of the body, a skillfully prepared hypnosis can be an effective therapeutic treatment for those variations of sleep disorder that respond to such. For disorders of a more organic nature, medicinal preparations or procedures may prove to be the desired treatment, or a combination of treatments may be called for. While hypnosis may also help in the patient’s compliance with other treatments, as will be discussed later, this editorial will mainly focus on the use of a hypnosis capable of helping a patient who is experiencing difficulty with some aspects of what one would expect to be healthy sleeping habits, such as trouble falling asleep, sleeping at the appropriate time, sleeping for an appropriate length of time, etc.

However, there is sometimes a certain confusion that may arise from the use of hypnosis when the goal is to normalise the patient’s sleeping habits. This confusion stems from the fact that hypnosis seems, at first glance, to be very sleep-like in and of itself. Even the very word hypnosis is something of a misnomer that leads one to think of hypnosis as sleep. The word is derived from ‘hypnos’, the Greek term for sleep, to which we add the suffix ‘osis’, indicating a condition that has been produced; that is, produced sleep. In the realm of clinical hypnosis, we generally know this to be an hypnotic state that has been induced, but not sleep. While the etymology may be from the word sleep, hypnosis certainly is not sleep, though one might see a person at rest who is in an hypnotic state and readily mistake it for sleep. Indeed, it is true that many people move quite easily from the hypnotic state into a sleep state. It is, like sleep, a state of mind in which some areas of brain activity are different from the awake state. Still, the true test for the presence of the hypnotic state is the level of suggestibility. Despite the great advances that have been made in measuring and recording various types of brain activity during hypnosis, the best determinant for detecting the presence of an hypnotic state of mind is a marked increase in the person’s suggestibility. During hypnosis, the person is responding to the suggestions of another entity.

Why go to such lengths to point out the difference between hypnosis and sleep? It is important to understand this distinction because the stillness, the relaxation and the refreshment that may occur during and after an hypnosis experience, do not replace the psychological necessities brought by actual sleep, with all of the associated dreaming and other special brain activity natural sleep causes. This is the natural sleep that is so vital for every person’s mental and physical health. Both therapist and patient should be aware that the goal is not to simply induce a person to rest. It must be for much more. The goal is the patient’s ultimate production of natural sleep, on an appropriate schedule, for an appropriate duration of time. Additional related medical goals may also be addressed in the formation of the hypnosis, but the primary goal for a person unable to sleep properly is her/his own production of natural sleep. To this end, discovering specific suggestions pertinent to the underlying cognitive causes of the patient’s sleep prevention is the pressing task of the hypnoterapist.

While it is true that hypnosis may be used as a strictly behavioural technique, simply giving instructions and demanding certain outcomes on the part of the patient, a more cognitive approach that also includes suggestions about the thinking of the individual could yield far better results. To clarify, a complete hypnosis experience consists of inducing the person into the mental state of heightened suggestibility and then making suggestions to the person for absorption into the thought routines of the mind, thus motivating the person toward the desired outcome. Modern hypnosis relies on the extreme concentration of the person’s attention to bring about induction, and the use of imagery is most helpful in doing this. Suggestion may be of a behavioural sort, or a more cognitive nature, or a combination of both. The reader may recall from earlier work a strategy that was devised several decades ago for the purpose of creating such a cognitive behavioural hypnosis, called Rational Suggestion Therapy (RST). Without going into too much detail about RST, here is a brief summary of some of the steps a hypnotherapist might take to formulate a cognitive behavioural hypnosis:

A. First, an in-depth interview must be conducted with the person in order to ascertain the thinking associated with the person’s presented behavioural difficulty. Such thinking may or may not occur at the exact moment of the behaviour occurrence, but may be part of the thought process that propels the person to the behaviour. Developing an understanding of where this thinking leads usually will point the way, conversely, to what thinking is necessary for heading in the desired direction. Every difficulty has a particular meaning unique to the suffering person. Revealing that meaning, as much as it is possible, will place the focus on the solution, instead of the problem. Additionally, the quality of interview, hopefully developing a sound rapport between patient and therapist, will also establish the person’s trust in the therapist, a condition so important for the person to feel secure enough to allow her/himself to participate fully in the coming hypnosis.

B. For the content of the hypnosis to be its most effective, it must be crafted to offer a rich, clear and precise meaning for the person being hypnotised. Working
closely with the person to find the most meaningful words and combinations of words that will be used to form the hypnosis suggestions is an indispensable step. Even if the words that resonate with the person are not in proper grammar and usage, personal meaning is what is paramount. The same is true for the imagery used during the induction portion of the hypnosis. That which works best is always that which has been chosen by the person him/herself.

C. Once the induction imagery and the suggestions have been formed, the hypnotherapist includes them in the creation of an hypnosis script. Recording the hypnosis in an easy to replay format is always a good idea, because the patient should have the ability to listen to the hypnosis as often as necessary, at least once each day, but more often if desired. After an agreed upon period of time, perhaps one to two weeks, another meeting to discuss the progress of the difficulty and the effectiveness of the suggestions should take place. It is sometimes necessary to make adjustments according to the person’s reaction.

Following this general framework, let’s conjure an hypothetical example of how this might be used for a patient with a sleep disorder. The patient, a middle-aged woman, has reported to the physician that she is tired all the time. After doing some medical tests to rule out organic problems, the patient reveals that she has difficulty falling asleep. Though she goes to bed on time, she just lies there, unable to sleep. After a while, she gets out of bed and reads or watches television. She finally falls asleep in front of the television or book, only to awaken after a few short hours to get ready for work. As a result of the sleep deprivation, she is irritable, does poorly at her job and is unhappy.

The physician refers her to a hypnotherapist. During the initial interview with the therapist, several items must be covered. Whether or not she appears to like the idea of hypnosis, the entire process must be plainly and fully explained. She needs to feel that she is a part of the creation and use of the hypnosis. Then the problem must be discussed. During the discussion, she reveals that she has been feeling anxious over her aging mother’s health, and frequently finds herself worrying that she will receive a call telling her that her mother is gravely ill. In the judgement of both the therapist and the woman, it is determined that her insomnia, at least in large part, is the result of her hypervigilance. She wants to always be ready and available to react if her mother needs her assistance. She did not relate her mother’s condition to her sleep disorder prior to this discussion, but sees it at this juncture. It is clear that a detailed antidote to this concept should definitely be included among the hypnosis suggestions. It should include whatever wording accurately reflects her need to live her life well, even as she cares for her mother. It also states that she can only be of help if she is well-rested and will serve her mother’s needs far better if she keeps her own health and happiness, satisfying her need to do her best for her mother. In addition, behavioural suggestions regarding when and how long she is to sleep for, with the caveat that she will awaken, completely ready to help if she is called to be with her mother.

In some cases, the patient may prove reluctant to reveal the true cause of the insomnia, but that does not mean that the hypnosis treatment is to be abandoned. Whatever points s/he raises during the interview can and should be addressed in the hypnosis suggestions. They will always prove beneficial along with the behavioural suggestions.

It should be said at this point that hypnosis is particularly useful for all types of patient compliance. In this hypothetical, for instance, the physician may have detected another medical condition and prescribed medicine as a result. A suggestion to strictly follow the doctor’s direction would certainly be warranted. Chances are it will be welcomed by a patient who has developed a rapport with the therapist. It is important to remember that the hypnosis is a partnership. The involvement of the patient is critical. After all, is such a partnership not for a sound night’s sleep.

Richard A. Blumenthal holds a Master of Science Degree in Counseling from Long Island University. He is a New York State Licensed Mental Health Counselor and the author of numerous professional works in the fields of hypnosis and counselling. Mr Blumenthal is the originator of the Rational Suggestion Therapy counselling technique. He was awarded a United States Patent for the invention of hypnosis software, which may be found at http://www.hypnosoft.com

Email: richard@hypnosoft.com
Effecting Change, Affecting Lives: The Case of Schizophrenia Patients

Patients with psychosis, such as schizophrenia, often suffer from poor life quality and deteriorated functional capacity, as well as the burden of social stigma and other socioeconomic pressures. Even though pharmacological treatment may provide psychotic patients relief from disturbing symptoms and enable them to gain greater control over, and satisfaction with, their lives, a huge percentage of them fails to comply with it during part or all of the process. Eighty per cent (80%) of patients with schizophrenia are non-compliant with their medication at some stage during their illness. On any given day, the median non-compliance rate is about 50%. This failure most often leads to reappearance of symptoms and re-hospitalisation, creating a great deal of turmoil for patients and their families.

Non-compliance is a ubiquitous issue in all medical conditions; however, the nature of psychotic disorders makes it especially difficult for patients to comply with treatment. Factors pertaining to the patient, such as lack of insight into the disorder, alcohol or substance abuse, poor social functioning, young age, male sex and severe symptomatology, appear to impede compliance. Also, attitudes towards medication may affect compliance; patients who perceive the direct or indirect gains from their medication are likely to achieve better compliance.

Factors related to the patient’s environment also affect the process of compliance with treatment recommendations. Lack of social support, social stigma and living alone are associated with poor compliance in psychotic patients. A poor therapeutic relationship with healthcare professionals also presents a major barrier to compliance, and so are treatment variables such as severe side-effects, delayed onset of treatment benefits and complex therapeutic regimens.

Interventions for Compliance

Several interventions at the individual, group, family or community-level have been devised and employed to assist compliance with antipsychotic medication. Interventions most typically incorporate psychoeducational, cognitive, behavioural, or a combination of those strategies. The literature on compliance generally supports the combination of multiple strategies and the repetition of important information throughout the process.

Psychoeducational interventions focus on providing knowledge about the nature of the disease and treatment, and attempt to increase insight and enhance coping skills. Cognitive interventions work with patients’ attitudes and beliefs towards illness and medication. Behavioural interventions target behavioural modification through reward and punishment, reinforcements, provision of cues and promotion of self-management.

One approach to improve treatment compliance is ‘compliance therapy’ developed by Kemp and colleagues (1996) focusing on patients with schizophrenia and psychosis using cognitive strategies and motivational interviewing. The approach aims to improve patients’ attitudes to medication and compliance with treatment, and thus enhance their clinical outcomes, and prevent potential and future relapse. Research indicates that insight and medication compliance rates can be considerably improved by compliance therapy, and that its effects last for at least six months, however, its long-term benefits have still to be documented.

An integrated care compliance programme is the ‘Munich Compliance Program’, run by the Center for Disease Management, Psychiatric Clinic, Technical University Munich. The programme has had profoundly successful outcomes in targeting non-compliance and consequently improving treatment effectiveness. An analysis of the programme showed that it managed to reduce relapse and readmission rate by 70% and save more than 50% of total costs. At the same time, quality of treatment and patient satisfaction increased. Some of the key elements of the programme include psychoeducation for patients and relatives, peer-to-peer psychoeducation, family-to-family psychoeducation, shared decision-making, incentives for patients, reminder systems, telephone monitoring, home treatment, wellness elements, and visits to a depot clinic.

Patient Adherence Support Programme: Our Approach

Layout of the Programme

Compliance with appropriate treatment recommendations can provide patients the opportunity of living fulfilled lives in the community. It is therefore of crucial importance to support patients and their families in their treatment journey with the ultimate goal of enhancing compliance and treatment outcomes. Aiming at providing the much-needed support and assistance to patients and families and increasing the chances patients would stick with a treatment regimen, PCC HELLAS run a patient adherence support programme mostly contained educational and behavioural components.

Our programme was a nurse home-visit programme designed to educate, assist, monitor and support patients throughout their treatment with LAI antipsychotics. The programme was conducted in close collaboration with patients’ psychiatrists. One of the major features of the programme was the alliance with patients’ families, when present.

Home nurses, if required, visited patients in the programme to assist with injection administration and disease information, as well as to return patient progress
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reports to the call centre.

The programme was offered through doctors as a mechanism for getting treatment information and adherence assistance to their patients. Thus, doctors assisted with enrolment of individual patients.

The programme lasted from February 2009 until August 2011. In parallel, we ran a survey to inquire about patient satisfaction (sample representing 20% of total registered patients). All services provided to patients were cost-free.

Features of the Programme

Nurse Visits at Home

Trained registered nurses paid home visits to educate and assist patients with the administration of their medication – to provide care in a convenient, non-restricting and non-stigmatising setting.

One of the points that we took real care of was to provide the same nurse for each visit to the patient. This proved to be a critical point for the success of the adherence programme and differentiated our service from similar programmes provided. Visits by the same person offered the stability to build trust and strengthen the therapeutic alliance.

100% of patients reported that they were satisfied by home nurse visits. It is noteworthy that there was no negative scoring at all.

Telephone Calls

Calls were made by a team of clinical psychologists: calls were conducted by our central call centre and served three main purposes: (a) to remind the patient/caregiver of the date for the next scheduled injection; (b) to provide a follow-up of the previous injection; (c) to offer support to the patient/caregiver.

The indirect positive impacts of calls were: engaging family members in treatment when possible and when beneficial to the patient, exploring barriers to treatment, resolving difficulties regarding the administration of treatment, encouraging consultation with psychiatrists when necessary, extending channels of communication between patients and/or family and doctors.

Offering psychological support can be a tricky issue. We have observed that stand-alone psychological support programmes may be treated with doubt. First and foremost, many patients cannot realise the magnitude of their illness or that they need help. Patients with schizophrenia are a typical example, since it is very common for a patient not perceiving that he/she is ill. Moreover, in countries of Southern Europe it is a common belief that talking to a psychologist or psychiatrist can terribly stigmatise you as “mad”.

Calling the patients at regular intervals instead of waiting for them to call the support service was an efficient way to get them to talk. Patients had the time to get accustomed to the people calling them, and we observed that even wary ones started to share things after a while. This is why 99% of patients and caregivers reported that they were satisfied by the calls.

Doctor Reporting

At the end of each month, doctors received a report presenting the dates that their patients took the injection, the dates and the content of the calls made, and any other comments the call centre agents or the nurses made (e.g. adverse events, reports of critical incidents).

In this way the doctors were able to assess how compliant their patients were, and have complete oversight of their progress and attitude towards the treatment.

This process has benefited doctors greatly, especially in cases where patients lived far from the doctor’s office, and frequent visits were not possible or in cases of doctors working in public hospitals and treating a large number of patients.

The Patient Experience

Through the constant communication with patients and doctors, we were able to identify several aspects that prevented patients from being compliant with doctor’s instructions:

- Patients’ intentional non-compliance (poor or no insight, negative stance, refusal to take medications, cases of aggressiveness)
- Patients’ forgetfulness (avoided by reminding patients)
- Practical difficulties in following treatment (personal, health-system related etc.)
- Absence of supportive environment

We asked patients whether being registered in our service has helped them in taking their medication. 57.6% of patients reported that they were very satisfied, and 40.7% that they were satisfied with the total adherence programme.

Improving Quality of Life

We asked patients in what way nurse visits make their life easier (more than one answer was possible) and we got the following responses:

- Discretion (15.9%) - being stigmatised as mentally ill is something that most patients and families want to avoid
- Saving time (65.9%) - people who have to wait in lines in public hospitals or have to drive long distances in order to get to the nearest hospital for their injection really appreciated the aspect of saving time
- Discussing their concerns and problems (56.8%) - people with mental illnesses suffer from social marginalisation. The aspect of human contact was a great one; several patients reported that the service nurse was the only person who visited their house. It proved a good way for patients to vent and overcome alienation.
• Tackling questions about treatment (11.4%) – forgetfulness and disorganisation are characteristic in people with schizophrenia. The nurse could always provide guidelines on taking the medication, especially in cases where patients could not reach their doctor.

Other factors that were considered important by patients were:

• Overcoming the barrier of restricted mobility (impairment or elderly)
• Enhancing medication adherence and making sure that the patient would get his injection (especially in cases where caregivers do not live in the same house with the patient)
• Saving effort and/or money
• Providing a familiar setting: very often hospitals were associated with unpleasant experiences

Moreover, we asked patients and caregivers: “If there was no nurse support, how compliant would the patient be?”

18.6% of survey participants reported that they would not be compliant at all, while 45.8% reported that they would be a little compliant. 32.2% replied that they would be somewhat compliant and 3.4% that they would be very compliant.

Thus, we observe that patients become self-conscious of the guidance they have to follow and the importance of the adherence programme.

100% of patients and caregivers reported that they would recommend the adherence programme to other individuals taking the same medication.

Indirect Benefits of Compliance Programme

Patient Segmentation

Patients’ expectations of treatment have been changed: higher education, access to vast information, and modern perspectives on health are only a few of the factors affecting an individual’s choices. Thus, segmentation should not only be demographic and psychographic; it also needs to be behavioural.

Segmentation identifies patients with similar needs and characteristics, and groups them together so that a specific pathway can be designed for them and different resources can be allocated to them.

We observed, for example, that patients with higher education and social status had a completely different attitude towards taking their medication compared to patients with lower socioeconomic status.

Understanding How, When and Why

The patient journey is unravelling the different stages the patient goes through, and the decisions that are made through the progression of a disease and treatment.

Each point in this journey can drive the patient to react to and engage with different messaging and types of information as they work through medical, emotional, financial and lifestyle issues. This involves other stakeholders as well (healthcare professionals, caregivers, national insurance etc), all of whom shape the patient journey.

Laying out a complete patient journey can enhance informed decision-making for the caregivers and healthcare professionals.

To give an example of one of the stages of the patient journey, it is interesting to examine the dropouts cases in our patient support programme.

The main reasons for patient dropouts were the following (Table 1):

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>patient/family refuse treatment</td>
<td>45.20%</td>
</tr>
<tr>
<td>drug switch</td>
<td>38.50%</td>
</tr>
<tr>
<td>communication impossible</td>
<td>4%</td>
</tr>
<tr>
<td>death</td>
<td>4%</td>
</tr>
<tr>
<td>hospitalization, health issues etc</td>
<td>5.50%</td>
</tr>
<tr>
<td>occasional visits</td>
<td>2.70%</td>
</tr>
</tbody>
</table>

1. Treatment switch decided by the treating doctor (38.5%).

There is also a proportion of patients who started seeing a different doctor, who decided a drug switch. The main reason for doctors deciding that the drug is no longer a solution for the patient was that there were not the expected results. In a few cases, there have been adverse reactions that led to changing the drug.

2. Negative attitude towards treatment (45.2%)

A compelling factor that led to dropouts was the patients refusing to take the drug prescribed by their doctor. Another major factor was the family’s attitude to the illness and treatment. We noticed that very often the relatives (caretakers) of patients were in denial regarding schizophrenia. They were also afraid of the social stigma of the illness.

3. Impossible communication (4%)

In several cases it was not possible to start contact with patients or keep in touch. Often they would provide us with wrong telephone numbers, or we would discover in process that the patient had changed numbers.

4. Health issues (5.5%) and death (4%)

Several patients dropped out of the programme due to health complications or adverse events. A small percentage of dropouts were due to death, either by natural causes or suicide.

5. Occasional visits 2.7%

In some cases we were asked to help patients with their injections, but not on a regular basis. For
example, patients who used to get their injection in the local hospital, and when away on holiday could not find help locally for taking their medication.

### Estimating the Turning Point

We have studied the time when patients drop out of the support programme, and identified the “critical” time for them to respond negatively.

According to our findings, the early stages of enrolment in the programme are decisive for the patient dropping out. 51% of patients drop out within the first two weeks of their enrolment, and 68% of dropouts occur within the first six weeks (Table 2).

[![TIME FRAME OF DROP OUTS](image)](image)

The vast majority of patients drop out because of their negative attitude and refusal to take the medicine prescribed. Most of these “early dropouts” have received zero or only one injection from the nurse. Therefore, it is crucial to focus our efforts at the beginning of the programme for each patient, when it is more probable for him/her to quit taking medication.

Underlying reasons that lead to this phenomenon can vary; perhaps the patient was not fully included in the decision-making about his treatment, or doctors enrolled patients who had no support network (friends or family). Significant differences in diagnosis, demographic data, clinical variable and patient experience can play a major role in patient dropout.

Our observations are in line with literature findings. In any case, this is a subject that deserves further investigation and could lead to enlightening results.

### Vision and Reality

The need for total adherence programmes focusing on people with schizophrenia is undeniable. The potential reduction of healthcare-related cost for public health organisations would be significant, and the quality of life for patients and caregivers would significantly improve.

Thinking ahead, new technologies will change the way we think about patient adherence and will allow customised approaches that would have been inconceivable a few years ago. Now is the time to turn to a multidisciplinary approach through coordinated action by health professionals, researchers and policymakers. Everyone will benefit.

### References


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**Zoe Tziakou**, Operations Manager, PCC HELLAS. Zoe has been dealing with patient adherence management problems and solutions on a daily basis. She has been an active participant in the design and management of patient adherence programmes carried out by PCC HELLAS, supervises all personnel involved in patient support, and receives daily feedback from patients and healthcare professionals. Email: ztzi@pccint.eu

**Constantina Georgaki**, Clinical Psychologist, PCC HELLAS. Constantina is involved in the development and implementation of patient adherence interventions for populations facing a variety of health conditions. She is also involved in the patient support centre, conducting one-to-one communication with patients and caregivers. Her other areas of special interest include relaxation training and crisis intervention. Email: dgeo@pccint.eu
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Harnessing Technology to Improve Patient Outcomes Through Engagement

Changing the focus of how healthcare is delivered has become an imperative for developed economies. These changes are exemplified by the pace of reform that is happening in both the US and UK. With ever greater proportions of national gross domestic product being spent on healthcare, and an ageing population, it is clear the status quo is no longer an option if we are to remain economically viable nations. Legislation through the Patient Protection and Affordable Care Act in America, and the Health and Social Care Bill in the UK, both have at their heart a fundamental shift in how providers of care need to operate. A central tenet of reform is the migration away from an episodic, transactional approach to healthcare delivery, to one where greater emphasis is placed on total population cost containment and demonstrable outcomes.

As healthcare professionals we have traditionally not been very good at working to a quality or outcome agenda, preferring a “see more and do more” output approach to the practice of medicine. However, if we are to embrace the brave new world of accountable care we are going to have to fundamentally change how we interact with our patients and actually engage them in an ongoing dialogue about their healthcare needs. Healthcare is the only industry that “discharges” its clients, and indeed actively discourages any ongoing communication between episodes of face-to-face contact. This approach is no longer viable, and may in fact be contributory to the poor health status of such a large proportion of society.

If the premise of reform is accepted, and there are few who would argue that carrying on as we have traditionally done is an option, then we need to look critically at how we can best accomplish these new goals. Central to achieving better outcomes is “engagement”; engagement of patients as well as engagement of physicians and other healthcare professionals. Providers of care need to understand that the way they approach their patient population has to change if they are to achieve the dual goals of cost containment and improved outcomes. The episodic, fee for service type approach to care has to transition to one where a provider has a greater number of touchpoints with the patients that they are responsible for over the course of the year. Only by establishing and maintaining a dialogue over time between healthcare provider and patient can we hope to influence behaviour and ultimately outcomes. Industries outside of the practice of medicine understand and respond to the needs and opinions of their clients. They regularly poll clients, send them information, and even recommend other products and services that may benefit them. This approach not only builds loyalty, but also has the potential to influence behaviour. Now

I am not necessarily saying that we need to publicise a weekly “special offer” to our patients, but what we do need to do is look critically at how effective client relationship management is executed and translate the appropriate aspects to our medical practice.

In tandem with changing how physicians interact with patients, we need to get our patients more engaged with the decisions and approaches that are made concerning their health and care needs. The overwhelming majority of patients are passive recipients of advice and recommendations from their healthcare providers. In fact, active involvement in decision-making is often discouraged by the medical profession. Is it any wonder that we haven’t really been able to shift the needle in terms of population health status over the last twenty years? Patients won’t suddenly get engaged after years of passive acceptance of the traditional medical model; they will need encouragement. We need to create a virtuous circle, one where providers of care encourage active participation in decision-making and provide an environment where this is attainable. Research has consistently shown that engaged patients are not only more satisfied with the care that they receive, but also have superior outcomes when compared to those who are not.

As healthcare providers we are actually in an enviable position; we are trusted by our patients. In fact we are one of the few professions that the general public still do trust. One of the reasons that health insurer- or employer-sponsored health initiatives haven’t delivered the improvements in population health that they might have done is that there is no fundamental relationship of trust in the relationship. We need to do need to do is look critically at how effective client relationship management is executed and translate the appropriate aspects to our medical practice.

One area of inquiry that is very under-utilised is that of patient self-report data, but it is one that could potentially both be valuable to the clinician, and also help patients feel they are actively involved in shaping their medical treatment. Much of the initial approach to diagnosis made by physicians is based on what a patient tells us. However, once that diagnosis has been made we often ignore self-report information, preferring to focus our attention on lab results or how the most recent scan looks. We are undoubtedly missing a trick here, both in terms of optimally managing a patient’s condition, but also in keeping them engaged as active participants in the management of that condition.
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Self-report health status data has been used extensively in the field of employee health management, especially in the USA. The humble health risk assessment, a structured health, wellbeing and behavioural survey, has been shown to be highly predictive of future care utilisation and costs in the short to medium term. It also allows for structured and proactive interventions to those with health and lifestyle risks. Why is it that we do not routinely collect this sort of data from everyone who walks through our hospital or clinic doors? Perhaps traditionally it has been difficult or time-consuming to get patients to complete questionnaires and to collate responses, however in the second decade of the twenty-first century we don’t have this issue. The ubiquity of internet connectivity in society now means that data capture is easy through computer or mobile device, and that data can be presented to providers of care in real time to help them holistically manage their patients.

The connected nature of the society that we now live in provides tremendous opportunities to engage individuals in an ongoing dialogue around their health and care needs and preferences. As I mentioned above, we need to have a greater number of touchpoints with our patients if we are to engage them and effect positive change, but these don’t necessarily need to be in the traditional face-to-face setting. I believe a technology-enabled patient engagement platform should form the cornerstone of every physician’s medical practice. Imagine if every patient coming to your clinic or office were to complete a secure online health assessment prior to the visit, and that information was available to you in a succinct and intuitive “dashboard”, much like lab test results, at the time of seeing the patient. Would it change how you conducted the consultation knowing that although the individual’s main issue was knee pain, they also reported high levels of psychological distress and excessive alcohol consumption? For most of us I think it would. It would lead to at least a brief intervention in terms of lifestyle advice. And we know that brief interventions from healthcare professionals are extremely impactful. Continuing with the scenario above, if you decided to treat the patient in question with analgesia and physical therapy, how much better would it be if you could get them to report back on their pain using a mobile or online tracker? You could monitor their pain status periodically over time and would not have to wait until they re-presented, feeling no better, a few months in the future. This sort of scenario could play out for many different patients and for many different presenting complaints. Not only would you as a physician be having a tangible impact on outcomes in your patients, but you would also be driving improved satisfaction with the services that you provide. Two areas that we will increasingly be judged and remunerated on in the future.

By capturing patient self-report data and amalgamating it with information already contained in the electronic health record, we have a tremendous opportunity to create something better than the sum of its parts. I have always been amazed at how healthcare data analytics organisations focus almost exclusively on cost, utilisation and health record data, to the exclusion of how the patient, and population of patients, is feeling in the here and now. These things have already happened; yes, they can give us some insight into what may be likely to happen in the future, but it is almost like driving exclusively using your rear-view mirror!

Another area where healthcare data analytics traditionally has lagged behind has been in the timeliness of the data that is used to make decisions. The plain fact is that our data is invariably old, and sometimes out of date. And the older it gets the less useful it is for proactive population management. There is no reason why much of the information we collect cannot be made available in real time. Can you imagine what the banking and financial sectors would have to say if the information they use to base their decisions on was as time-lagged as ours? Of course data is only truly useful when it is presented in a way that provides insight to the viewer. The majority of us do not have time to sit down with a spreadsheet and analyse a dataset on a regular basis. But this is where modern technology can also come to the rescue. Modern approaches to real-time visualisation of data can not only help healthcare providers understand the prevailing health issues in the populations they serve, but also can allow them to easily segment the population based on these health issues. An interactive population dashboard gives the provider the opportunity to initiate proactive outreach to patients based on specific and collective health risks. A simple example of this could be sending a secure communication to all patients who are sedentary, informing them about local facilities for physical activity, or informing all individuals with certain medical conditions how to book their annual flu vaccination. A more complex example might be inviting all current and ex smokers who report symptoms of breathlessness on exertion or persistent cough to a COPD screening session. The combinations are almost limitless; however, the key element that has been missing from medical practice to data is the “actionable” data that drives the outreach. This is true population health management, and this is what we need to do if we’re going to meet the dual goals of population costs containment and driving improved patient outcomes. The technology is ready - are you?

Peter Mills is co-founder of nGage Health, an organisation specifically focused on creating technology enabled patient engagement and health management solutions for healthcare providers. He trained in medicine at the University of London and is a specialist in respiratory medicine. He still practices on a part-time basis at the Whittington Hospital in London.
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Challenges and Opportunities from Worldwide Serialisation Initiatives

Coding of Drug Packs is a Step Towards Mobile Healthcare
What if there was an ethical way to engage with individual patients using tools they are already comfortable with, and processes that will in any case be mandatory in pharmacies and production plants? It would certainly be a great place to look for new gains in compliance and persistence. The thrust of my argument in this article is that one of these new processes, pack-level serialisation, will have multiple benefits for health outcomes as well as for product security. Serialisation will give every box or bottle a unique code number that can be traced. There are a number of related concepts such as “e-pedigree” and “track-and-trace”, but for the purposes of this article we can ignore the differences. References to serialisation below should therefore be taken to refer to any code-based traceability system.

Modern Technology

Introduction to Serialisation
The origin of serialisation in pharmaceuticals is linked to the rise of counterfeits and the need to gain better control of the legitimate supply chain. The types of counterfeit medicines are many and varied – see my book¹ for a fuller discussion. However, the reason they exist is always the same: criminals see an opportunity to exploit weaknesses in the drug supply in order to make a profit. This problem is not limited to high-profile drugs for erectile dysfunction. Nor is it confined to branded drugs, primary care, western markets or any other facile generalisations. Fake drugs are everywhere, albeit at widely varying prevalence. We have been slow to tighten up our supply chains to prevent the worst kinds of organised counterfeiting, but a number of initiatives over the next few years should help that process. California has been leading the way in the USA, and in Europe a decisive act was taken by the European Parliament in June 2011.

What is the Falsified Medicines Directive?
The passing of the EU Falsified Medicines Directive² – hereafter abbreviated to FMD – in 2011 has changed the landscape for anti-counterfeiting in Europe. It will have far-reaching effects within the pharmaceutical supply chain, and it will change the way we interact with patients. The FMD will create major challenges for drug companies in Europe when the key changes will likely become mandatory. The two fundamental packaging requirements stipulated in the directive are tamper-evidence and serialisation. In broad terms, this means that all packs must be sealed at the point of manufacture and traceable through the supply chain; neither are universal practices today.

How pharmaceutical companies adapt to these challenges will determine how well they are equipped to compete in the serialised world. But manufacturers should not make the mistake of thinking that this is just a manufacturing issue. It has big implications for patient compliance as well. In this article I will discuss the challenges imposed by the FMD, and also how a traceability initiative aimed at reducing counterfeiting can be used to drive patient value, improve outcomes and increase revenue.

Manufacturing Challenges
Many of the earliest technical problems posed by the FMD will fall onto the shoulders of those in the pharmaceutical manufacturing function. Putting codes onto boxes requires new equipment at the production line, and new software to allocate, reconcile and control the code generation across the business, and to share information with public systems outside the firewall. Making packaging tamper-evident may entail adding a new label applicator for security seals, or initiating a pack redesign to incorporate a perforation feature. Both of these take time and require validation and (in the case of re-design) external regulatory approval. This first wave of technical work is currently being undertaken or planned at most of the medium- and larger-sized manufacturers. However, not all production directors, in our experience, have asked whether this could actually add value to their business – let alone talked to their colleagues in marketing about it.
External Challenges
Implementation of the pack coding, data sharing and tamper-evidence requirements will be a considerable task. At the other end of the supply chain, in the pharmacy, there will also be challenges and opportunities. To make traceability secure, it is important to have rapid and universal take-up at the final check, which will be the point of sale. This may be influenced by factors outside central control, such as broadband access. There are many countries in Europe where the medical and pharmacy professions are not fully online. Accelerating the connection of all EU pharmacies to the internet may be the most important long-term legacy of the FMD.

What about the Patient?
The FMD is largely silent about the role of the patient in authenticating medicines, but clearly there is great potential to involve the end user in the verification of their drugs. This should be as a final check, not as a replacement for supply chain control, but it could potentially be a useful augmentation of other security measures. Sometimes the medical profession and the pharmaceutical industry are guilty of patronising their clients. Experience in the developing world has shown that there is tremendous appetite for consumer interaction with pharmaceutical brands. In areas where counterfeit drugs are endemic and common, patients want help to enable them to protect themselves. In the next section I will look at some of those tools, and how they can be used in a highly ethical way to augment marketing activities.

Case Study: India
There are two prevalent systems of pack coding in India. The first, catalysed by the need to control the perceived quality of exported drugs, was mandated by the Directorate-General of Foreign Trade (DGFT). This ruling requires manufacturers to put datamatrix codes onto packs. The codes will eventually be mandatory throughout the packaging hierarchy, but presently are required only for those pack levels containing more than one unit of sale. Datamatrix coded packs, when available, will provide some opportunities for user verification, but will require the use of camera-enabled smartphones. Since the penetration of these devices is currently less than 10% in India, this will remain a limiting factor for some time.

The second system, which presently carries government encouragement rather than the force of law, uses SMS as the data carrier. Pack-specific alphanumeric codes are printed onto each unit of sale (typically a blister) together with instructions for the user to send the code by SMS to a short code number. These systems typically require only low literacy levels and use simple phone technology that is almost universally accessible, even in poor areas.

India is often written off as too poor to enable adherence methods to work, but the advent of SMS services is proving this generalisation wrong. There is a large and growing segment of the population that is hungry for direct, low-cost or free services. The individual sale price may be relatively low, but keeping people loyal to your brand with simple and cheap messages delivered to their mobile phone means that these aggregated transactions can add significantly to the bottom line.

Case Study: Nigeria
Nigeria has been at the forefront of the war on counterfeit medicines in the developing world for a number of years. The National Agency for Food and Drug Administration and Control (NAFDAC) has been proactive in seeking out fake drugs with infrared scanners and other enforcement tools. More recently, they have also stipulated that all anti-malarial drugs and antibiotics must carry scratch-off labels containing SMS codes. In contrast to India, these labels are typically on the outer carton, not the blister, and the code is concealed beneath a one-time scratch-off coating. To verify the product, the patient removes the scratch-off layer and sends the revealed code by SMS.

Nigeria is a country of more than 160 million people, with an incomplete state health service. Many people live on less than two dollars per day. However, mobile phones are ubiquitous, even in the poorest districts. There is a genuine appetite for health advice, simple tips and medication reminders. Finding a way to deliver these at no cost to the receiver will pay dividends for forward-thinking brands.

How does this Apply in the EU or the USA?
The developing world is arguably ahead of the west in some areas. For instance, I get a better mobile phone signal in most African countries than I do at my rural home near Cambridge, UK. There are lessons to be learnt from the use of direct interactions with patients in developing nations that can be applied even in highly regulated markets such as the EU and USA. The higher penetration of smartphones in these more developed markets means
that camera-based code recognition becomes feasible. Those datamatrix codes that the manufacturing division is complaining about as a compliance issue for the FMD (or California e-pedigree depending on your focus) may just be an unexploited goldmine.

**General Trends**
The take-up of SMS verification, and latterly scanning with camera phones of datamatrix, linear, QR and codes has been accelerating over the last few years, driven by a number of factors. Firstly, the technology is relatively quick, simple and cheap to implement. Manufacturers have thus started using codes as a way to differentiate their product from the competition, as well as seeing them as a way to counter fake drugs. Secondly, users are starting to look for the codes as a sign of authenticity. Finally, service providers and brand owners have realised that there is more than one interaction to be had.

The primary contact with the patient is to confirm the identity of the code and to verify that it is recognised within the database of numbers used by the original manufacturer. This can be followed up with a separate but related message initiating an opt-in process for downstream benefits. For those patients who opt in, the service provider might provide dosage reminders, refill reminders, health tips, referrals to a medical professional, etc. The details vary by geography and the local legal framework, but these services are usually provided by a third party and ultimately paid for by the brand owner. In some cases the user may pay for any outbound text messages and calls, although even this step can be made free to the user (i.e. the charge picked up by the brand owner) if required. All of this can be achieved without collecting any information other than mobile phone number and product code. At no time does the service provider or brand owner need to record medical or personal details about the respondent, or contact them without their consent.

Not everybody sends in the code, and the take-up rate depends heavily on how much the service is promoted by the brand owner. However, of the users who do verify their medicines, the subsequent opt-in rates are typically quite high. These are people who tend to value their health outcomes and want to be sure that their medication and their dosage regime are effective. They are therefore potentially well-suited to a range of services which both improve their medication experience and rates of persistence, as well as helping the brand owner to achieve higher profits.

**Conclusions**
The challenge for Big Pharma in the twenty-first century will be how to deliver better health for more people with less revenue per transaction. Using codes that were intended for another purpose (anti-counterfeiting) as a way to generate a carefully controlled, ethical and limited dialogue with patients is one innovative option to look at.

These technologies are not bulletproof from a security point of view. Any one transaction can be vulnerable to copying, even with scratch-off codes. However, as take-up rates increase there is a marked “network effect” where the improved connectivity and visibility of events in the supply chain means that the security value of the system increases more quickly than the transaction volume. The usage rates are driven, in turn, by the perceived value to the users. Therefore, the more we use mobile channels to deliver these simple verification messages and compliance reminders, the more secure the drug supply becomes and the more adherent patients become. Better adherence, tighter control of the supply chain, improved bottom line. Maybe it is time to make that call to your Production Director and set up a meeting.

**References**

Mark Davison is an entrepreneur with a senior background in pharma, biotech, CROs and security systems. He is the author of “Pharmaceutical Anti-Counterfeiting” (Wiley, NY, 2011) and founded consultancy Blue Sphere Health to help pharma companies with serialisation, anti-counterfeiting and patient engagement. Mark is also acting Chief Business Officer for PharmaSecure Inc, working at the interface of authentication and adherence.

Email: mark.davison@bluespherehealth.com
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The fact that smart technology could save the NHS £billions is not disputed, certainly not by us. But why should we wait years for a solution that is achievable much quicker and much more cost-effectively? PriceWaterHouseCoopers’ report found that “measures such as more use of text messages for negative test results, electronic prescribing and patient records and information portal could improve care.” Bravo.

In technology terms, however, five years is an absolute eternity. The very real danger is that the recommendations being made today (and being budgeted for out of our taxes, now) simply won’t be relevant by the time they are implemented. And there lies the challenge for the public sector, and the NHS specifically. Many commentators have previously identified that Government projects follow Parliamentary timescales and agendas, yet few have the ideas, the solutions and the conviction to propose tangible actions that will make a difference to us all in the short and medium term.

Vision
Our vision for the NHS and indeed all organisations is a simple one. A world where intuitive data handling becomes second nature and becomes so well integrated into the organisation’s operations, that there are no joins whatsoever. One powerful data source sits behind everything, enabling patients and users to control their preferences and receive the information they want, when they need it. Constantly updated in real time, there is to be no duplication; no misunderstandings; no information gaps. Just a simple history of exactly who did what, when, and how, and what stage any particular process is at right now. Only authorised people can access the appropriate hierarchies of information, with the patient able to (once their identity is verified) access the appropriate hierarchies of information, process is at right now. Only authorised people can did what, when, and how, and what stage any particular process is at right now. Only authorised people can

Indeed many patients, not benefiting from automated information systems at all. We would like to see a more rapid transformation towards, in the first instance, total automation of the simplest communications processes, which we believe there is no good reason to hold back on - either from a quality, cost, or patient experience perspective.

Flaws
The first flaw in this public sector process was perhaps the assumption that an expensive report from PriceWaterhouseCoopers was required to establish that technology and SMS messaging in particular might improve care, reduce paperwork and improve operating efficiencies. Look at the technology the present generation are using and witness the gulf that is developing between what our children take as second nature and the communication techniques and systems deployed by institutions such as the NHS at a local, regional and national level.

The historical culture of the NHS in the UK unfortunately means that layers of bureaucracy need to surround purchasing decisions and announcements, so much so that there is never any real accountability and someone always has someone else to blame. Blame is a negative, divisive culture, and has no place in a forward-thinking commercial operation, and until the people within any organisation think it’s their job to suggest “how do we fix that?” and “how do we make that better?”, we, and they, may all quite frankly be fighting a losing battle. Culture really is key. But assuming resistance to cultural changes can be overcome by the Gerry Robinsons and all the other consultants who have suggested ideas to fix the archaic and cumbersome way the NHS behaves administratively, there are real things you can do at a local level to act as a catalyst for positive change and improve patient, client or customer care in your own working environments. And remember that these principles apply everywhere, not just in public health workplaces.

Opinion
A quick exit survey in a busy GP’s practice, for example, can easily take public views on communications and patient care. With these benchmarks you can then ask people if they’re prepared to take part in a three-month trial on improving key areas of the service. A specialist business software company with experience in this field will be delighted to walk you through the process of technology integration and deployment, and give you a modest, fixed-price quote to conduct the technology trial. Remember though to initially keep it simple, don’t over-engineer the survey, and always analyse the results carefully. The positive effect of change could be dramatic and rapid. We agree with Mr Hunt that this is the right way to go.

After analysing the results of the technology trial and polling your audience (in this case the patients and
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staff) again, if the results are astonishingly positive (as we believe they could be), you extend the trial to another 10 practices, and to several other areas of the country, make sure it works there as well, and you then constantly refine and develop the model as you roll it out nationwide.

Once the smart technology is installed, you should pay only a small licence fee and then it’s a ‘pay-as-you-go’ model based on usage. If you use it a lot, and as you find patient care and efficiency is improved and you are massively more effective as a company or organisation, you may re-negotiate your unit charge. But under no circumstances should you be paying £Millions up front – or be contracted to pay £millions over several years – for something that is not properly tried and tested, may never be released or launched in time, and which may be out of date before live date because nobody thought to include ongoing development work in the contract.

This is technology that’s available right now to introduce online appointment booking with integrated SMS, email and traditional correspondence like letters. And if the country was really serious about reducing unnecessary admin costs in the NHS, and at the same time improving patient care, this one simple technology deployment could for a relatively small sum save hundreds of thousands (or millions?) of phone calls a year, tying up overworked admin staff who could be redeployed to higher value or more urgent priorities. Yes, I’m sorry to say that in the long run it means you do not need as many administrators in the health service and similar organisations, because the dependence on administrators would be markedly reduced. And what we are talking about with online appointment booking would be only one element of a sophisticated communications platform that would enable clinicians and administrators to concentrate on what they do best – patient care – rather than getting bogged down in low value / high volume correspondence.

Public Procurement Problems
Pay-as-you-go models of technology like this involve little or no capital cost up front, and you get to see it working and put it through its paces before deciding to deploy it across an entire Trust, department, company or country. Here’s the rub, and another problem with the current public procurement regime; the public sector tendering process itself seems culturally quite a negative one - a punitive process where companies are sometimes penalised for not having an adequate turnover or employing a large enough number of people, rather than being rewarded for having great ideas and solutions at affordable prices.

Why are we so confident we have the answers? Nobody can solve the massive logistical and financial nightmares and dilemmas of the NHS overnight and we’re not promising to do that; yet some really simple principles of technology integration apply whether you are a director of an NHS Trust; a senior manager at a pharma; or an ops manager at a medical insurer or brokers. These businesses are extremely diverse, yet good technology can benefit them all and bad technology can ruin them all, grinding them to a halt.

We do have a fair bit of experience in this field and are confident enough to put our neck on the line and take responsibility for what we say, and what we do. We are integrating smart systems with online portals and (for example) SMS messaging integration, today, and could introduce such time- and cost-saving technology for any public body at a tiny fraction of the cost of the numbers being quoted for the so-called ‘paperless NHS’ project – whilst significantly reducing the NHS’s carbon footprint in the process.

Whoever you choose for your technology review, and whatever area of patient or client care you’re involved in, there are a few things that you should consider. National Health Authorities, Government departments, major corporates and SMEs alike should seriously think about these issues before investing in new technology and data systems to improve their businesses and patient care.
Peak Performance

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Be Realistic
When we talk about a paperless NHS, everyone knows there can never be truly such a thing. Not as long as there are lawyers, GPs, patients, people in general. Because for legal reasons among many others, there will always have to be duplicate and triplicate paper copies of certain documents. So whilst the idea of a paperless NHS might get plenty of media coverage, what we’re really talking about is a much faster, more effective, more risk-managed NHS where letters/emails/texts are sent out and appointments made in a timely fashion; where less critical appointments are on a standby list and if you have a cancellation these people will have pre-subscribed to SMS to say they would be interested in a last-minute appointment if one became available.

An integrated environment where all information input, output and aggregation works constantly to improve the machine and patient care, making things gradually better, rather than grinding everything to a halt, lowest-common-denominator-style. No, what we all surely want is in fact a highest denominator approach – namely that the best use of technology that provides the best improvements in patient and client care drags the rest of the machine with it, so the benefits can be felt in other areas.

So to my mind we shouldn’t be simply talking about a paperless NHS in isolation. We should be talking about a completely different NHS, one which drives efficiencies, is cost-effective and strives to improve the patient journey – by its smart use of technology. I understand the headline “Paperless NHS” may sell newspapers, but this issue goes way beyond that – we are talking about the entire future of healthcare in this country.

Focus on Patient Needs and Wants
What do patients and staff actually need, and what do they want? That’s what should be driving new technology deployment, not some political agenda or a desire to leave a legacy that we achieved x over time period y.

If the real opportunity is to significantly reduce the administrative burden on the NHS, streamline processes and therefore improve care through better communications, the rationale is good but the implementation may currently be over-engineered and too little, too late. Particularly if patients themselves have not been properly consulted.

Harness the Cloud
Cloud Computing – What Is It?
In short, cloud computing can be defined as the delivery of technology applications as a remote service, rather than a product that you purchase and own locally. So shared resources such as patient data can be securely shared between authorised users over the internet, without the need for a specific piece of hardware onsite at your own practice, department or ward. The term ‘cloud’ is often employed as a metaphor for the internet, and if you look at it in this way, ‘cloud computing’ translates as using the internet for your computing needs. Another analogy is rather than everyone having an electricity generator in their own home, it is far more convenient to connect to an electricity provider – and you simply take advantage of the service offered. Ditto enhanced telephone features for business – these are not held locally, but on the telco’s own exchange (or ‘switch’), so many businesses already use technologies and services akin to the cloud without perhaps realising it. The main advantage of this approach is that a business or organisation can concentrate on delivering its key function (patient care, medical insurance or whatever) without needing to understand or maintain the system that is supplying the ‘power’.

Spaghetti Junction
Cloud computing is all about removing the spaghetti infrastructure of parallel networks, wires and applications all doing their own thing and existing in their own little bubbles, without communicating with each other. The cloud is about bursting these bubbles and integrating the individual technology platforms. Applications that speak the same language, communicate with each other bi-directionally and provide meaningful management
data to business owners and centralised bodies alike. True cloud solutions are open environments that allow other cloud solutions to share information seamlessly with them through the use of standard, well supported web services. A simple interface that is visible to other applications, that allows data to pass back and forth in two directions. If one application is to be replaced, the new solution simply plugs into the same interface. Forget about complex software development kits, this is all about the sharing of data and the extending of functionality.

Security
Many people reading this article may think yes, ok, but what about security of all this information? And you’re quite right. The security of patient and client data is paramount. Patient data is secure in the cloud, and the centralisation of data means that someone cannot simply break in and steal it like they could a computer, laptop or pen drive. Security in the cloud is better than many traditional systems, as technology providers offering these services are experts in their field and devote significant resources to delivering security that individual users may not wish to pay for directly.

You should look for a provider that has achieved Statement on Auditing Standards SAS 70 certification, which is an assurance that the highest security standards are being adhered to. ISO27001 and PCI accreditation for exemplary data security management will also give you some comfort, as will a provider that lodges your data files securely for you in escrow.

For the healthcare and many other industries like insurance, cloud computing provides a way to ensure continuity of service, increase the business capacity, or add new capabilities – without investing in costly new infrastructure. So no need for training for staff, licensing new software or buying new hardware. This model delivers real business agility and can be used either to extend or enhance existing capabilities.

Return on Investment
Finally, when you are happy that your technology provider can deliver technically, on time and to budget, and will continue to update and develop your systems for you, don’t forget the all-important return on investment calculations. A good technology company will happily run the numbers for you up front, and illustrate in advance what a sound investment you’re making in their technology platforms.

Edward Shropshire is Managing Director of Aquarium Software, with major clients both at home and abroad in the public and private sectors, from the smallest of SMEs right through to commercial Insurance giants and FTSE listed companies. A former GB competitive rower and a graduate of Electrical and Electronics Engineering, Ed’s role is now firmly at the helm at Aquarium. He designs and specifies bespoke technology solutions to solve often complex business and organisational problems. He is a thought leader on the topics of data handling, web security and application integration, and his views are regularly featured in national publications and on industry blog sites.

Email: edward.shropshire@aquarium-software.com
Compliance Against the Odds: Keeping Pace with the Complexities of an Ageing Population

In recent years, the caring community, comprising residential, nursing and domiciliary care, has become increasingly receptive to the use of future-focused technologies to aid patient compliance. However, the argument for putting in place a robust infrastructure to encourage adherence has become even more compelling since the introduction of QIPP (Quality, Innovation, Productivity and Prevention); the NHS’ Six Sigma-esque approach to eradicating waste and maximising efficacy and efficiency to marry healthcare needs with the reality of the current care budget.

Improving medication adherence addresses two of the four key areas of the QIPP agenda – Innovation and Productivity. By improving quality of care and preventing unnecessary hospital readmissions caused by patients diverting from their medication regimes, monitored dosage systems have now become a fundamental element of best practice in the care sector. And as long-term age-related conditions such as dementia continue to require a bespoke approach to care, the elimination of avoidable errors represents relatively ‘low-hanging fruit’ in the effort to get the basics of care right, in turn enabling care professionals to deliver tailored, hands-on care to optimise patient outcomes.

Since their inception in the nineties, MDS systems have become a crucial tool in combating the numerous obstacles to compliance. Dementia, complex regimes, apathy and forgetfulness all contribute to the ongoing problem of drug error. In a hospital, care home or in domiciliary care, limited time and resources, plus a lack of training, vastly increase the risk of drug error and jeopardise patient welfare.

The ageing population and associated long-term health conditions add another layer of complexity to the compliance challenge. This demographic shift presents a call to action for pharmacists, prescribers and carers – how to keep our elderly population in good health for longer, using the limited (and rapidly dwindling) resources available.

When Age Gets in the Way
When it comes to complying with prescribers’ and pharmacists’ instructions, the elderly typically have more to contend with than most:

- Swallowing problems / dysphagia
- Convenience – difficulty ordering or collecting prescriptions if patients have limited mobility or live alone
- Memory loss, confusion or dementia

Dealing with Dementia
For over half a million dementia sufferers in the UK, ensuring compliance with often complex medicine regimes, whether living alone or in a home, is a significant obstacle to optimum health. Complying with medication regimes is doubly hard for dementia sufferers; in a sense it’s a vicious circle. Dementia sufferers are often prescribed complex combinations of medication, however, the symptoms of dementia itself make taking this medication correctly or monitoring medication compliance in sufferers, a greater challenge for carer and patient.

The current reimbursement model doesn’t help pharmacists support dementia sufferers either. The community pharmacy contract encourages pharmacists to source the cheapest generic medicine or parallel import; the clawback mechanism assumes they are doing this and penalises them if they don’t. This means patients are often given a different colour or shape of tablet each time they receive their prescription, increasing the risk of confusion and error for dementia sufferers or care staff in a home setting. While there’s nothing pharmacists can do to change the pricing model, there are other ways they can support dementia sufferers and their care staff in adhering to their medication regimes, such as introducing monitored dosage systems.

Indeed, in pockets of the UK, pharmacists are taking the initiative on dementia by supplying prescriptions to care homes and domiciliary care organisations in a monitored dosage format, with excellent results. Pharmacists providing dementia sufferers’ medication in pre-measured personalised Biodose monitored dosage systems (MDS), have reported up to an 80 per cent increase in adherence across patients at home or in residential care. These simple systems have proven their worth in helping dementia patients overcome the confusion of managing multiple medicines at once.

Until now, the success of these tools has relied on the completion of a traditional paper MAR sheet to record patient compliance data. However, Protomed has since developed BeMAR, the market’s first electronic...
Myth One: MDS Don’t Accommodate Liquids

Spot the incorrect statement from a communication by the British Medical Journal: a) prescribers are four times more likely to give the wrong dose of medicine with liquid prescriptions compared with tablets and b) monitored dosage systems don’t accommodate liquid medicines. The latter is the most outdated (yet still extremely common) assumption in the world of MDS; that monitored dosage systems are only suited to solid dosage forms.

This myth dates back more than ten years, to a time when MDS was in its infancy. Historically, the lack of a watertight MDS deterred many care homes from adopting early models, or meant they had to administer liquid medicines from the bottle as well as managing a pre-measured MDS pack. Bearing in mind that the raison d’etre behind MDS’ inception was to uncomplicate drug rounds, this was a less than ideal solution.

To date, the vast majority of MDS on the market have tried to get around the problem by including features such as reminder cards that direct carers doing the drug round to any medications not packed within the MDS. This extra step in the process opens up yet another opportunity for human error to set in, and defeats the object of centralising all of a patient’s medications in one system.

Biodose came onto the market to overcome this issue. Given that to date, it is the only system to accommodate liquid and solid medication side by side, BeMAR eliminates the need for paper and allows carers to record patient medication information instantly during the medication round, via a wireless, user-friendly iPad, for live monitoring of patient compliance patterns.

In reality, community pharmacies are ideally placed to offer a lifeline to dementia sufferers and to deliver compliance programmes into dementia care. While the pricing structure of generics is out of pharmacies’ control, introducing systems to contain all patients’ medicines, regardless of colour and shape, whether liquid or solid, is a step in the right direction in helping them take medicines as prescribed.

Ignorance and misunderstanding are the enemy in the battle to make adult residential and social care more effective, efficient and economical, without compromising quality or affordability. Even in this, the information age, an outdated understanding of MDS technology is standing in the way of vast savings and improvements in patient outcomes. With the cost of drug error and wastage an ongoing focus for the UK’s QIPP initiative, getting up to speed on countermeasures to the compliance problem is no longer an ‘optional extra’ for the care sector. For this to happen, it’s critical to cut through some of the myths about the impact monitored dosage systems can have on the care sector, from a quality, productivity and economical perspective.
it’s understandable that this particular myth is still doing the rounds. However, the availability of a single anti-error solution that accommodates liquid and solid dosage forms makes MDS technology accessible to an audience that may have previously overlooked its real value. In truth, the problem of non-compliance is more prevalent in the elderly, and the elderly are more likely to suffer from swallowing difficulties and require their medicines in a liquid format. Therefore dispelling the untruths around liquids and MDS is vital to improving quality of care for older patients.

Myth Two: MDS can Store a Maximum of Four Doses per Day
This common misconception portrays MDS as inflexible systems that are appropriate for a limited number of patients. With the average number of prescriptions dispensed annually to people over 60 having doubled in a decade, and elderly patients in care homes taking an average of eight prescribed medicines per day, a four-a-day system would be useful for only the minority of older patients.

True, the majority of MDS are limited to accommodating doses at mealtimes and before bed, which makes compliance almost impossible. However, a minority of systems allow virtually unlimited doses during the day, to take account of the importance of accurate timing and the complexity of many drug regimes for the elderly.

Containing sufficient doses for the patient is crucial to the efficacy of an MDS, and all systems are certainly not created equal in this respect. The most sophisticated systems incorporate software that can adapt to up to 11 dosage intervals throughout the day, which don’t have to be limited to breakfast, lunch and dinner. This means each individual dose is labelled with the specific time the medicine should be administered, leaving the minimum room for error to creep in, whether the patient is self-medicating or in a care home environment.

Myth Three: Medication in MDS Affects Product Stability
To address the relative stability (or otherwise) of medication contained within a monitored dosage system, let’s compare how liquid medication is administered the traditional way with the MDS alternative.

Let’s assume a carer is administering medication from the bottle, three times a day for a month. This means that monthly, the bottle is opened 90 times and will be open for approximately one minute per dose, to open, pour and close. This equates to the bottle being open for 90 minutes per month. In contrast, compare that with an MDS such as Biodose. In this case, the individual dose of medicine is exposed to the atmosphere only seconds before it is administered, and as each dose is pre-measured and individually packaged, the remainder of the medication is not exposed to the atmosphere every time a single dose is administered.

Myth Four: MDS Only Adds Value to the Management of Oral Medicines
US studies show that non-compliance is as great a barrier to recovery in the context of topical medication as it is oral medication. In the field of dermatology, it is observed that that the rate of non-compliance among topical medication may be as high as 40 per cent. Despite the fact that the immediate physiological consequences of not applying creams and lotions as prescribed is perceived as less threatening, it clearly contributes to the estimated £150m of avoidable medicine waste in the UK.

In the past, MDS have focused on oral medications, and only now are more advanced tools coming onto the market to help counteract topical drug error and provide a more comprehensive approach to the compliance conundrum. As well as accommodating larger quantities of liquids in a safely sealed container, the more sophisticated systems such as Medigram from Protomed have proprietary software that creates a MAR sheet specific to topical drugs, in the form of a body map. This literally maps out the areas where medication is to be applied to the patient, aiming to make the process as foolproof as it can be. So while topical MDS are a relatively new development, expect to see them used more and more in future as budget holders in healthcare look to plug the leaks in their steadily shrinking drug budgets.

Myth Five: One Size Must Fit All
The options available to help manage medicines have multiplied in the last ten years. The days of housing tablets in egg cups are long gone, and in their place...
is a variety of intelligent systems designed to take the thought and the risk out of the drug administering process.

Despite the speed of innovation in MDS, the diverse spectrum of options on the market ranges from the very simplistic (Dosette boxes and blister packs) to the sophisticated (electronic MARs). With so many preconceived (and often inaccurate) ideas about what MDS can (and can’t) do, many in the care sector are still in the dark as to the features and benefits they can expect from a monitored dosage system. As more and more copycat products enter the market, to differentiate one from another, carers, pharmacists, doctors and individuals will be asking the following questions:

- Can it contain liquid and solid medication?
- Is it available for use with topical medication?
- Does it accommodate all the doses needed throughout the day?
- Is it easy for the patient or carer to use?
- Does it offer the option of an electronic MAR?
- Are the dosage instructions, time and patient details clearly visible?
- Are the medicines clearly identified on the tray?
- Is the system tamper-evident?
- Can individual doses be removed to take on days out? If so, are their instructions / patient details on each individual dose to maintain continuity of compliance?
- Does it have any features to combat MRSA / minimise infection, such as antimicrobial packaging?

What’s Next for MDS?
At the more advanced end of the innovation scale, on the horizon is telehealth; an area where we are investing heavily, and specifically, in our next product to launch to the domiciliary care sector; TelePAK. The launch of TelePAK will improve the flow of information about patients’ compliance (or otherwise) between relatives, carers, medical professionals, pharmacists and nurses, and elevate the quality, choice and affordability of care options available to an increasingly diverse patient population. But what will the fusion of MDS and telehealth look and feel like? Picture this. 85-year-old Frank, who lives alone, pops open his Biodose TelePak MDS pod for the day. Through a microchip embedded in the TelePak tray assembly, this automatically sends an SMS alert to the Protomed Monitoring Centre and then to relatives, carers or other designated persons, such as his GP. TelePak also logs the time in a database to be reviewed at Frank’s next MUR with local pharmacist. Over the next few days, Frank starts missing doses, which triggers a rule pre-programmed into the system, and sets off another chain of events. A warning text is sent to Frank’s relative (much in the way of a personal alarm) and GP, to prompt them to check on him and find out why he isn’t taking his medication as prescribed.

In Conclusion
As government calls for us to pull together to weather the continued loss of public funding, pharmacists are an even more vital part of the healthcare family than ever before. With a call for more elderly patients to be cared for in their own homes, the compliance challenge will move further into the spotlight, and pharmacists’ ability to offer MDS will become a vital point of differentiation in attracting their share of healthcare contracts.

And as lifespans grow and healthcare budgets shrink, there is no doubt that MDS and in future, telehealth, will become the norm. Were it not for the many myths surrounding intelligent packaging, we may already be seeing the fruits of greater compliance on a wider scale. That said, the medical and caring profession and the patients in their care are reaping the rewards MDS has to offer, and as telehealth takes compliance to the next level, may the healthy innovation continue.

References
1. Report published by National End of Life Care Intelligence Network, June 2010

Norman Niven is CEO of Protomed and creator of Biodose, the only monitored dosage system to accommodate liquid medication. Formerly a director of BUPA, Norman also brought to market a pioneering MDS - Nomad from Surgichem - and continues to innovate in the field of improving patient compliance in care homes and domiciliary care. Email: info@protomed.co.uk
Difference in Pill Colour May Affect Patient’s Adherence

Generic medications are biologically identical to their brand-name counterparts, however, their physical traits, like shape or colour, usually differ. Patients who take generic drugs that differ in colour are 50 percent more likely to stop the intake of the drug, producing possible negative reactions, according to a new study by Brigham and Women’s Hospital (BWH).

The findings were published in the Archives of Internal Medicine. The case-control study analyzed patients taking antiepileptic drugs and looked at the probability that patients who did not refill their prescriptions had been taking medication with a different shape or colour from earlier prescriptions.

Aaron S. Kesselheim MD, JD, MPH, assistant professor of medicine in the Division of Pharmacoepidemiology and Pharmacoeconomics at BWH, and principal investigator of this study, explains: “Pill appearance has long been suspected to be linked to medication adherence, yet this is the first empirical analysis that we know of that directly links pills’ physical characteristics to patients’ adherence behaviour. We found that changes in pill colour significantly increase the odds that patients will stop taking their drugs as prescribed.”

The investigators used a large national database of filled prescriptions. When they discovered a gap in a patient’s use of the drug, they reviewed the previous two prescriptions filled and checked to see if they were the same shape and colour.

Merck’s Adherence Estimator aims to improve patient health outcomes

Online Survey helps doctors and patients address underlying issues leading to nonadherence

Merck understands that one of the most significant problems facing the U.S. healthcare system is that many patients do not take their medicines as directed. In fact, research shows that 75% of adults fail to adhere to their prescribed medications. The cost of patient nonadherence approaches $300 billion and causes 125,000 deaths each year in this country. With healthcare costs projected to reach nearly $3 trillion this year, improving patient adherence represents a way to cut costs and save lives.

The packaging community continues to address the issue, often with calendarised packs for solid-dose pharmaceuticals and easier-to-use pens, injection devices, therapeutic patches, and other dosing methods. Merck, too, is researching adherence-promoting packaging. But the Whitehouse Station, NJ-based maker of vaccines, medications, and consumer and animal health products also seeks to actively involve patients and health care professionals in an effort to not only understand the reasons behind nonadherence, but also uncover what interventions can be taken to greatly reduce it. One tool it has developed in this effort is the Adherence Estimator®, Adherence Estimator is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

The Adherence Estimator is a three-question survey that can help health care professionals quickly gauge a patient’s willingness to take a newly prescribed medicine for a chronic condition. “By understanding that a patient has reservations about taking a newly prescribed medicine, a health care professional is able to have a more effective conversation with the patient about these concerns,” says Colleen A. McHorney, PhD, Senior Scientist for Merck’s U.S. Medical Affairs organization. “The Adherence Estimator serves as a means to jump-start the discussion.”

Patient adherence goals drive Walmart’s new compliance pack launch

A recognized leader in retail trends and sustainability issues, Walmart is poised to further drive the use of patient-compliant calendarised packaging in the U.S. with its December 2012 launch of paperboard-based ecoslide-RX® packs supplied by Keystone Folding Box Co.

The new portable, calendar-style prescription packs, which aim to increase patient adherence to drug regimens, are now rolling out at nearly 4,600 Walmart retail pharmacies across the U.S., initially for 40 different items, with plans to use the packs for another 35 to 40 items by early 2013. Walmart will employ the ecoslide-RX® packs for prescriptions as an additional package configuration, joining traditional amber vials and caps, as well as other calendar-style packs made of other paperboard and plastics.

For Bentonville, AR-based Walmart, improved patient adherence will yield economic, supply chain, and sustainability advantages. “The biggest opportunity that we see for consumers in a compliance pack is the ability to help them adhere to a medical regimen,” says Jon Sasine, Walmart’s senior director of packaging for private brands. “So often, what we see in a treatment pattern is that the patient is very diligent at the outset of that regimen. But we start to see a drop-off or a lack of adherence weeks and months later. So the real beauty of this type of a pack is it provides a physical printed reminder and an opportunity for consumers to see whether a dose for a certain day has been taken or not. It really gives—and we have seen the medical literature that supports this—a strong uptick in patient adherence to medical dosage.”

Online survey on the management of patient adherence

Researchers at Keele University have launched an online survey to learn about health care professionals’ (doctors, pharmacists and nurses) approach to supporting patients with taking medicines and promoting adherence.
Dr Wendy Clyne and colleagues at NPC Plus, Keele University, are coordinating the survey which is part of a larger project on medicines adherence called the ‘ABC project’ (www.abcpoject.eu/) funded by the European Commission. The survey is taking place in countries across Europe including Austria, Belgium, France, Germany, Greece, Hungary, Italy, Portugal, Poland, Switzerland, The Netherlands and England. The survey will run until the end of March 2012.

The survey aims to investigate health care professionals’ perceptions of the extent and nature of non-adherence, as well as the things that health care professionals do to support patients with medication taking. The study also aims to find out about any barriers to supporting adherence as reported by doctors, pharmacists and nurses. Dr Clyne, Head of the Medicines Partnership Programme at NPC Plus, said ‘With more patients taking medicines than ever before, encouraging patients to get the most out of their medicines is essential to avoid unnecessary ill health as well as reduce waste and unnecessary cost. We are really interested to find out what healthcare professionals do to support patients with medicine taking, and how effective they think their actions are. At the end of the study we should have a really clear picture of the role of these three key professional groups in supporting patients with medicines, how that support fits together, and whether we have a consistent picture across Europe, or whether there are variations in practice from one country to another.’

The results of the study, which is set to be the largest study of the management of medication adherence in Europe, will be used to inform teaching and learning for healthcare professionals, inform future service design, and make sure that skills mix in adherence support is optimised.

As Patients Turn to Internet, Companies Build Dedicated Adherence Teams

Drug companies are increasingly building centralized Patient Adherence teams, as revealed in our latest study on patient adherence. This is a recent development, with most companies reaching the decision to create a more centralized and dedicated adherence team in the last 1-3 years.

• Of the 12 companies with dedicated teams, only two have had their teams in place longer than three years, and both of them specialize in providing adherence support to other companies.

• Six companies have had teams in place between one and three years.

• Four have only established groups within the past year.

The recent move to develop adherence teams reflects the shifting focus of the pharma industry’s resources from purely bringing products to market to establishing support for the target users: the patients. This is a timely shift, as never before have patients had access to as much information about their health. A recent Harris Poll survey on patients’ use of online healthcare information shows people are increasingly – and more frequently – visiting search engines and medical websites to gain a better understanding of their conditions. In fact, of the 1,019 adults surveyed in 2011: “Three quarters (74 percent) of all adults have gone online at some time to look for health information, and 60 percent have done so in the previous month.”

This could be worrisome, as a Health Site Intercept Study by About.com revealed only 35 percent of patients trust doctor’s healthcare regimen without also researching their prescription online. That leaves 65 percent of patients turning to the internet to learn about alternate therapies, fuelling the incidence of non-adherence rates. This in turn leads to preventable illnesses or conditions going untreated, resulting in increased hospital expenses and, in some cases, even death. Dedicated adherence teams that provide patients access to data presented in a non-promotional manner can help patients sift through the vast amount of information available on the Internet and find resources that are reputable and trustworthy.

Data Sneak Peek: Which Groups Are Involved in Patient Adherence Teams?

The Research team is right in the middle of our new study of patient adherence and compliance, and we’ve now interviewed executives from a variety of companies in the life sciences industry about their patient adherence groups’ reporting structures and organizational charts. Over half of all companies surveyed report having a dedicated team; the rest use staff on an ad-hoc basis. While no two companies have exactly the same structure due to different needs and resources available, several trends have emerged.

Over 80% of companies involve their patient communications/education/marketing group. This group has its ear closest to the patients’ voice, so it is natural that they are involved in many companies’ groups geared toward improving adherence. Next most commonly involved are brand teams, with 72% of companies involving brand and product teams in their patient adherence and compliance efforts. When companies are looking at adherence on a product level, brand teams must explore every avenue to best reach patients. Market access teams are only involved in patient adherence groups at a third of the companies surveyed. This may seem surprising because payers work closely with physicians and pharmacists – who work with patients – to find drugs and devices that will best increase the health outcomes of their representative patient population. However, efficacy of adherence programs is harder to quantify than pharmacoeconomic data might yield, so market access groups are only involved in adherence programs on a case by case basis.
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