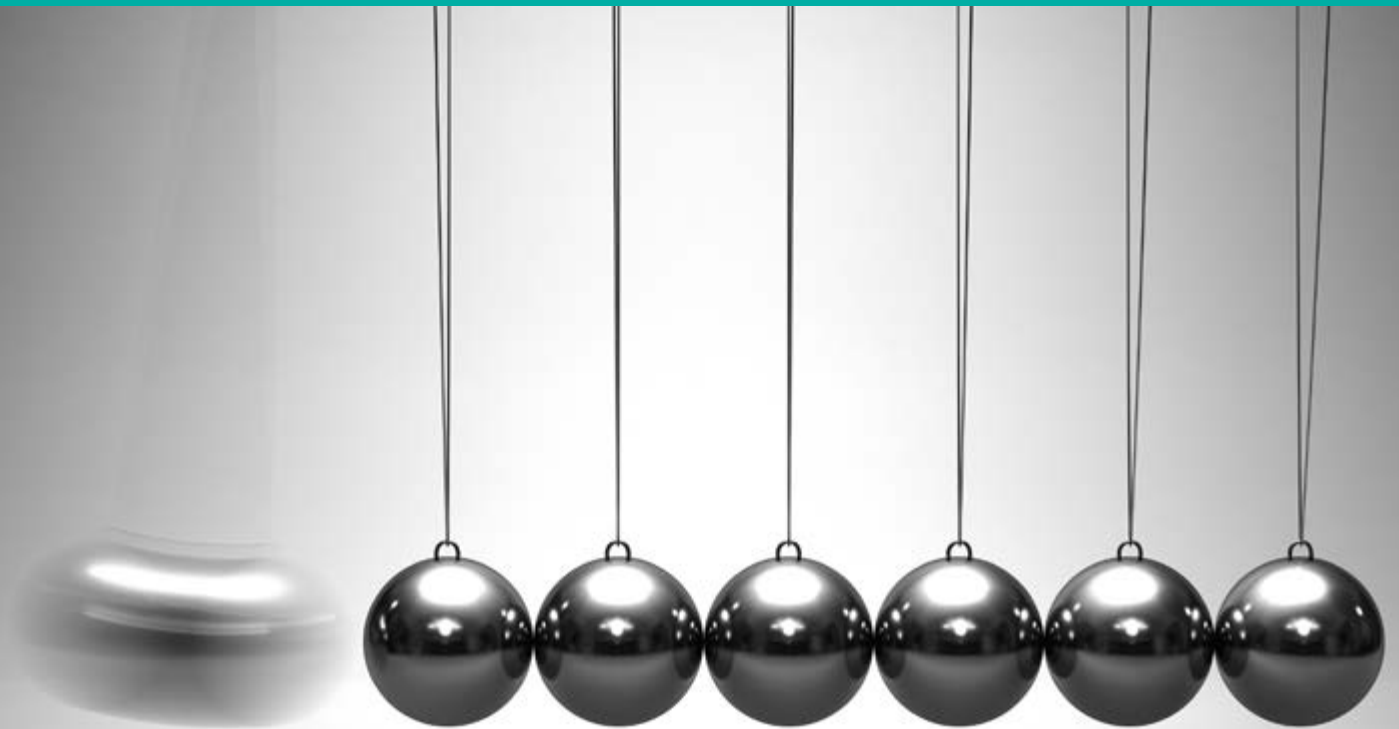


Creating opportunities for improving patients' access to medicines

A systems view of medicines integration in the UK,
and recommendations going forward



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Executive summary

Despite positive health economic assessment, patients in the UK are not getting timely access to the innovative medicines and technologies they need. Why does this challenge persist, and what meaningful steps can be taken to mitigate this?

This paper, from Aurora, sets out to examine the UK challenge of medicines access through the lens of 'systems thinking'. This conceptual framework suggests that problems can be better solved by seeking a holistic understanding of the healthcare system, and the interactions of parties within it. Through this lens, we can see recurring patterns that hinder our ability to achieve strong medicines uptake.

To counteract these patterns, we lay out **seven key dependencies**, which we believe can positively impact the uptake and flow of medicines in our health system. These dependencies are not 'quick fixes'. Instead they require new behaviours and practices to be adopted across the healthcare system, and by all its stakeholders. We change things when we act, when we take just one purposeful step forward.

1. Leadership by example

Organisations are entrenched in a 20th Century operating model, which is built upon rigid structures and fixed milestones. These structures have created an environment where longer-term, higher goals of improving patient outcomes have been eclipsed by short-term, financial measures of success. It will be the job of leaders to encourage us to transition to a more progressive model, which allows us to reclaim higher goals.

2. Planning for alignment

There is a considerable lack of alignment between the major players in the health system, from conflicting priorities to mismatched operating cycles. We need to better understand each other's perspectives and constraints, to more effectively anticipate where tensions and gaps may exist. Early engagement is key to achieving this.

3. Contextual decision-making

Organisations typically take a very narrow viewpoint of medicines access. Efforts are concentrated in limited siloes of activity often at the expense of other critical influence points that have not even been assessed. A broader view, with a wider stakeholder set, which includes patients, needs to be considered. Their perspectives can shed valuable insight, particularly around service delivery environments.

4. Real world data

Clinical and cost-effectiveness data are proving to be insufficient evidence to release funding for medicines uptake. Real world data has the potential to reflect what clinical data cannot – the value of medicines in context and over time. Although still an emerging discipline, with risks associated, real world data is increasingly viewed as an inevitability that organisations will need to prepare for.

5. Collaboration and governance

Actions taken, without the consultation of other parties, are more likely to result in conflict, duplication and failed endeavours. Collaboration between parties is required. However there are longstanding issues of mistrust and concerns around compliance, which create obstacles to collaboration. To overcome this, organisations such as patient groups have the potential to serve as 'third-party glue'.

6. Patient involvement

Barriers to access can be found in patients' journeys and experiences, but their perspectives are routinely overlooked. Patients are in fact a source of rich insight and have the potential to make an active contribution towards commissioning, design and delivery of healthcare. We need to help build their capacity and reframe their status from 'passive recipients' to leaders and experts.

7. Best practice sharing

Pockets of success through rapid adoption of guidance get trapped within organisations. This best practice, which is likely repeatable within other local health economies, is not shared, resulting in inefficiencies and inequity of access and care. We need a greater collective will to share, not only the protocols of best practice, but the principles and behaviours behind it.

In writing this paper, we hope to lay out a compelling case for the changes needed to improve medicines access in the UK. We believe that we must take a hard look at our roles, responsibilities and relationships going forward. It means crossing boundaries and forging deeper relationships with other stakeholders, around our common goals. It will mean creating an environment where honest, adult conversations can take place.

We welcome future collaborations with stakeholders, across the healthcare spectrum, to effect change and enhance patients' access to innovative medicines and technologies.

Introduction

Fragmentation of diseases, services and decision-making
requires new approaches to delivering healthcare



The debate around the provision of healthcare in the UK is one that remains highly emotive and politically charged. We, in the UK, hold a passionate belief in our right to a health system that befits our standing as a highly developed, progressive society, whereby we all have access to a high standard of medical care. As such, the role and performance of the National Health Service (NHS) is always being judged against a founding principle of 'free healthcare at the point of delivery'.

The NHS is the world's largest publicly funded health service, treating one million people every 36 hours¹ and with the vast majority of patients reporting good experiences. However, there are growing misgivings about the sustainability of the current health system, and the resources and operational structures required for it to adequately serve us in the longer term.

One of the biggest concerns is around patients' timely access – or lack thereof – to innovative medicines, which have been deemed to be both clinically and cost effective, and necessary for patients to lead fulfilling lives and contribute to society. Indeed, what is the value of having innovative medicines if they do not reach the people who need them, at the time they need them most. This issue, and how to resolve it, is the central topic of this paper.

For the remainder of the discussion, when we speak of medicines uptake, access or medicines access we are referring to the challenge of integrating any new medicines into care pathways, following a positive health technology appraisal (HTA), specialised commissioning, or other alternative process. This discussion is primarily centred on medicines access in England, although we believe the principles outlined can be applied to the devolved nations of the UK, and other developed country healthcare systems.

The recent report by the Office for Life Sciences² painted a fairly dismal picture of the current status. It suggested that when it comes to uptake of innovative health technologies and medicines in the UK, we are only achieving 11% of the average of other developed nations by year one, and by year four, this figure has increased only to 50%.

This is in spite of the mandate from The National Institute for Health and Care Excellence (NICE)³, which 'rubberstamps' the majority of drugs, stating:

"Commissioners have a statutory responsibility to make funding available for a drug or treatment recommended by a NICE TA or HST [evaluation] within the timeframe recommended in that guidance. Compliance is therefore achieved if a clinician and their patient think a health technology is the right treatment and it is available on the NHS,

as described in the NHS Constitution, and without any local funding or local formulary restrictions.

For the avoidance of doubt, when NICE recommends a drug as 'an option', this is an option for the clinician and patient to consider alongside other potential treatments, not an option for commissioners or providers to not make the treatment available."

The Innovative Medicines and Medtech Review is currently underway, reporting in late 2015, and will potentially point the way to future recommendations. In the meantime, the outlook remains uncertain and finding solutions to meet future demand will be incredibly challenging. Sir Bruce Keogh⁴, Medical Director of the NHS in England has described the 'quadruple pincer' facing the NHS – difficult increasing demand, escalating costs, increasing patient expectations all within a tightened fiscal environment. These factors will only compound an already congested medicines access journey for patients.

The stakes are simply too high for us to continue seeking solutions within the usual parameters, which have repeatedly fallen short of expectations. So it is incumbent on all of us engaged in the delivery of healthcare to disrupt our current model and create the space for new ideas and new ways to think about the challenges we face.

However, for leaders, both in government and within healthcare organisations, the pressure to promise definitive solutions has led to rhetoric that works very hard to avoid full acknowledgement of the tremendous complexity inherent in the system.

The truth is, we are in a time of unprecedented societal and technological change, at a global level. We are facing challenges with a degree of complexity that we have not seen previously. Our traditional models of thinking are outmoded and they are failing us.

Government and organisational leaders are increasingly turning to concepts such as systems thinking and complexity theory as a means of trying to cope with the scale of challenges we face in this 21st Century. We believe that these concepts have a great deal of merit for those examining the challenges facing the overall healthcare system in the UK. But equally, these concepts can help us make better sense of the issues surrounding medicines access.

This paper is not intended as an academic treatise on systems thinking or complexity theory. Rather, we have tried to distil the key concepts, drawing out some of the most relatable principles, which may help shed a new light on the long standing problem of medicines uptake in the UK, and in doing so, help us to unlock our thinking about this critical issue.

...what is the value of having innovative medicines if they do not reach the people who need them, at the time they need them most

So it is incumbent on all of us engaged in the delivery of healthcare to disrupt our current model and create the space for new ideas...

What is systems thinking and why should you care about it?

Affecting positive change in uptake of medicines requires a holistic understanding of the healthcare delivery system, rather than just its component parts



211
Clinical commissioning
groups

156
Acute trusts

56
Mental health trusts

8k
GP practices

800
Independent sector
organisations

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The primary purpose of this paper is to explore ideas that may help improve integration of new medicines within the intricate tapestry that is the UK health system. These ideas were borne out of taking a 'systems thinking' view of the barriers we face. For this reason, we wish to briefly introduce some key concepts, which underpin our thinking.

Firstly, consider that in England alone, there are 211 clinical commissioning groups (including 201 now authorised without conditions), 156 acute trusts (including 100 foundation trusts), 56 mental health trusts, approximately 8,000 GP practices, and 800 independent sector organisations providing care to NHS patients from over 7,000 locations¹. Not to mention all the community providers and individuals engaged in the delivery of our healthcare system. All of whom play a role, in some shape, in the flow of medicines to patients.

In its most simple terms, systems thinking offers an approach to problem solving. It provides a holistic framework whereby multiple component parts, as illustrated above, and their successes or failures, can be understood by viewing them in the context of relationships and interactions with other components in the 'system'. The system being viewed as a purposeful, whole entity – greater than the sum of its parts. This is wholly opposite to the traditional discipline of critical analysis, which is built upon the principle of breaking down component parts to find root causes (and someone or something to blame).

So taking a systems perspective, we will be referring to the 'health system' as the total environment containing parties engaged in the delivery and consumption of healthcare in the UK. This includes, but is not limited to, all NHS bodies from a national level to local level; from commissioning professionals to clinicians; from policy makers to regulators, NICE, pharmaceutical companies, patient groups, carers and most importantly, patients themselves.

UK HEALTHCARE AS A COMPLEX ADAPTIVE SYSTEM

We propose that the health system in which we operate displays all the conceptual characteristics of what is termed a 'complex adaptive system'. These include:

- Multiple and fragmented components acting and reacting to each other
- No centralised decision-making; decision-making is dispersed, power is diffuse
- Interactions between parties are non-linear
- Beliefs and behaviours are heavily shaped by the past

- The system is impacted by outside forces – political, economic and cultural
- The system is dynamic and evolving – it never stands still

To add further complexity, organisations within the health system are in fact complex systems in their own right, with further subsystems nested within them.

The nature of such a system is that the action of one component can – without any conscious intention or forewarning – have a disproportionately disruptive effect across the system.

While it may be very difficult to truly comprehend complex adaptive systems, we can take comfort from the fact that they are all around us – we see them in air traffic control, in the stock market, in culture and all around us in the natural ecosystem such as migration of birds.

A useful analogy is that of congested traffic systems. From his or her vantage point, each driver will act and react to 'events' in their immediate proximity. Closer inspection from that vantage point will likely not reveal the root cause, and actions taken by each driver changes the overall situation again. The aerial view, however, will expose a far more accurate picture of what is really happening – the causes and the solutions for which may be five miles away. This is at the very heart of complex adaptive systems theory.

Although it is less tangible, these dynamics occur throughout the health system whereby the plans we have made are disturbed by the actions of another, which we do not have sight of, or whose impact we have underestimated. Linear outcomes will rarely occur – specifically, what we 'put into the system' does not correlate with what comes out the other side. Even with expertise and past success, we cannot confidently predict what will happen in the future.

In addition, there are multiple parties with different perspectives and values, so there are multiple truths co-existing, and often in conflict. And since the system is constantly shifting and evolving as a result of all the components in play, we cannot impose a top-down rigid structure in the hope that it will stand still. It never has, and it never will.

It has been said that trying to navigate a complex adaptive system is akin to walking through a maze that changes with every step. If you accept the premise that the health system is a complex adaptive system, it should come as no surprise then that our current tools do not equip us to deal well with it.

SO HOW DOES THIS RELATE TO THE MATTER OF MEDICINES ACCESS AND UPTAKE IN THE UK?

The case in point lies with what happens to medicines, post-approval. As discussed earlier, whether through NICE, specialised commissioning or an alternative route, once approved and recommended for use, the medicine should be available to those who are clinically suited to using it. This is a clear example of our expectations for cause and effect linear outcomes. Pharmaceutical companies, patients, and even many clinicians believe that once this hurdle has been overcome, access *should* follow. So why is this not the case?

We believe the historic and current structures put in place for medicines access were full of good intentions. But from a systems view, these structures sit in a larger system, which evolves and takes on a life of its own. As a result we have been repeatedly caught off guard by unforeseen barriers, and unintended consequences from our interventions.

This is probably the most predictable outcome within a complex adaptive system, when parties do not recognise the nature of the system they are operating within.

If we were to pick out the single greatest benefit that systems thinking has to offer, it is this: the ability to recognise the recurring patterns that have been playing out in front of our eyes. If we can see them, if we know to look out for them, we can dramatically increase our chances of positively changing the outcome.

RECOGNISING THE CYCLES WE NEED TO BREAK FROM

Within complex systems are recurring patterns, which reflect the misguided efforts of perceived system ‘authorities’ to design rigid structures that can solve access.

In academia, these recurring patterns of behaviours and negative outcomes are cyclical in nature, and are referred to as ‘system archetypes’⁵. For readers who wish to delve deeper into the concepts touched on in this paper, we would recommend using the archetypes as your entry point. Further reading recommendations are included at the end of this paper.

For now, and in the interest of brevity, we will outline the predominant patterns most visible within the UK health system.

We experience ‘**fixes that fail**’ and ‘**shifting the burden**’. These represent initiatives that initially alleviate the ‘symptoms’ but unintentionally

create new problems or in fact make the original problem worse. Well-intentioned NHS reforms by UK governments are clear representations of these – whereby each successive restructure confounds stakeholders with new levels of complexity and unintended consequences.

Initiatives such as the Cancer Drug Fund, or other early access schemes provide vital treatment to patients, but they can also be viewed as ‘shifting the burden’. Although there are genuine beneficiaries of these schemes, they are in truth very expensive work-arounds that do not address the underlying causes of hindered medicine access in the UK. Critics argue that these schemes cannot be sustained, and in addition they create inequity between disease areas.

‘**Eroding goals**’ is another pattern we see within our health system. While all parties initially claim the higher ground, namely the quality of life and health of the population, the reality and complexity on the ground makes attainment of these ‘lofty’ goals feel out of reach. As a result, focus is downgraded and goals drift towards more base measures, which are short-term and typically stated in financial terms, be they savings or revenues.

As parties within the system are squeezed from all directions, relationships suffer. ‘**Accidental adversaries**’ is a prevalent system archetype that can be witnessed in our healthcare environment – notably, but not exclusively, with the difficult relationship between NHS bodies and the pharmaceutical industry. Relationships that were, once upon a time, based on win-win goals and built in good faith, have been damaged by perceived or actual betrayals along the way.

Unfortunately, this dynamic can then move into the ‘**escalation**’ archetype where parties view each other as a threat and take defensive counter measures. Trust has eroded over the course of many years and these negative biases are now built into our current mindsets and operating practices. The rigid regulatory framework and the notion of ‘arms length’ relationships are a testament to this.

‘**Tragedy of the commons**’ refers to the pattern of parties making quite rational decisions in their own interest, to make use of a shared resource. The result is that the shared resource is then severely depleted and no longer able to serve the function it was originally created for. We see this all over the NHS environment where commissioning bodies and clinicians are struggling with capacity to meet the demand and expectations placed on it.

Systems thinking helps us not only recognise these patterns that lead to unintended consequences and negative outcomes, but

Systems thinking helps us not only recognise the patterns that lead to unintended consequences and negative outcomes, but also gives us a new framework to counteract them

also gives us a new framework to counteract them. The language of systems speaks of organisations and individuals being 'agents', each exerting influence, intentionally or not. It speaks of circles of influence rather than straight lines. Of interdependency over independence, of adaptive and flexible structures rather than rigid ones; and of feedback loops that reveal emerging truth, rather than static 'facts'.

Through this systems lens, a great deal of assumptions we hold about how the world works around us, and our roles in it, are fundamentally challenged. Crucially, it provides new parameters within which to solve complex problems.

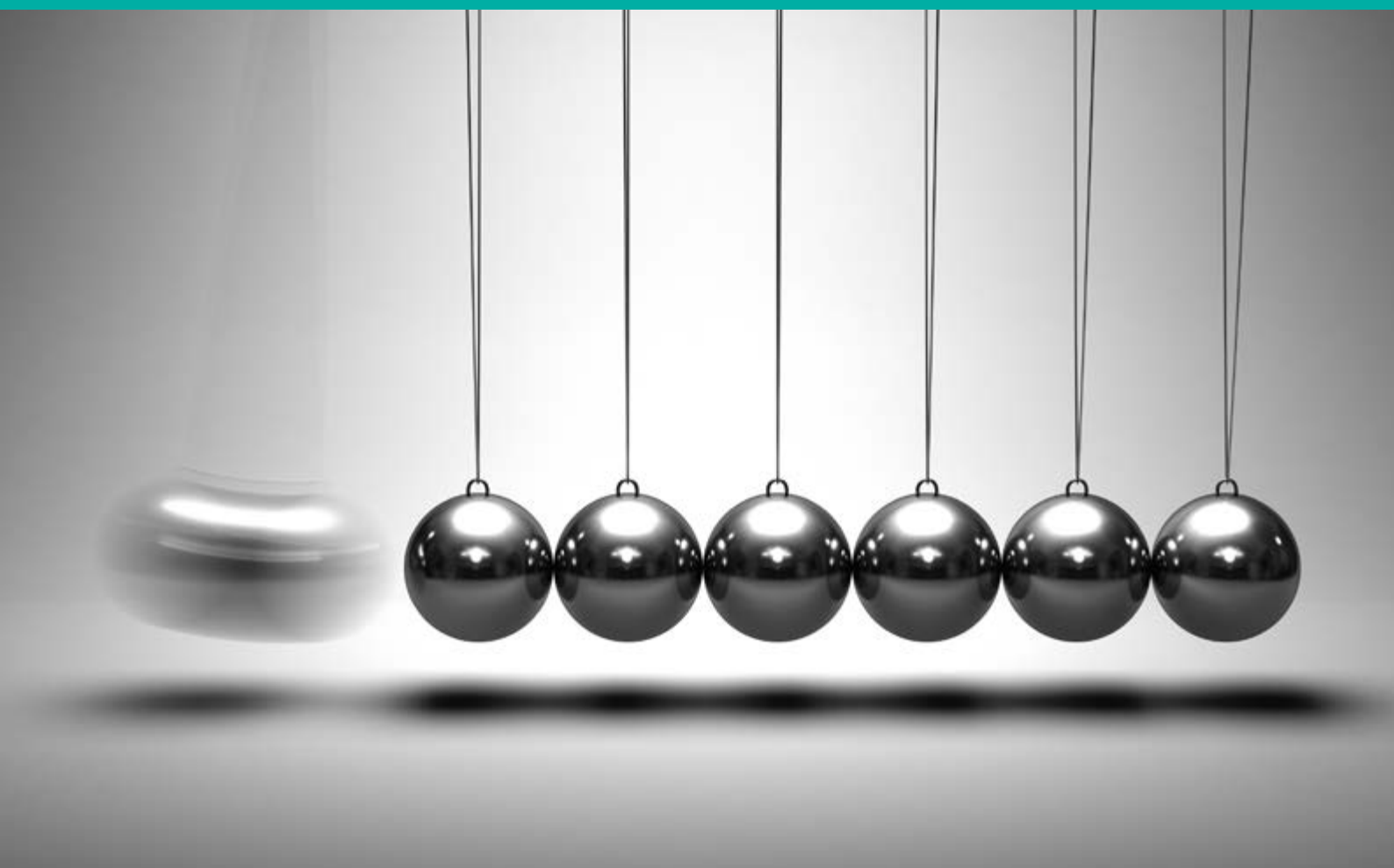
While this paper offers only a small glimpse into the world of complex systems thinking, we believe that anyone working in today's health system and dealing with medicines access will recognise the validity or at least the compelling nature of the concepts outlined.

It speaks of circles of influence rather than straight lines. Of interdependency over independence, of adaptive and flexible structures rather than rigid ones; and of feedback loops that reveal emerging truth, rather than static 'facts'



7 key dependencies to affect positive change in medicines access

Affecting change to medicines access will depend on new mindsets and practices across the system



Rather than a singular viewpoint from within a silo, it is recommended that we take a holistic view of the system

If our hypothesis is that the healthcare system is a complex adaptive system, then what does this mean for us and what we do next?

The systems viewpoint tells us that there is no silver bullet, nor is there one single party who should shoulder all the blame for the challenges we face. Instead it falls to all parties, at all levels of the system, to work in tandem to resolve the issues and generate better outcomes for access.

Rather than a singular viewpoint from within a silo, it is recommended that we take a holistic view of the system, recognising how every entity is connected. This involves mapping interactions between parties, building relationships, prioritising the common goals, recognising interdependencies, operating levers at multiple points of influence, and utilising 'feedback loops' to make constant adjustments.

It is through this systems lens that Aurora considered the viewpoints of key stakeholders in the health system – namely pharmaceutical companies and patient groups – captured in a qualitative research exercise. (Details of this research, and the accompanying report, are available at the end of this paper.)

THE 7 KEY DEPENDENCIES THAT IMPACT MEDICINES ACCESS

What emerged from our research were seven themes. We consider these themes to be key dependencies that impact the success or failure of a medicine's integration into care, post approval. Due to the nature of complex systems, they should be seen as inter-related. These dependencies are not 'quick fixes'; instead they point to changes needed in our beliefs and the way we operate, which can be implemented at the macro (national level) through meso to micro level within individual teams.

The 7 key dependencies:



1. Leadership by example



2. Planning for alignment



3. Contextual decision-making



4. Real world data



5. Collaboration and governance



6. Patient involvement



7. Best practice sharing

1. Leadership by example

Strong progressive leadership is needed to help us
reclaim higher goals





Access problem: Organisations are entrenched in a 20th Century operating model – one that is built upon rigid structures, command and control hierarchies, tightly defined roles and responsibilities and unbending lines of demarcation.

This 'top-down' architecture is designed with a mechanistic world-view where predictable, linear outcomes are expected, and these take the shape of fixed milestones and targets. The prevailing belief being 'if everyone does their job properly, then x, y and z should happen'. This mindset prevents us from seeing the true dynamics of the health system, which do not cooperate with our desire for predictable outcomes. As is the case with medicines access, post approval.

It is this mindset that has inadvertently led to recurring patterns of 'fixes that fail' and 'eroding goals' and leave us in our current predicament of poor medicines uptake.

Currently, parties within the health system are being crushed by the high-pressure environment and relentless focus on targets and mandates. Time horizons are short and there is little to no continuity. Partnerships wither at the first obstacle and transactional relationships are the norm. Short-term goals have eclipsed long-term priorities. Success is only measured in terms of financial gains or savings. And patients are still not getting equitable access to medicines.

We need to always aspire to excellence and must not be constrained to the normal, the usual, the middle of the pack

LEADERS TO RECLAIM HIGHER GOALS

It will be the job of leaders across the system to set the example that helps us transition to a more progressive environment. One that encourages us to reclaim higher, longer-term goals where decisions taken regarding medicines access are driven by the pursuit of improving outcomes. This requires a profound shift in mindset, and this shift must cascade through organisations.

This shift was passionately articulated by Sir Bruce Keogh, Medical Director of NHS England:

"To front-line clinical and managerial staff, I say please, do not aspire to mediocrity. I hear people talk about meeting the European average. I have no interest in meeting the European average and I hope you don't either. We need to always aspire to excellence and must not be constrained to the normal, the usual, the middle of the pack."

"Push the boundaries. Do not ignore cost, but seek value because it is through value that we will acquire the best possible treatment for everyone. Show courage, and give each other permission to try new things. Take risks with processes, but not with clinical outcomes. And through all of this, help turn taxpayers' money into good clinical outcomes."⁴

We need leaders who can learn to accept ambiguity and unpredictability as the environmental norm, and adapt accordingly. Who can embrace models built on relationships, interdependency, collaboration, flexibility and responsiveness. Who have the willingness to give up long-held beliefs, and the courage to try and to sometimes fail. Who can encourage us to do the same. This will require a strong personal vision and the ability to defend this vision to their superiors and peers across the system.

RECOMMENDATIONS

Change can be ignited from anywhere in a complex system: top-down, bottom-up and laterally. 'Leadership' does not only exist at the top of an organisation.

- Ask yourself, what can you do in your team to shift beliefs and behaviours?
- Consider what progressive leadership will cost in the short to medium term.
- How can we make managing upwards a reality?

2. Planning for alignment

Parties in the system must take steps to align more closely,
more of the time





Access problem: *Lack of alignment between the major players in the system, from conflicting priorities to operating practices, result in delays to medicines access for patients.*

If leadership is about instigating a cultural shift, then planning for alignment is about the operational shift that reflects this. This is the job of both leaders and people on the ground.

Currently, there is considerable lack of alignment between key players in the health system. This is most clearly seen in the interactions between NHS commissioning bodies and the pharmaceutical industry. And it manifests on many levels.

Firstly, there is a critical mismatch between organisational priorities. The NHS is charged with the delivery of healthcare in its entirety. The pharmaceutical industry is predominately concerned with medicines and technologies, which play only one part.

NHS and local commissioners are often working across multiple disease areas simultaneously and across whole patient pathways, whereas their pharmaceutical counterparts are typically concentrated on far fewer.

The NHS viewpoint is largely shaped by the burden of long-term chronic conditions, which affect millions of people. The care and management of these conditions – typically utilising generics, off-patent medicines originally developed by the pharmaceutical industry – consume a huge proportion of the total resources available to the NHS. By contrast, the pharmaceutical industry by its very nature must be primarily concerned with innovation of new medicines in areas where there are proportionately high levels of unmet needs, regardless of patient population size.

It follows that business planning cycles are also mismatched. The NHS must work to a fixed cycle, allocating its budget by April, having commenced this process the preceding autumn. The pharmaceutical industry, by contrast, works to a cycle determined by favourable phase III data leading to approval, which rationally fires up commitment to resourcing activity at country level. This then leads to a sharp focus on the HTA process, with limited activity to plan either ahead or downstream of this event. Meanwhile, the NHS will be horizon scanning and making decisions about the impact of new innovations with largely no input from the pharmaceutical industry themselves. All of this leads to the planning cycles of the NHS and the pharmaceutical industry being out of sync, only righting themselves after several years post HTA.

NHS and local commissioners, due to acute financial constraints, are pressed into measuring cost-effectiveness at the point of delivery. The pharmaceutical industry

and patient representatives argue that value should, instead, be measured along multiple dimensions including long-term outcomes for patients, and benefits for the system itself, far broader than even bodies like NICE currently take into account.

Misalignment exists between other key relationships within the systems – between NHS bodies; between commissioners and clinicians; between patient groups and the pharmaceutical industry. It is not within the scope of this paper to cover all of these areas comprehensively. However, the principles and recommendations apply to all.

EARLY ENGAGEMENT AS THE KEY TO CLOSER ALIGNMENT

The systems view argues that parties are reliant on each other for positive outcomes. A prerequisite of planning for alignment is, therefore, striving to generate greater empathy and mutual respect for each other's situations. It means reshaping operating models to embrace the interdependency of all involved in healthcare delivery.

We recognise the limits placed on those working in UK operating companies where timeframes are dictated, and necessary information is held by pharmaceutical company global functions. However, the key first step in dealing with misalignment must be to engage earlier. Create even a small amount of time and space to understand each other's perspectives, to see where tensions and gaps may exist. Sharing perspectives should also include a willingness to be more transparent about the limitations and constraints each party is working within.

This greater understanding can help parties better anticipate where hurdles down the line might appear, and what pre-emptive or corrective actions can be taken. Early sight of these potential hurdles can also be used to manage upwards within organisations, and help reset expectations.

RECOMMENDATIONS

Look at your operating practices. Consider where there are alignment gaps between you and the organisations you need to work with.

- Ask yourself to what degree do you know where gaps exist? And how much consideration have you given these gaps in your organisational planning?
- Even if you cannot take corrective action, communicate the gaps up the chain. Those on the ground may have a clearer view, which leaders do not see and would benefit from.

Create even a small amount of time and space to understand each other's perspectives, to see where tensions and gaps may exist

This greater understanding can help parties better anticipate where hurdles down the line might appear, and what pre-emptive or corrective actions can be taken

3. Contextual decision-making

A broader view is required, with multiple perspectives, in order to better anticipate barriers and recognise opportunities for access





There may be multiple leverage points that can help open up access, but they can only be seen when we are prepared to look wider and from multiple perspectives

Access problem: *Historically, organisations have taken a very narrow viewpoint of medicines access. Efforts are concentrated in limited siloes of activity, often at the expense of other critical influence points. Access barriers and opportunities that exist upstream or downstream of them are often missed as they are not even assessed.*

The systems viewpoint is that only by evaluating the wider landscape, from multiple perspectives, can problems be understood and rectified. It recommends a shift in perspective, of 'zooming out' rather than 'honing in'.

As with the traffic congestion analogy discussed earlier, consider how the health system is densely populated with multiple players operating simultaneously, acting and reacting to each other. No party has full view of the whole system in play, and each tends to direct its efforts and resources to proximal areas of immediate concern.

With medicines access we see this concentration of effort kicking off after approval at first with the HTA process. But cost-effectiveness is just one factor, and as is the focus of this paper, it does not resolve the issue of integrating medicines into care. Critics suggest that HTA serves only as a rubber stamp or 'tick-box' exercise, with the real job of access taking place both before and after approval.

What happens next is the race to commissioners. Commissioning groups are indeed a powerful set of agents within the system, and critical for access as they control the purse strings. And with all the demands on their time from around the system, gaining their attention becomes a high priority. But they are not the only group, nor do they have full view of the system. By focusing all our attention on them, we are missing other crucial barriers and opportunities for access.

LOOKING BEYOND TRADITIONAL STAKEHOLDERS

We need to consider a wider stakeholder set. We need to try to think in terms of circles of influence rather than straight lines. Stakeholder mapping is vital and it must go deeper than job title. Understanding attitudes, preferences, beliefs and biases is as important as knowing simply who these stakeholders are. Achieving this suggests a significant increase in workload and investment but taking incremental steps, and using technology as an aid, will make this easier. But first there must be a will to do it.

The wider stakeholder set includes 'experts' in the field whose perspectives can be very useful to both industry and commissioners.

They take the form of clinicians, nurses, pharmacists, and even pharmaceutical representatives.

The view from the ground, via the 'field experts', can provide enormous insight into barriers to access. They especially can shed light on the constraints within the service delivery environment e.g. lack of trained staff, lack of supporting technology or other infrastructure required to deliver the intervention. Field experts also include patients and we will return to them later in this paper.

The broader view, in what it reveals about service delivery environments, may throw up questions of who is responsible and who has legitimacy to design improvements for access. But it will show us more clearly where value of medicines actually resides. It might be clinical efficacy; but it might be service convenience for NHS bodies or for a better treatment experience for patients; it might be highlighting an area of unmet need. There may be multiple leverage points that can help open up access, but they can only be seen when we are prepared to look wider and from multiple perspectives.

RECOMMENDATIONS

Consider your current perspective.

- Are you concentrating on traditional points of influence or are you exploring different angles?
- How willing are you or your organisation at a local (or even global) level to extend the scope of your activities, or conversely let other parties into your domain?
- Be prepared to make trade-offs. Understanding the wider landscape will also mean having to make critical choices around what you can and cannot do within your current constraints.
- Consider small experiments and pilot initiatives. Test the water with incremental steps, and learn from them.
- Accept that context is dynamic. The landscape is probably going to change faster than you might want it to. It is the nature of the system.

4. Real world data

Real world data has the potential to become a strategic tool for reaching quality and outcomes-led decisions





Real world data can reflect what clinical data cannot – the value of medicines in context, and over time

Access problem: *Clinical and cost-effectiveness data are proving to be insufficient evidence to release funding for medicines uptake.*

Historically, new medicines access has hinged upon clinical data for regulatory approval, and in more recent years, upon cost-effectiveness modelling for HTAs. By necessity, these clinical and financial models are laden with assumptions. In an economic climate of spiralling costs, these models and mandates are often not enough to inspire pressurised commissioners to release funding.

Real world data, and its application, while still an emerging discipline, represents a potentially huge opportunity to overcome this barrier to access. Real world data can reflect what clinical data cannot – the value of medicines in context, and over time. Not just clinical value, but service value; it can in principle capture variables such as prescribing behaviours and patient health behaviours, including adherence and service delivery factors.

REAL WORLD DATA AS AN INEVITABILITY

There is growing consensus on the importance of real world data as a strategic tool for reaching quality and outcomes decisions, which open up access. In the present day we are held back by lack of knowledge, experience and technical infrastructure. But as technology and its adoption advance, real world data will become an inevitability. Technology is creating the means for not only large scale, ongoing data acquisition, but also data management and sophisticated data visualisation for interpretation of trends.

Human behaviour is already changing in line with technology advances. We see this with the market proliferation of smart devices and applications, which support the 'quantified self' trend e.g. Fitbit, MyFitnessPal, Heartwise, SleepCycle. At the current rate, and with the burden placed on the health system, it seems a certainty that the next generation of patients will accept a requirement to log their health behaviours, even if not all welcome it.

However, real world data also poses risks in the view of some parties. There are fears that data will be used in service of negative agendas – counting for the sake of counting and using data as a stick to beat others with. Even more troublesome is the fear that data will reveal uncomfortable truths about either medicines or the system itself.

From a systems view however, this can only be a good thing. In a dynamic environment where reality can only be known in context,

it is the job of feedback loops to continually discover new information, for new truths to emerge, which shape and balance the system. Real world data represents that continuous feedback loop, which has until now been very far from reach.

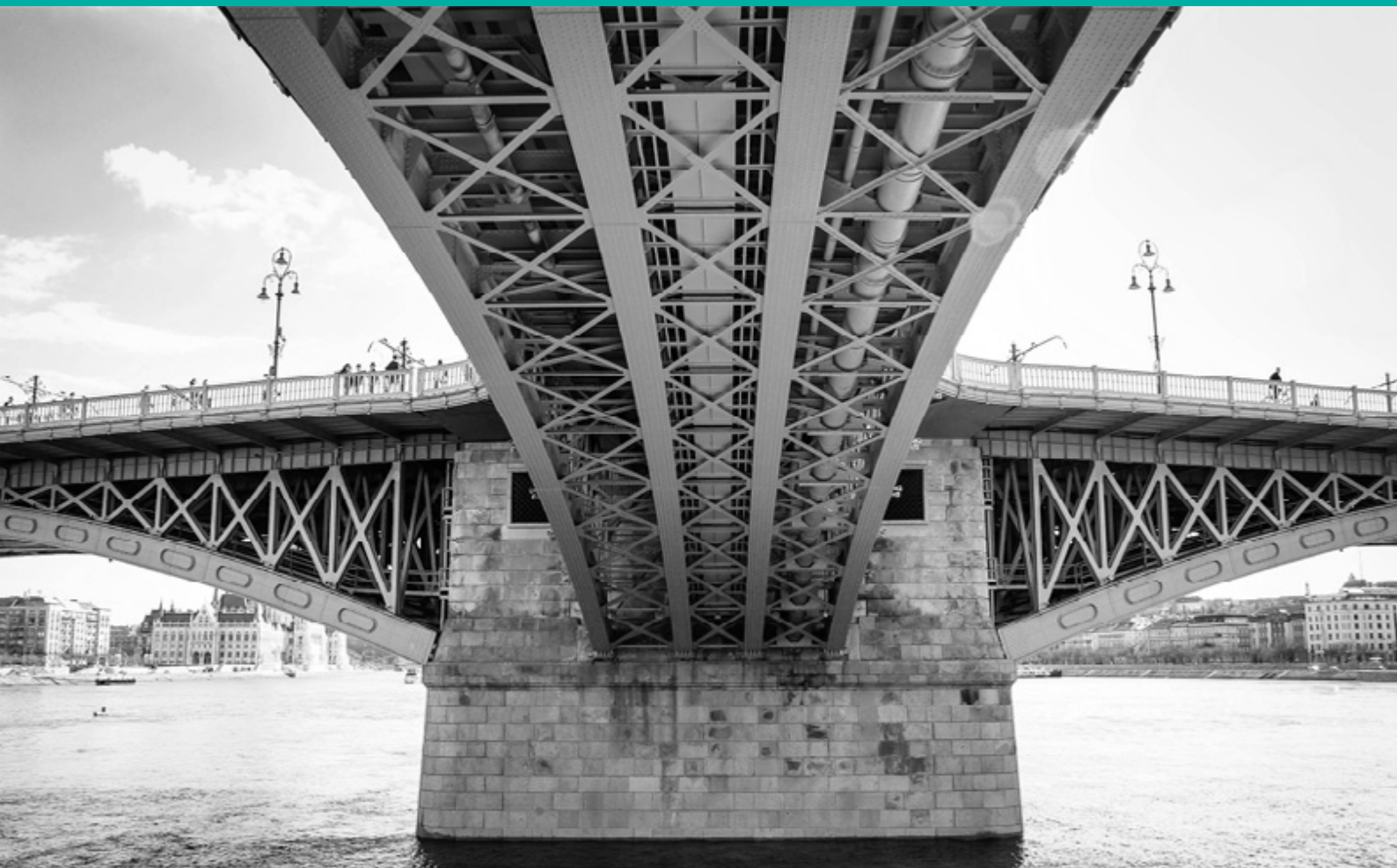
RECOMMENDATIONS

- Ask yourself how much importance you place on real world data? To what degree are you gearing up for collecting it?
- How do we get commissioners to consider real world data as a credible source of information? What information will they see as useful in their day-to-day roles, and in what formats?
- Think about what interim actions you can take as we wait for real world data to become viable at scale.
- As you set up valuable support tools for patients, think about data collection. If your organisation's policies prohibit collection of anonymised data, perhaps it is time to challenge this.
- Consider the role of real world data for the duration of the medicine lifecycle – from development to patent expiry.
- Consider what it might mean to be collecting and interpreting data throughout the patient treatment journey, rather than at discrete intervals. What constraints does this highlight?
- What might it mean if data develops new meanings over time e.g. new products, new health behaviours?
- How ready are you for data to reveal uncomfortable truths? How can these truths be presented honestly and constructively?

Human behaviour is already changing in line with technology advances. We see this with the market proliferation of smart devices and applications, which support the 'quantified self' trend

5. Collaboration and governance

Medicines access requires collaboration between parties but this needs to be governed to ensure integrity of purpose





Access problem: *Actions taken, without the consultation of other parties, are more likely to result in conflict, duplication and failed endeavours. This creates delays and barriers to access.*

As stated earlier, a broader view, informed by multiple perspectives, can reveal much about the barriers to and opportunities for access, not least within service delivery environments. But from this can arise difficult questions of legitimacy – whose right is it to intervene, whose responsibility is it, who will bear the cost?

...we are all agents in the system, working towards common goals and, as such, we have a shared responsibility for enabling solutions. But it demands collaboration...

Our current model provides divisive answers to these questions. A systems view, by contrast, tells us we are all agents in the system, working towards common goals and, as such, we have a shared responsibility for enabling solutions. But it demands collaboration.

Collaboration, however, does not come easily. Uncomfortable relationships and mistrust exist between parties, such as those seen between NHS bodies and the pharmaceutical industry. There are legacy relationship issues, which have led to the accidental adversaries and escalation archetypes discussed earlier. And our current structures do not lend themselves to crossing pre-established boundaries.

There is a great deal of trepidation in entering relationships and activities 'out of traditional scope'. It requires parties to tread very carefully to ensure compliance – who can they talk to, when and about what. In particular, where an intervention is offered by the pharmaceutical industry, the line between 'helping' and 'manipulating' may be perceived as blurred. The Code of Practice (Clause 20 on joint working), issued by the ABPI, provides clear guidance to mitigate this. And its Joint Working Initiative⁶ is a positive step, with good case studies, towards enhancing relationships to achieve aligned outcomes. However, the question of legitimacy of purpose continues to be a sensitive one.

With such uncomfortable relationships and difficult questions, there is a strong need for an acceptable third party to facilitate and support collaborative efforts; to govern and to ensure the integrity of fragile alliances – especially between parties from seemingly opposing ends of the spectrum.

PATIENT GROUPS AS 'THIRD-PARTY GLUE'

Patient groups have the potential to play this crucial role as 'third-party glue' – specifically more experienced patient groups who are involved with access (we recognise that patient groups are not homogenous and not all will have the skill set, knowledge or will).

These groups often have a strong grasp of the landscape, and the differing priorities and pressure points facing all the key players. Therefore they can offer a coherent evaluation of the situation, and perhaps serve as an honest broker.

Clause 27 of the ABPI Code of Practice sets out clear guidance on transparency for pharmaceutical company relationships with patient groups. In addition, the ABPI and National Voices⁷ are developing a comprehensive guide, to be issued in 2015, to aid collaborative working with patient groups and will promote the highest standard of transparency and accountability. This should help further alleviate concerns around conflict of interest, and sources of funding in particular.

Effective collaboration will still be challenging. It requires sustained commitment by parties towards achieving a shared goal, in the face of obstacles. There must be clear expectations and total transparency in dealing with each other. With this in mind, invitations to collaborate must take place early enough for subsequent input to be meaningful, influential and actionable. And all parties must be mindful of the risks they each face in entering collaborations. Consensus means compromise. Self-interest must give way to common interest and everyone must be ready to defend the partnerships which will be subjected to scrutiny by their peers and the public.

RECOMMENDATIONS

Reflect on your approach to collaborations and partnerships to date.

- What can be learned from the successes?
- Where mistakes have been made, are you able to acknowledge them to move forward?
- Which parties should you consider reaching out to? What would need to happen to enable a partnership to develop?
- Consider whether you are willing to defer to a third-party facilitator. What beliefs, ego, agendas might you have to give up?
- Consider whether you can bring integrity to the table and sustain it. What mechanisms can build transparency and honesty into the relationship?

6. Patient involvement

Patients can be agents for change, but first they need a seat at the table





Access problem: *Barriers to access can be found in the patient journey and experience, but they are not anticipated or catered for, leading to delays in access.*

Historically, patients have, for the most part, been viewed as passive recipients of healthcare. But from a systems view, they are a powerful force as the drivers of demand for healthcare. Their expectations, experiences of treatment, health behaviours and interactions with the system play a key role in shaping the system and its dynamics. Yet their perspective is routinely overlooked, or given only token attention.

Access barriers can look quite different from patients' perspectives – the impact of potential misdiagnosis, the time and difficulty of reaching a diagnosis, treatment lags, logistics pressure caused by service delivery requirements such as frequency or duration of hospital visits, travel time, and even car parking. These are all access issues as they prevent people receiving timely treatment.

Capturing patient perspectives can provide rich insight. Even more compelling is that this insight can create access opportunities and even drive healthcare innovations.

Capturing patient perspectives can provide rich insight... even more compelling is that this insight can create access opportunities and even drive healthcare innovations

PATIENTS AS EXPERTS AND LEADERS IN THE FIELD

Patients can also be seen as 'field experts' who can make an active and meaningful contribution in many different forms, including commissioning, design, and delivery. Consider the view that commissioners, by the nature of their role, see 'paper not people'. Introducing the patient 'expert' viewpoint can be a powerful catalyst for change and decision-making.

Patients can also serve as 'feedback loops' in their own right. Not just as sources of quantitative data, but qualitative as well, and can play a role in monitoring services.

However, patients are not a homogenous group. There is enormous variation in health behaviours, health conditions and circumstances. There are individual, cultural and generational factors that affect their willingness and ability to engage with the health system. It is a case of 'ask, don't assume'. Some people simply do not want to engage, while others demonstrate 'white coat syndrome' behaviour, often cited as a barrier to access in relation to alternative treatment choices.

Greater consideration needs to be given to how we work more closely and appropriately with different patient segments. We need to help build patient capacity – with sensitivity to their health conditions – so that they have

both the confidence and the competencies to contribute. It requires educating patients not only on their rights to care and treatment, but also on the processes and structures of the health system, and how it impacts their access to medicines.

Once again, Sir Bruce Keogh, Medical Director of NHS England, has captured this sentiment:

*"To patients, I say be more confident and more assertive – do your research, don't be shy to ask questions and, crucially, don't be shy to take charge."*⁴

This was echoed by Professor David Haslam, chairman of NICE when he was reported as saying that *"too many patients were not being offered medications approved by NICE – and should learn more about their conditions and ask for drugs which should be prescribed for them."*⁸

Crucially there is a need to reframe patients' status to achieve parity with other dominant parties in the system. This requires an acknowledgement that paternalistic clinical behaviour is perhaps just as unhelpful and outdated as top-down organisational structures, and needs to change to be more inclusive.

Related to this is the need for alternative language. Presently terms such as 'patient-centricity' or 'patient empowerment' – while being very important and progressive notions – are perceived negatively by many patients as being either hollow or patronising. How instead can we start to frame patients as 'leaders', 'entrepreneurs', 'enablers' and 'champions'?

With a shift in power also comes a shift in accountability. This is a highly sensitive issue shaped by history, yet there is a need for more honest conversations with patients about the burdens placed upon the health system, and about their own behaviours and responsibilities. The 'choice agenda' and shared decision-making could ultimately move upstream, extending beyond individual treatment decisions to collective decision-making and determining trade-offs needed to achieve medicines access, and improve the health system as a whole.

This seems a very long way off, but we should not underestimate the societal changes already underfoot. We have already touched upon changing human behaviours and the increasing democratisation of information. We are seeing the trend of health self-monitoring through technology. The idea that health is a two-way responsibility may well start to gain traction in the medium term.

From a systems view, patients are already active agents in the system exerting influence, consciously or not. We need to recognise them, include them and value them.

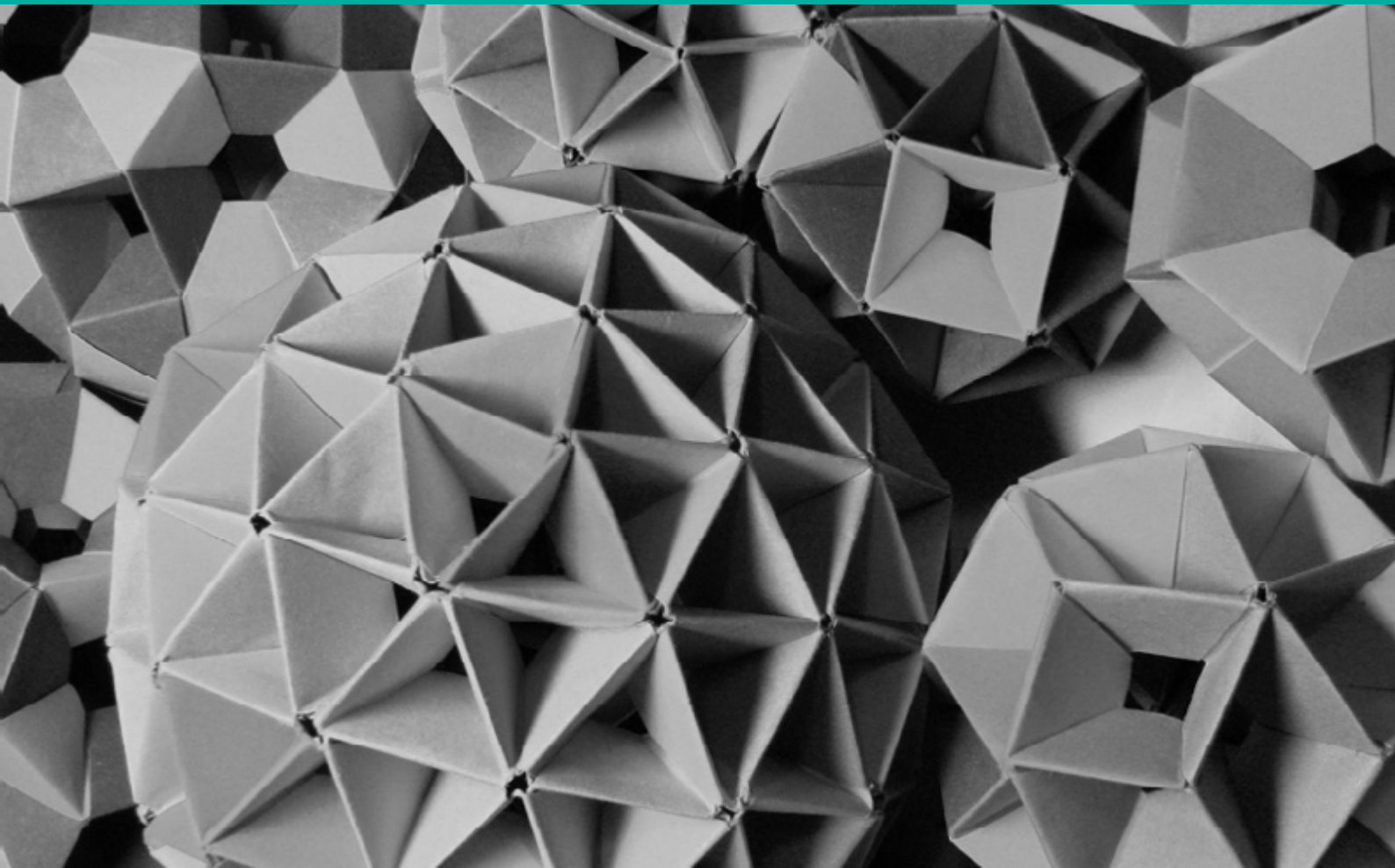
RECOMMENDATIONS

- How much do you know about patients' experiences within the pathway of which your medicine is part?
- Do you really recognise the unmet needs of patients, beyond the clinical trial publication or the market research report? Have you ever actually met with patients, do you really understand their lives?
- Look at the patient pathway more holistically than just your medicine intervention. By looking more broadly, how might you contribute to securing better patient outcomes?
- Challenge what assumptions and biases you hold towards them.
- Are you bringing their perspective to commissioners and service designers?
- How can you incorporate issues such as quality of life and wider societal impact into discussion and feedback?
- What mechanisms and support can be given to help patients become equal partners in discussions?



7. Best practice sharing

Best practice as principles based, rather than just protocol based





Access problem: *Pockets of success through rapid adoption of guidance get trapped within organisations. This best practice, which is likely repeatable within other local health economies, is not shared, resulting in inefficiencies and inequity of access and care.*

The barriers to medicines integration are significant. But there are in fact many instances where access is achieved. The difficulty lies in replicating success, and at scale.

It is a commonly held view that the difficulties in achieving best practice sharing and best practice adoption are largely due to the NHS being a 'patchwork quilt' of organisations, lacking the consistency and standardisation of processes needed for ideas to travel well.

A commissioner in a given geography rapidly assesses guidance, implements the recommendations within their local health system, and puts outcome metrics in place to record the impact of this change. The model then remains local, never to be shared and means people constantly have to reinvent the wheel. This then leads to greater inconsistencies in patient experiences and in practices across the system, making it more difficult to apply best practice. In addition, it generates huge inefficiencies, and gives rise to concerns of inequity of care.

The situation is a cause of much distress to parties across the system. People speak of their frustration in trying to find good ideas or implement good ideas within their own organisations, let alone across organisations. There is frustration about the lack of centralised resource for accessing best practice case studies and guidance. Worst of all is the fear that attempting to implement a recommended practice will fail to generate the same positive outcome. So is it even worth the effort, time and heartache?

From a systems viewpoint, these concerns and sentiments are not entirely without merit. The nature of complex adaptive systems is that of multiplicity, endless variety and continuous change. As such, outcomes cannot always be perfectly replicated in spite of expertise and past experience. A useful metaphor from theorists⁹ to help comprehend this notion is the difference between baking a cake and raising a child. Following a protocol or formula is helpful for the former, but has limited application for the latter. Past experience and success of raising a child provides no guarantee of success for the next one. There will always be a degree of unpredictability and uncertainty.

So where does that leaves us. And what does best practice even then look like?

A PRINCIPLES-LED APPROACH TO BEST PRACTICE SHARING

We believe that best practice is principles based. That best practice looks like the dependencies discussed in this paper, even if our day-to-day language frames them differently. It is about 'leaders' having the courage to try new approaches; getting planning cycles better aligned; taking a broader view and inviting different perspectives, including patients; making better use of real world data; and collaborating around common interests.

Ideas do migrate across systems but the goal should not only be to replicate the nuts and bolts of good practice, but should as importantly be about creating openings in the system, and processes that can facilitate best practice sharing. And it is about populating the system with the beliefs and attitudes that can create the conditions for good principles and new behaviours to migrate.

RECOMMENDATIONS

- Consider your own attitude towards sharing good ideas. How proactive are you currently? Is there room to do more both inside your own organisation, and with other organisations?
- As a commissioner, how willing are you to share your hard work, for the common interest?
- Think back to previous successes – what were the conditions that existed, what choices did you make, what patterns did you break, what assumptions did you hold, from what assumptions were you free?
- Think about the occasions that did not work out so well? What lessons might be learned? Upon reflection, what might you have done differently?
- From both successes and failures, what are the principles you can share?
- How can the system be constructed differently to accommodate sharing best practice?
- How can the pharmaceutical industry play a credible role in facilitating best practice sharing? What beliefs need to be overcome for this to happen?

...it is about populating the system with the beliefs and attitudes that can create the conditions for good principles and new behaviours to migrate

Final thoughts

Time for adult conversations



We must strive to move with the system, rather than against it. And because it never stands still, we need to think in terms of how to improve the way the system is trending

Our choices around medicines access to date have often been predicated on the belief that we are operating in a linear environment, where cause and effect are within our control. We need to start making different choices that recognise the complexity and unpredictability in the system. There is no single fix and the solution will not be found in a single group trying to impose order on the system.

We must strive to move with the system, rather than against it. And because it never stands still, we need to think in terms of how to improve the way the system is trending. This means we need to cross boundaries, we need to forge deeper relationships based on our common goals, and we must collectively work hard to share the principles that can lead to better practice.

We are cocreators of the system and its dynamics. The conditions of medicines access in today's landscape are a consequence of models of organisational behaviour that have developed over decades. They are of our making, and so must be the new models we take forward.

TIME FOR ADULT CONVERSATIONS

The system demands that we take a hard look at our roles, responsibilities and relationships going forward. It will mean leaving behind our prejudices and being willing to have difficult but honest adult conversations inside our organisations, and with all organisations across the spectrum of roles.

- **Leadership by example** – what does progressive leadership look like and what will it cost us in the short to medium term? What must we be willing to give up in order to reclaim higher goals?
- **Planning for alignment** – how will operating practices need to change? How can we engage earlier within current constraints? What would a new 'balanced score card' look like?
- **Contextual decision-making** – what will investing in a broader perspective cost us in terms of resource allocation and time? How can we ensure legitimacy of purpose in activities beyond traditional scope? What trade-offs will need to be made?
- **Real world data** – How do we begin to integrate continuous real world data into our practices? How prepared are we to accept the truth on the ground, revealed by real world data?

- **Collaboration and governance** – can we learn the art of compromise as part of collaboration? Can we accept a facilitator to govern us? Are we able to bring integrity to the table?
- **Patient involvement** – are we willing to move away from paternalistic behaviours and give patients more status in the system?
- **Best practice sharing** – how willing are we to be proactive with driving best practice sharing? What behaviours will need to change?

We believe that the concepts and dependencies outlined in this paper encourage a different way of thinking about our health system, and the flow of medicines access within it. We change things when we act, when we take just one purposeful step forward.

It is also worth stating, that while we have chosen to focus our attention on the medicines uptake lag that occurs in the period between positive HTA and actual integration into care pathways, the work of solving medicines access is about the entirety of the journey end-to-end. The dependencies highlighted in this paper, and the recommendations made, apply to organisations no matter where they are in their access journey, and to individuals no matter where they may sit within the system.

Our hope is that this paper serves as a platform to stimulate thought, open up new discussions, and generate cooperative actions. We would welcome feedback from all parties and invite contributions to developing future resources.

About the authors



Aurora is an award-winning healthcare marketing communications agency who genuinely wants to make a difference – to our clients' brands and, in turn, to the impact those brands can have on healthcare and society as a whole.

Aurora works with patient groups, professional health bodies, and most frequently, with devices, diagnostics, and pharmaceutical companies to enhance their reputations, their brand propositions, and to deliver positive value within UK and global health economies.

Our services to these organisations include strategic counsel, strategic communications, stakeholder mapping and engagement, brand strategy, media relations, medical education, disease awareness and patient engagement.

Aurora is also working with its partners at GLOBALHealthPR (www.globalhealthpr.com) to deliver 'Reimbursography' – a strategic communications programme, which helps clients to shape the global value context of medicines.



Aurora is a general affiliate member of the ABPI.

ABOUT ACCESS ALL AREAS

Launched in January 2015, Access All Areas is an Aurora initiative that aims to uncover the variables affecting timely access to medicines in the UK, and hopes to surface some greater understanding by bringing the pharmaceutical industry, patient representatives and members of the NHS together to generate tangible change.

Aurora has made a three-year commitment to Access All Areas, initially with a UK focus. Our intention is to provide constructive dialogue, fresh ideas and useful, practical guidance for all parties striving towards the common goal of improving patients' access to medicines. With this in mind, we sincerely invite feedback on this paper, and we welcome collaborations with parties across the healthcare spectrum in developing future resources and activities.

This paper is the first resource to be shared, in June 2015, as part of Access All Areas and represents our reflections from insight gathered to date via:

Qualitative research – focus groups were conducted, in February and March 2015, with representatives from the pharmaceutical industry and from patient organisations. The focus groups were managed by an independent market research professional. Aurora conducted follow up in-depth interviews with an additional representative of each cluster, as well as a Commissioning Support Unit (CSU) medicines management representative. For a copy of the Research Report, please contact Aurora to request one (see details below).

Access All Areas inaugural meeting – this meeting, held at the Royal College of General Practitioners on 12 May 2015, was attended by nearly 100 professionals spanning the pharmaceutical industry, patient groups and consultancies. At this meeting, Aurora introduced the seven dependencies outlined in this paper, but with specific on focus on patient involvement, collaboration and governance, and best practice sharing. Aurora gratefully acknowledges the insight provided by expert speakers on each of these topics as well as the feedback provided from attendees during and following the event, all of which is reflected in this paper.

For more information about **Access All Areas**, or to find out how to get involved please do not hesitate to contact Aurora Managing Director and owner, Neil Crump.



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This paper and the systems principles discussed have been derived from the work of key thinkers and commentators in the field of systems thinking. The material has been deliberately distilled for our intended audience and does not reflect the full rigour of the conceptual premise. Aurora does not claim to be an authority on systems thinking but we are committed students of the discipline and believe that it has significant relevance to the issues we face in the UK healthcare system.

For readers wishing to delve further on the subject, a recommended reading list is provided below.

READING LIST

Understanding and Managing the Complexity of Healthcare, William B. Rouse and Nicoleta Serban, 2014

Complexity Science: Complexity, Leadership and Management in Healthcare Organisations, Paul E. Plsek and Tim Wilson, BMJ, 2001

The Systems Archetypes, paper by William Braun, 2002

The Fifth Discipline: The art and practice of the learning organization, Peter Senge, 2006

Complicated and Complex Systems: What Would Successful Reform of Medicare Look Like, paper by Sholom Glouberman and Brenda Zimmerman, July 2002

Systems Thinking for Safety: Ten Principles – A EUROCONTROL White Paper, Steven Shorrock, Jörg Leonhardt, Tony Licu, Christophe Peters, August 2014

Evidence Scan: Complex Adaptive Systems, The Health Foundation, 2010

The future is now, The King's Fund, February 2015

GLOSSARY

ABPI	The Association of the British Pharmaceutical Industry
CAS	Complex adaptive system
HST	Highly specialised technology
HTA	Health technology assessment
NICE	The National Institute for Health and Care Excellence
TA	Technology appraisal

CREDITS

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