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Supporting the patient journey
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John Procter, Senior Director, Global Service & Solution Development – Patient & Market Access
Peter Rutherford, MD, PhD, Vice President, Integrated Market Access

Putting the right support in the right place at the right time in order to meet patients' specific needs is the key challenge for the healthcare ecosystem

Executive summary

Chronic disease management can be challenging, however it is widely accepted that patients who are engaged in their own health and treatment tend to have better outcomes. This can be facilitated through patient support programs that are tailored to the disease type and stage, and to the patient's preferences and situation. Getting this right leads to what is known as patient activation[1,2].

Patient Activation Measures (PAM; a patient-reported score) can be used to measure a patient's involvement in managing his or her disease, and in maintaining health and preventing illness. These scores can be used to predict health behavior and clinical outcomes, healthcare use and costs, patient experience rating, adoption of healthy behavior, rates of hospitalization, and service satisfaction ratings.

The increased emphasis on the provision of patient support and engagement is largely driven by ongoing changes in chronic disease prevalence, allied to shifts in company pipelines, an evolving regulatory and access environment and current political agendas.

Biopharma, healthcare professionals and patients need to work together and take time to focus on how to build and structure the best possible patient support programs, this could include solutions such as mobile apps and patient websites. By empowering and educating patients, robust support programs can have the greatest short- and long-term impact on patient health and healthcare costs.

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Introduction

The aim of medical practice is to improve health state as well as length and quality of life for patients. Those with chronic or life-limiting diseases have particular needs due to the progressive and/or long-term nature of their condition. Research shows that patients who are more engaged with their own health achieve better outcomes, therefore biopharma companies that take a proactive approach to patient support are more likely to see the sorts of outcomes, that are demonstrated in clinical trials, become a reality in everyday practice. Patient support programs can therefore help patients, carers and healthcare professionals to achieve the desired outcomes, as well as improving patient satisfaction through personal empowerment.

The role of patient support

Patients with chronic diseases can benefit from support throughout their journey, starting at diagnosis and continuing as the disorder develops. Putting the right support in the right place at the right time in order to meet patients' specific needs is the key challenge for the healthcare ecosystem, including healthcare providers and biopharma.

Patient support programs take a variety of different forms, from awareness raising and educational resources, through to patient forums and communities, to motivational coaching apps and software that can help patients and physicians manage and monitor disease.

The shape of a patient support program, and its channels of communication, will differ across disorders. For example, a program for a genetic disorder may need to be positioned towards children and their carers. In contrast, an application for diseases such as multiple sclerosis or rheumatoid arthritis should target adults in their 20s, 30s and 40s who may be working and raising families, and need help to manage life around the disease. Patient support programs for diseases such as type 2 diabetes and COPD will target middle-aged and older patients and focus on changing habits and lifestyles.

Because patients live in the "here and now", their needs will change as the treatment journey progresses. A well-designed patient support program will need to be adapted for steps throughout the entire patient journey and not just provide a one-size fits all approach. As an example, one patient may have been newly-diagnosed with advanced disease, whereas another may have been identified at the very earliest stage, and remained without progression because of good management. The program should also be tailored depending on the complexity of the disease and treatment protocol, as well as any requirements to provide longer-term data about the safety, efficacy or value of a drug to decision-makers. And it will need to take account of cultural and practical differences across countries.

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The drivers for patient support

Based on market research commissioned by Quintiles, biopharma allocate between 10 and 20% of the brand manager's budget for each drug to patient support and engagement after drug launch, and this is expected to grow in the current value and outcomes led era. These changes in budget allocation have led to an increase in patient support activity within biopharma. The four key drivers for increasing number of patient support programs are:

Changes in chronic disease prevalence

Shifts in company pipelines

An evolving regulatory environment

Current political agendas

Changes in chronic disease prevalence

Chronic disease prevalence is growing worldwide, as people are living longer, lifestyles are changing and levels of obesity are increasing. Patients with chronic diseases such as diabetes or cardiovascular disease have to contend with an array of decisions and drug regimens. Patient education, which focuses on developing skills and increasing confidence, can result in patients feeling that they are more in control and are able to take steps to manage their disease[1].

By providing patient support programs, biopharma can provide much needed support including increases in patient activation. These programs need to be tailored to the individual. For initiation of a program this means, for example, smaller steps for the patients who have lower activation levels and need to have their confidence built up[1], and larger challenges and goals for those who are already involved in managing their disease.

Shifts in company pipelines

Many company pipelines focus on chronic diseases, as these are conditions that affect a large percentage of the population over long periods, and there are still areas of unmet need, or potential improvements in formulation and delivery that could improve compliance. There have been significant levels of innovation in biologics in chronic diseases such as multiple sclerosis, rheumatoid arthritis, psoriasis, and severe asthma. These will be launched over the next few years and if the potential demonstrated in clinical trials is to be realized, then the use needs to be supported with patient programs.

Compliance is an issue with any drug because of a variety of factors, including lack of symptoms, lack of confidence in the treatment, not wishing to take drugs over long periods, or perceived risk of side effects[3]. This may be further complicated with biologics because of uncertainty with unfamiliar forms of administration or delivery devices, including injectable delivery[4].

Biologics are also often already quite costly drugs, and the additional expenses resulting from poor compliance also adds to the healthcare costs. These factors can lead to a perception that the drugs are less effective, thereby having a negative impact on the company's reputation. It can also mean that the real world data may not reflect the drug's true value.

Patient support programs can have a positive impact on compliance by removing these barriers to treatment. According to research, carried out on behalf of Quintiles, almost 60% of doctors believe that compliance apps could help patients take their treatment correctly, including a higher proportion of older doctors. By creating compliance apps, the perceived value of the drugs is enhanced as the efficacy potential is realized. These also provide support for healthcare providers[5]. This support may be by reminding patients to take drugs or improving patient education, or simply by providing reassurance. However, it is important to remember that the use of apps will depend on the target patient, as not everyone has the same level of comfort with digital devices such as smartphones and tablets.

Launches of new drugs will drive the need for provision of patient support programs and packages, and their uptake should help to ensure that patients use the drugs properly and that the outcomes are the best they can be.

An evolving regulatory environment

Biopharma and regulatory authorities are increasingly moving towards using real-world evidence to support drug development, approval and continued reimbursement. Real-world studies linked with patient support programs can help companies to understand the use of drugs in 'normal life', research new indications, provide context for marketing, or gain earlier approval.

However, patients will look to get something they value in return for providing real-world evidence, for example an app that helps them to manage their disease, take their drugs regularly, or simply learn more about their health. Doctors will also look to gain from this process too. For example, over a third of doctors believe that using an app to record patients' symptoms could be useful, allowing a more detailed analysis of health and disease[6].

~60%

of doctors believe that compliance apps could help patients take their treatment correctly

By creating compliance apps, the perceived value of the drug is enhanced as the efficacy's potential is realized

As an example of the regulatory use of real-world data provided through patient support programs, the European Medicines Agency (EMA) has created an adaptive pathways approach that allows companies to seek early approval for drugs for a specific patient population, conditional on the collection of further post-approval data in the real world[7]. The regulatory authorities are also looking towards the collection of real-world data to support reimbursement or approval from health technology assessment (HTA) bodies.

Current political agendas

The key political agenda behind patient support programs is their potential to reduce overall healthcare costs. Across Europe, funding pressures are driven by a number of factors, including population growth, and increases in lifestyle-related disorders such as cancer, cardiovascular disease and metabolic disorders. While innovative therapeutics, particularly biologics and complex delivery systems, are generally more effective and safer, they are also higher cost, increasing the impact on healthcare budgets. Finally, the financial downturn and national and global austerity measures have also led to overall budget reductions.

Biopharma can play a role here by developing and implementing patient support programs. These do have to be planned carefully, however, as it could potentially be difficult to cut funding once the program is in place, and companies cannot act as a surrogate for the healthcare system.

Measuring patient support: Patient activation levels

Treating illnesses has traditionally been based on an authoritative model. In this approach, which does not encourage patient involvement, patients are told what drugs to take and what lifestyle changes to make. There is evidence that patients who are actively involved in their own healthcare, including in the decision-making process, have increased compliance, better clinical outcomes, and greater patient satisfaction, and increasing these factors could potentially reduce healthcare and societal costs[8].

Managing a chronic disease can be difficult, with patients having to change their lifestyle, handle complex regimens (which may include unfamiliar delivery devices or routes of administration), monitor their disease and decide when they need to visit the doctor or hospital. This approach requires higher levels of patient involvement (also known as patient activation), which can be maintained and encouraged through patient support and engagement programs. Patients who understand their health or condition and who have the skills and the confidence in managing these are generally better at seeking help when they need it than patients who do not. Supporting patient activation is also important in maintaining health and preventing illness, as well as managing chronic disease[1,9].

Patient activation can be assessed using the patient-reported Patient Activation Measure, which is scored from 0-100[1,9]. The Patient Activation Measure scores, which work across a range of different languages, cultures, demographic groups and conditions, can be used to predict:

Health behavior and clinical outcomes

Healthcare use and costs

Patient experience ratings

Adoption of healthy behavior

Rates of hospitalization

Service satisfaction ratings

40%

of doctors believe that using an app to record patients' symptoms could be useful, allowing a more detailed analysis of health and disease

There is evidence that patients who are actively involved in their own healthcare, including in the decision-making process, have increased compliance, better clinical outcomes, and greater patient satisfaction, and increasing these factors could potentially reduce healthcare and societal costs

Table 1 Patient activation levels

High activation levels	Low activation levels
• Percentage of the population: - Patients taking a highly active role in their own health – 37% - Patients taking some degree of action in their own health – 41%	• Percentage of the population: - Patients who tend to take a passive role in their own health – 7% - Patients who lack confidence in their knowledge or ability to take a role in their own health – 15%
• Better understanding of their role in their own healthcare	• Less confident about managing their own health, and more likely to feel overwhelmed
• More likely to exhibit healthy behavior patterns	• Less likely to ask questions
• More likely to attend screenings, check-ups and immunizations	• May not feel able to make changes
• More likely to adhere to treatments	• More likely to have unmet medical needs
• Less likely to be hospitalized or attend Accident and Emergency	• More likely to delay medical care
• Better satisfaction with services	• More likely to go to Accident and Emergency and/or be hospitalized
• Lower healthcare costs	• More likely to be re-admitted to hospital after discharge
	• Higher healthcare costs

Source: The King's Fund[1]; Hibbard and Cunningham[10]

Individuals have different activation levels (see Table 1), and those with high activation levels (both healthy people and those with a range of different long-term physical conditions and mental health disorders) are more likely to have better health outcomes[1]. The levels vary within conditions and even within socio-economic groups, and it is important to tailor interventions to these specific groups, in order to best support those with high activation levels, and empower those with lower levels.

Patient activation measures can be used to track changes in the quality of life, understanding of their disease or condition, and levels of self-management in individuals and groups of patients, and to assess how well the interventions are working[1]. The measurement can also be used to design and test group- and population-wide approaches, with an aim to improve outcomes and reduce healthcare costs[9].

Conclusion

Solutions such as mobile apps and patient websites can contribute to patient-centric care by improving disease prevention and management by empowering and educating patients[11]. However, biopharma companies will have to tailor these patient support programs to the local culture, funding requirements and regulatory restrictions. It is also vital to tailor interventions to patient activation levels, as well as to the disease and the drug. Because of this, patient support can never be a 'one size fits all' solution.

Biopharma, healthcare professionals and patients need to work together and take time to focus on how to build and structure the best possible patient support programs to have the greatest short- and long-term impact on patient health and healthcare costs.

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About the authors

John Procter
Senior Director, Global Service & Solution Development
– Patient & Market Access

John Procter is responsible for the design and delivery of new services and solutions to help patients and the pharmaceutical industry improve access to innovative medicines. He works with teams in Europe, the US and Emerging Markets to match patient and market insights with customer needs and build new services that deploy the range of Quintiles capabilities with patients, payers and providers to improve outcomes and deliver value.

John has been with Quintiles since October 2010 and previously spent eleven years at Pfizer, initially in sales and marketing, before going on to set up and lead Pfizer Health Solutions, which won several industry and NHS awards for innovation and partnership with the NHS. Prior to this he spent eight years in the NHS and began his career as an NHS graduate trainee.

Peter Rutherford, MD, PhD
Vice President, Integrated Market Access

Peter Rutherford is responsible for strategy and execution of Integrated Market Access and patient centric services within Europe and Emerging Markets for Quintiles. Peter's background includes twenty-plus years of scientific experience gained from working across academia, industry, payers and providers.

Most recently, Peter was Medical Director and EMEA Head of Medical Affairs for Baxter Healthcare, where he was responsible for Baxter's patient support services, leading physician relationships and advisory systems, phase IV studies and medical communication. Prior to that he was with the North East Wales NHS Trust, where he was the Medical Director and responsible for patient pathway reorganisation across the trust. He was also appointed to chair the NICE Guidelines Review Panel, a multi-disciplinary team tasked with reviewing evidence analysis, health economics and responding to stakeholders.

About Quintiles

Quintiles (NYSE: Q) helps biopharma and other healthcare companies improve their probability of success by connecting insights from our deep scientific, therapeutic and analytics expertise with superior delivery for better outcomes. From advisory through operations, Quintiles is the world's largest provider of product development and integrated healthcare services, including commercial and observational solutions. Conducting operations in approximately 100 countries, Quintiles is one of FORTUNE's "Most Admired Companies."

Contact us
Direct: +44 203 564 4649
Website: www.quintiles.com
Email: marketaccess@quintiles.com

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