

Patient centricity beyond the medication

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INTRODUCTION

“Patients have changed, systems have not”

- Patient expectations rise as they are more educated and desire to vocalise their condition
- Technical advances have raised public expectation about the clinical potential for personalized medicine

Pharma industry needs to partner with patients using a common language and guided by agreed principles

Companies are looking to provide solutions that are patient-centric, rather than product-centric



DEFINITION



First collaborative definition of **patient centricity**, co-developed by AstraZeneca with patients and caregivers:

“Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family”.

Defining patient centricity with patients for patients and caregivers: a collaborative endeavour. [Yeoman G et al. BMJ Innov. 2017;0:1–8](#)

DEFINITION

KEY POINTS:

- Patients want an ethical and sustained relationship and this needs to be reflected in how we develop medicines and the way we involve patients so they are not treated as transient commodities but are an integral and valuable partner in the process.
- Patients quite rightly expect to be treated with respect and compassion for who they are and the feedback they give. For example, taking into account some of the practical limitations they may face because of their condition and ensuring interactions are designed to consider health needs.
- Patients want us to deliver an experience that they and their families want – not necessarily the experiences and outcomes we want them to have.

DEFINITION

This definition encompassed five clear points of importance to patients:

- (1) inclusiveness;
- (2) sharing goals that are patient and family centred;
- (3) empowering patients to take control of their own health;
- (4) working in a way that shows respect, compassion and openness; and
- (5) working in partnership.

PATIENT = “No decision about me, without me”

PHARMA = stop focusing on *what* we deliver, and think about *how* we deliver it.

INTEGRATIVE RESEARCH ...beyond the pill



Collaboration with patients in the research process:

- Patients have experience that provides insights on the way people react to illness and how this affects treatment choices
- Patients are well informed about the conventional as well as non-conventional treatments for disease management
- Understanding how patients view the management of their diseases and how they view the use of conventional versus non-conventional interventions is imperative to researchers
- Drug discovery
- Drug design
- Treatment design that encourage compliance and positive health outcomes



Improve how we develop and use therapies.

INTEGRATIVE RESEARCH ...beyond the pill



“If you want to understand the behaviour of animals, don’t go to the zoo, go to the jungle”

Otsuka’s antipsychotic drug, Abilify (aripiprazole) development:

An executive in Japan wanted to understand how schizophrenic patients think, and to understand what caused the barriers to their use of medication because the rate of compliance was very low. He lived with patients who suffered from the ailment for two months, and the insights that he gleaned helped design Abilify, which became at one point the top-selling medicine in the US and one of the top-selling medicines in the world.

CLINICAL TRIALS



The FDA was early to recognise the importance to make patients a more integral part of the drug development and review process:

- **Patient Engagement Advisory Committee**
- **Office of Patient Affairs**

Objectives:

- to increase integration of patient perspectives into the regulatory process, allowing the patient voice to provide input on clinical trial design; patient recruitment, enrolment and retention; and the communication to patients during, as well as after, the trial.
- to be a central point of contact for patients, advocates and other stakeholders looking to interact with FDA
- to gather views about unmet needs and existing treatments

CLINICAL TRIALS



“We are entering an era of ‘patient-centered’ medicine in which patients and their care partners participate actively in decision-making and priority-setting about all aspects of health care. Americans are becoming increasingly active consumers of health care, making choices about their doctors, diagnostics, treatments, and healthcare experiences rather than simply allowing health care providers to make the decisions for them. Moreover, FDA believes that patients can and should bring their own experiences to bear in helping the Agency define meaningful benefits or unreasonable risks for certain new devices.”

Nina Hunter, Associate Director for Science Policy

CLINICAL TRIALS



Patient-Reported Outcomes (PROs): a direct response from the patient regarding his/her health condition, without a healthcare provider or caregiver interpretation.

- Over 500% increase in 5 years in the number of clinical trials including PROs
- More than 2/3 of clinical trials utilised PROs
- A study published in the *European Medical Journal* examined the relevance of PROs in the management of inflammatory bowel disease (IBD):
 - Direct correlation in the amount of feedback the patients were able to provide and disease-outcomes.
 - Increasing patient knowledge and understanding of their medication may work to improve patient adherence.
 - Most patients would like more information regarding new medications and a closer collaboration with their physician
 - Patients may often be better placed to determine their own symptoms and able to aid physicians more effectively in the kind of treatment offered to them.
 - PROs do not always correlate with the physician's view. Evidence has shown that physicians often underestimate the severity of a patient's illness, report fewer problems than patients, and overestimate the improvements of treatment.
 - Patient empowerment can improve treatment success.

CLINICAL TRIALS AND BEYOND

Direct impact on health technology assessments and healthcare payer decisions

- empowered patients have better outcomes
 - clinical findings based on patient-substantiated evidence
-  future payments linked to patient outcomes

Patient-centered business models are becoming more popular in the pharma industry

- move to performance based payments. Lowering the cost of treatment and engaging in profits based on treatment success shows the pharmaceutical industry as willing and wanting to change its standard practices for the benefit of patients.

Data can be used to research areas such as pharmacovigilance (drug safety), pharmacoeconomics, and drug utilisation

PRODUCT DEVELOPMENT



Despite heterogeneous patient populations, selection and design of the dosage form and finished product is often the result of traditional standards.

Adapting the dosage form and design of the pharmaceutical product to the needs of the targeted patient population:

- used appropriately, intuitively, and as intended
- improve therapeutic outcomes
- prevent medication errors
- prevent drug related issues

Patient-centric drug products:

- designed to meet the needs of the patients that will receive the treatment, taking into account their specific characteristics in terms of age, physiology, morbidity/comorbidity, functional impairments, comedications, etc.
- starts with a characterization of the targeted patient population and its specific needs with regard to safe, easy, convenient, and intended administration and management.
- based on existing or new formulation and drug delivery technologies, along with efficient, highly flexible, and innovative manufacturing technologies and platforms that allow the provision of personalized therapeutics like individual dose strength, fixed dose combinations, and appropriate packaging solutions, etc., but also efficient adherence monitoring systems.

PRODUCT DEVELOPMENT



Three-dimensional (3D) printing

1. Personalized drug dosing

Select the drug/combination of drugs

Load optimal medication dose

2. Unique dosage forms/drug-eluting devices

- Tailor the size and geometry of the device to completely accommodate the anatomic features and medical needs of patients

3. More complex drug release kinetics

Targeted and controlled drug release

PRODUCT DEVELOPMENT



Remote-monitoring devices can also add value by increasing patients' adherence to their prescriptions - one of the major reason behind therapeutic failure.

- Smart bottles that help track usage
- Smart pills that can release drugs and relay patient data
 - First Digital Medicine, a drug/device product, combines:
 - Otsuka's ABILIFY® (aripiprazole), embedded with Proteus® ingestible sensor (that communicates with a wearable sensor patch and a medical software application) in a single tablet to digitally record ingestion and, with patient consent, share information with their healthcare professionals and caregivers
 - ⇒ provide an objective measure of medication adherence and physiologic response

PATIENT CENTRIC SERVICES



Deliver Value to All Stakeholders

Consider the needs of the entire health ecosystem and develop solutions that provide value to all stakeholders.

One Drop is a digital service helping people manage their type 2 diabetes. Also delivers value to providers and payers by offering data around how patients manage their disease and also encouraging adherence and better outcomes.

Use Data to Deliver Additional Value

Data to be leveraged within the organization to support among others patient insights and clinical studies.

Daiichi Sankyo with Partners Healthcare to create a coaching platform that engages patients in their care, supporting behavior change for patients with atrial fibrillation. One of the key goals of the service is to build a robust data set on patient outcomes, providing evidence for value-based care.

PATIENT CENTRIC SERVICES



Omada Health: program that helps patients manage chronic diseases like diabetes by encouraging healthier habits and lifestyles through custom plans, health coaching and success tracking. Customers only pay if outcomes are achieved.

BioPharma and Astra Zeneca with Vida Health: free health coaching services to heart attack sufferers.

Novo Nordisk: digital portal for patients, offering education resources and customer plans.

Pharma gains access to more detailed personal data that can help deepen and improve engagement with its patients

BARRIERS

- Difficulties in communication with patients
- Cultural barriers - scepticism about their input
- Unwillingness to relinquish control
- Building new capabilities – electronic data collection and processing
- Considering unfamiliar business models
- Partnering with different kinds of companies
- Monetary and resource investment.

Patients, while currently given more weight remain just one piece of the complex healthcare puzzle

CONCLUSION

- Patient-centered model:
 - proposes an infrastructure to identify unmet needs and amplify the voice of the patient
 - increases connections with consumer groups
 - generates novel intervention targets
 - expands innovative health management targets
 - Competitive advantages

NEXT STEPS FOR PHARMA



- Healthcare shift from volume to value.
- Systems that build trust in pharma and encourage relationships between patients and pharma.
- Challenge: identify ways to help patients understand, adapt and work with their HCPs and peers towards quotidian improvements in their health.

Prescription for success: engage directly with the patient.