Patients Involved – Patient medication labeling (USA)

Introduction

Collaboration between patient advocates with academic institutions (Northwestern University and Emory University) and a pharmaceutical company Merck (Health Literacy and Healthcare Disparities Strategy group) to obtain a simplified label with a format that nearly everyone can understand.

Where in the process?
Phase III Trials
Phase III trials are generally large (comprising thousands of patients) and involve several study sites, sometimes in different countries. They compare the new medicine to existing treatments or a placebo, in order to show the safety and efficacy of the new medicine. Most Phase III trials are randomised. Phase I, II, and III trials are commonly known as 'clinical development'. Phase III studies are critical to applications for marketing authorisation.

When does it happen? – Phase III

Description of the case

According to the National Assessment of Adult Literacy, only 12% of adults possess 'proficient health literacy'. Some 14% are estimated to be 'below basic' in health literacy, an estimated 30 million people. Groups most vulnerable include those over age 65, recent immigrants who don't speak English, people with limited educations, and those with limited

incomes.

The patient label is important because it provides patients information about dosing, potential side effects, and conditions for which the product is used. It also forms the basis for communications to patients about our medications. This may include patient education materials, product websites, print advertisements, and direct to consumer TV advertising.

The simplified label is the result of a two-year cross-divisional effort within Merck and in partnership with health literacy experts at Emory and Northwestern universities to create a labelling format that nearly everyone –including people with limited health literacy levels –can understand.

We are working with the FDA to share our data and hope to result in a new standard for patient labelling.

Type(s) of patient (advocates) involved

- Patients with personal disease experience.
- Expert patient / patient advocate with good expertise on disease and good R&D experience.

Benefits of patient involvement

The comprehension test used in the research sought to measure, among other things, whether the patients understood what condition the medicine was meant to treat, how it was dosed, and possible side effects. Research by Northwestern and Emory had shown a significant gap in comprehension between limited health literacy and adequate health literacy respondents. Testing of our new format showed we virtually eliminated differences in comprehension between low-literacy populations and the general population. In addition, comprehension of the

draft patient label was very strong for both limited health literacy (86%) and adequate health literacy (95%) respondents.

The best practices developed during Merck’s efforts could be a significant public health benefit when companies and other organisations understand how to identify the right populations for testing their products and services.

Challenges and barriers

In the past, Merck has had extremely small or no representation from individuals with limited literacy in our market research. By working with external experts at Northwestern and Emory, and our own marketing research team, we learned how to recruit this population for our patient labelling research.

Developing a new standard meant tapping into groups that do not typically self-select to participate in research and are not in recruiter databases: people whose health literacy levels are limited.

For example, the initiative required creative new approaches to finding study participants, including recruiting from literacy centres and senior centres. Patient research commonly excludes people over the age of 75 from studies. Those over 75, however, typically have the greatest burden of multiple chronic diseases requiring prescription medicines, and are more likely to have limited health literacy.

Learnings

Compared to historic comprehension testing trials performed within this one pharmaceutical company, the application of health literacy evidence-based practices via partnership with an academic research team led to unprecedented performance in its evaluation, especially among those with limited health

literacy. This partnership should be viewed as a model that could be adapted by other pharmaceutical companies as well as other industries in healthcare (i.e. health insurers, medical device makers), and perhaps health systems that generate patient-facing communications.

A3-Patient-medication-labelling-V1.0

Attachments

- Patients Involved case report: Patient Medication Labelling (USA)
  Size: 868,314 bytes, Format: .pdf
  An infographic describing a case of collaboration between patient advocates with academic institutions and a pharmaceutical company to obtain a simplified label with a format that nearly everyone can understand.