

What are the Sources of Uncertainty When A Patient Is Faced With A Choice?

“Characterizing and Communicating Uncertainty
in the Assessment of Benefits and Risks
of Pharmaceutical Products”

Institute of Medicine | May 12, 2014

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**“Medicine is a science of uncertainty
and an art of probability.”**

Sir William Osler



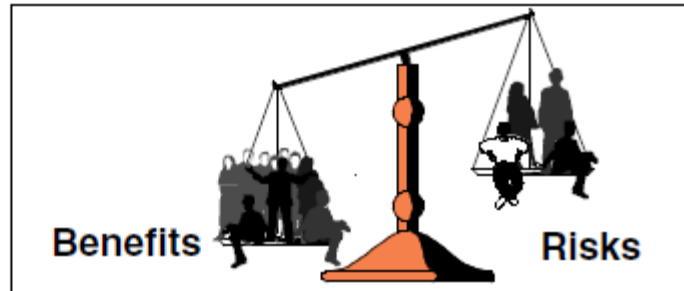
Patients facing life-altering conditions face life-altering trade-offs and uncertainties



Patient view of uncertainty differs from regulator and provider views

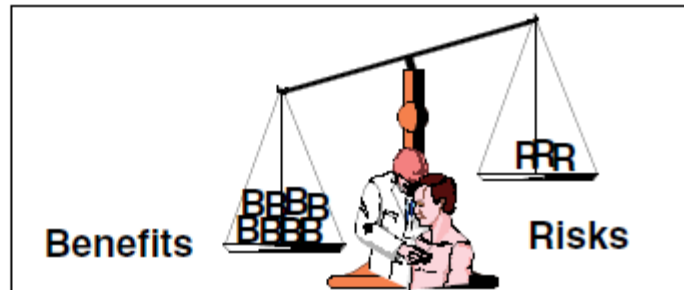
FDA

evaluates
benefits and risks
for the population



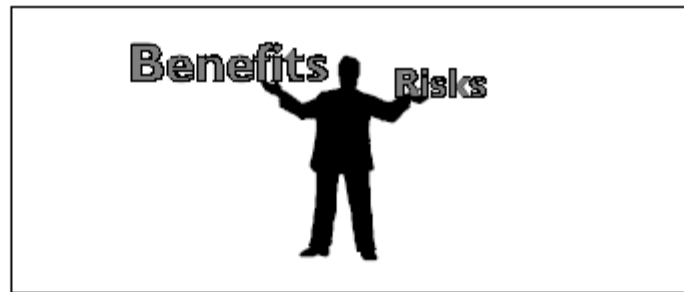
Provider

evaluates
benefits and risks
for a patient

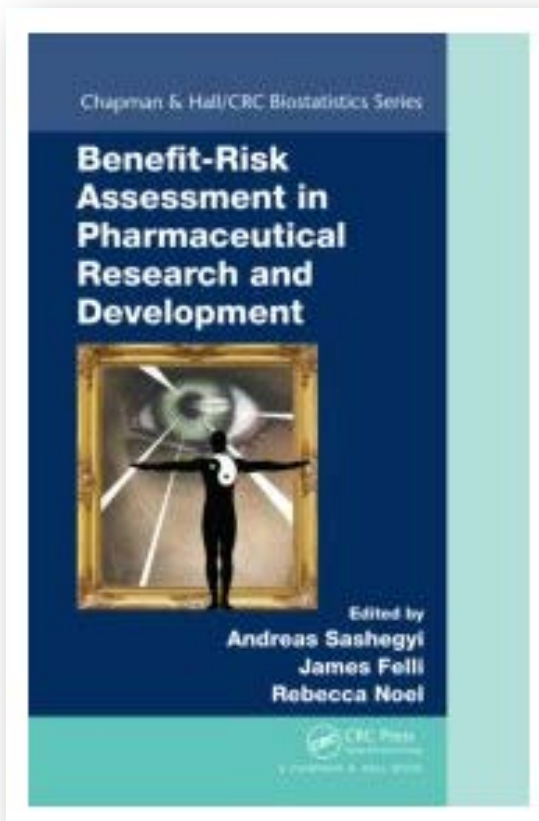


Patient

evaluates
benefits and risks
in terms of
personal values



"Understanding the Benefits and Risks of Pharmaceuticals: A Workshop Summary"
Institute of Medicine, 2006



“No party is better able to assess a drug’s acceptable risk than those living with the illness the drug is designed to address.” – *Timothy Franson and Philip Bonforte, FaegreBD*

“Attitudes toward bearing risk and related behavior depend strongly on the decision context, sources of risk, and content of available information, as well as specific characteristics of the risks in question.” – *F. Reed Johnson, A. Brett Hauber, and Jing Zhang, RTI*

“Broader inclusion of multiple researchers, healthcare providers, and patients in a larger benefit-risk communication effort, geared toward a more dynamic communication process, might encourage a more mutual goal regarding informing the public of evidence and uncertainty around important public health questions.” – *Marilyn Metcalf, GSK*

Patients' BR trade-offs may be based on needs + life experience



Disease Prevention

- safe
- minimally invasive
- durable effect



Acute life-saving

- effective
- immediate
- manageable AEs



Chronic treatment

- durable
- minimal AEs
- convenience for desired activity level



End of Life

- minimal AEs
- based on desire for hospital, hospice, or home care



Chronic disease delay

- durable
- manageable AEs
- convenience for desired activity level



Curative

- targeted
- durable
- manageable AEs

Varying levels of medical evidence & options



Varying levels of medical evidence & options



Other sources of information & influence













Other factors

Insurance coverage

Reimbursement

Out of pocket costs

Disability vs.
employment

Geographic proximity

Support system



Other factors



Opportunity to participate in clinical trials to gain access to experimental therapies



**Confusion
between
research and
treatment**

Evaluating evidence



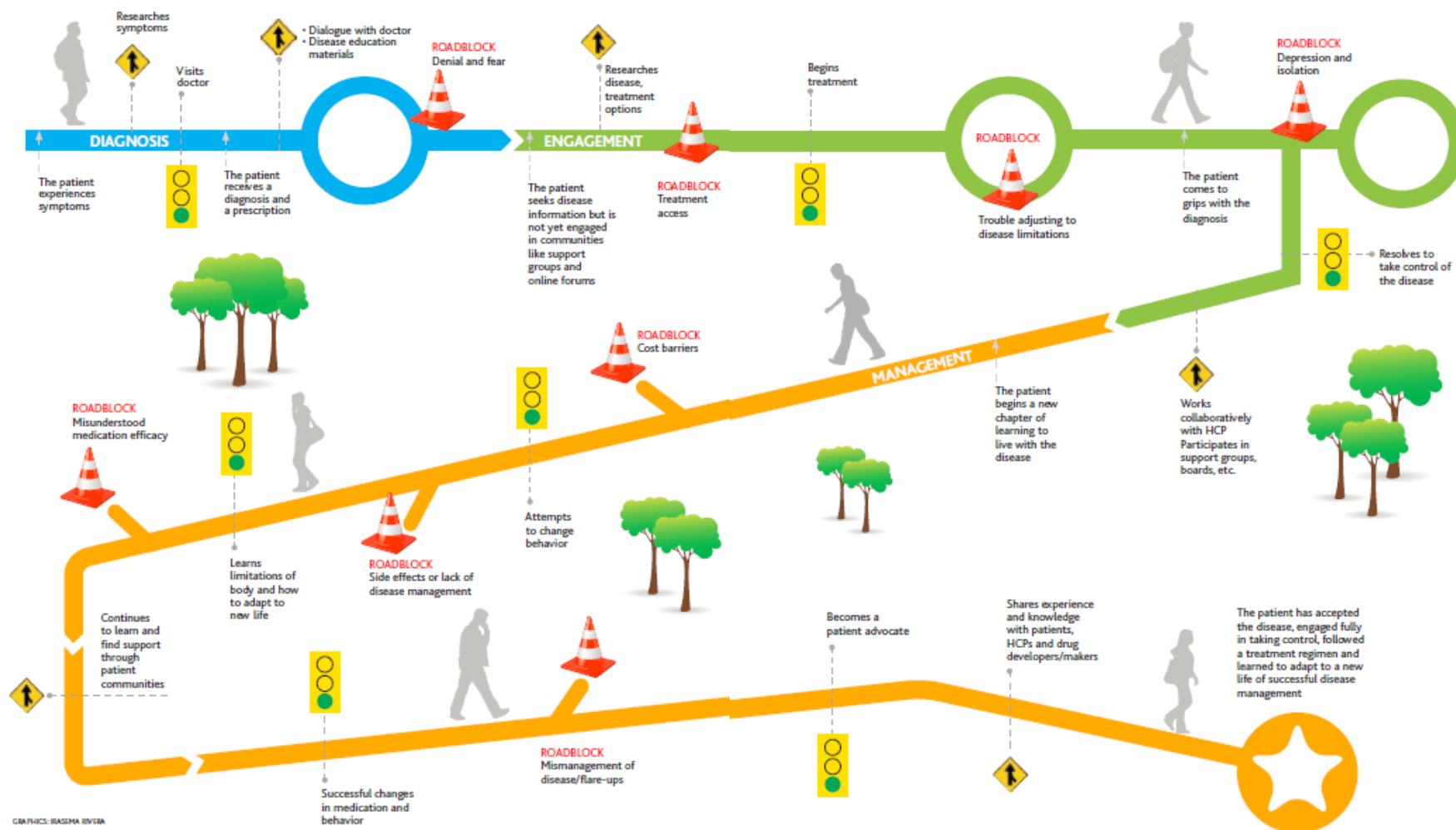
- Age
- Gender
- Race
- Stage of disease
- Severity of disease
- Subtype (pharmacogenetics, others)
- Comorbidities
- Prior medical history
- Prior treatment history
- Prognosis
- Family history/genetics
- Lifestyle factors
- Risk tolerance

How closely
do the study
participants
resemble
me?

How well do
the potential
benefits meet
my needs?

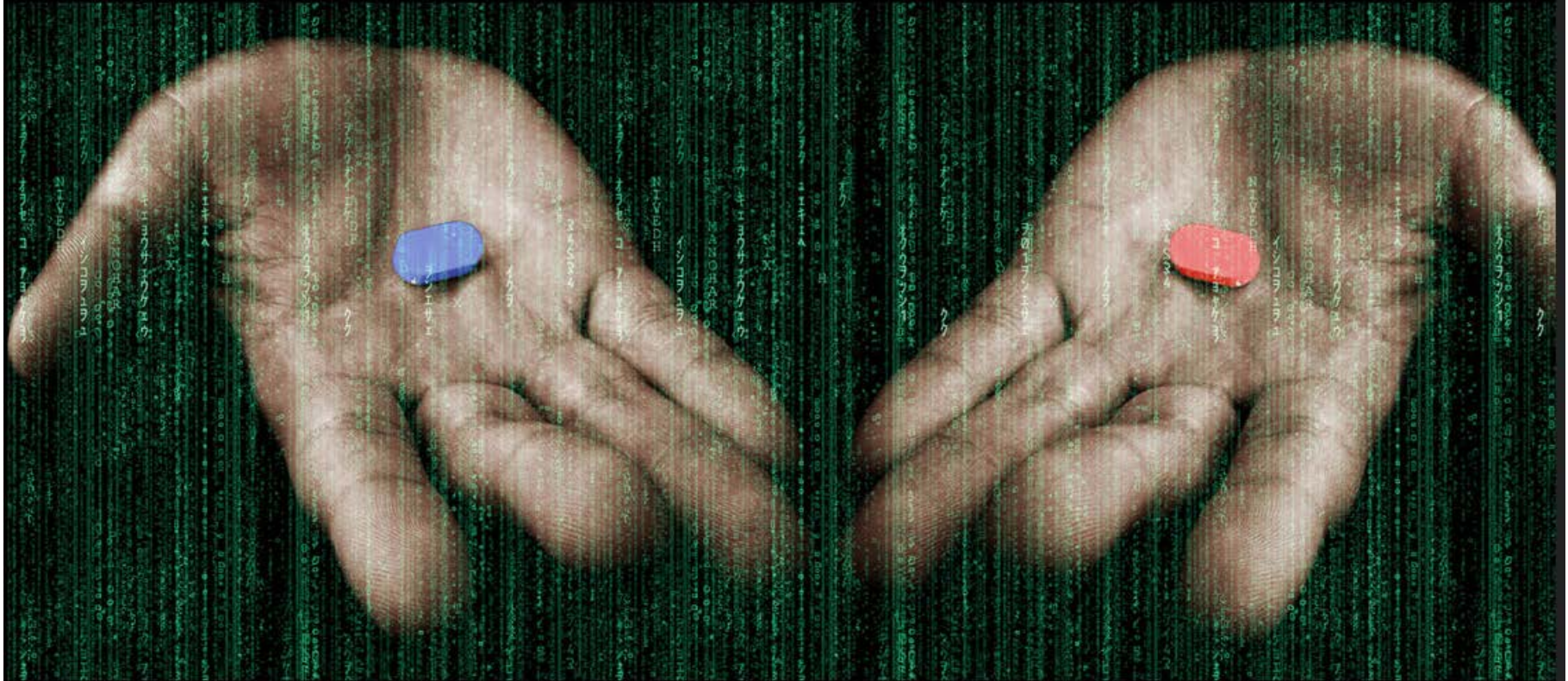
The Patient Journey

Illuminating gaps and opportunities in the case of a rheumatoid arthritis (RA) patient



The Patient Journey | Medical Marketing & Media

After this there is no turning back



You can take the red pill, wake up in your bed and believe what ever you want to believe or you can take the blue pill, stay in wonder-land and I will show you how deep the holerabbit goes

THE
MATRIX

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Our name. Our mission.

Breaking down barriers that stand in the way of medical progress.

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read



link



watch



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