

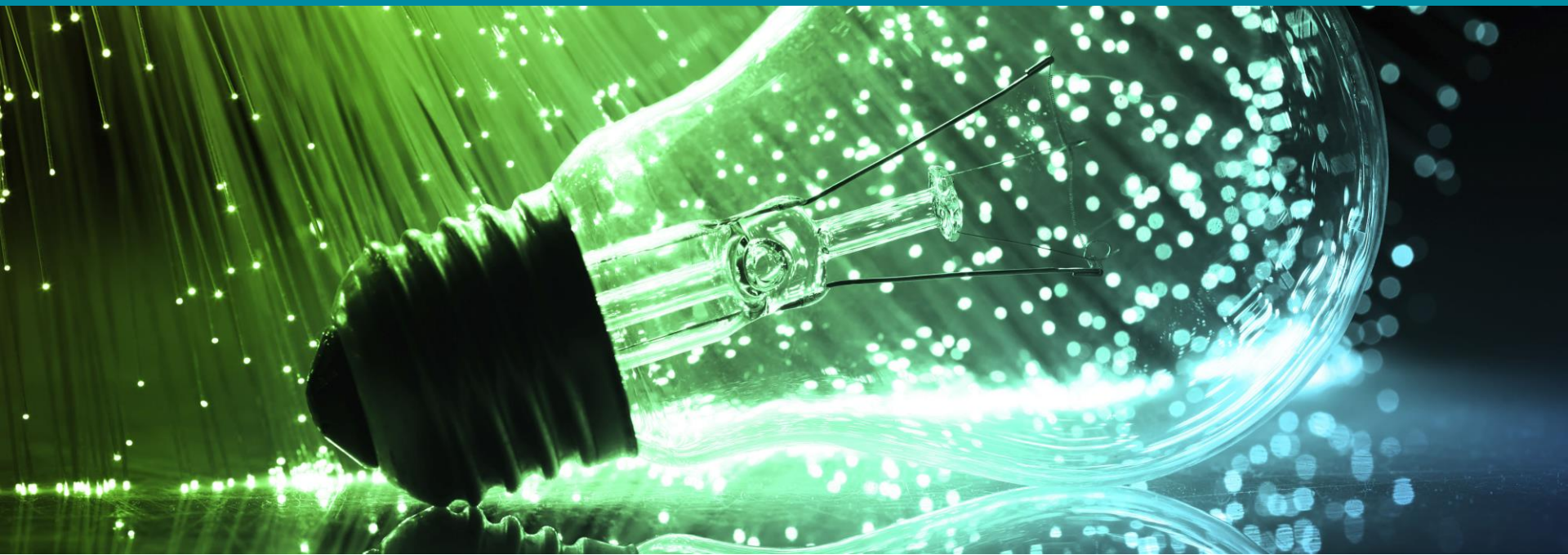
The Use of Antibacterial Drugs Developed Via Streamlined Approaches: Perspectives of Patients, Caregivers and Healthy People

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Methods

**Quantitative Research
vs
Qualitative Research?**

Sample Question

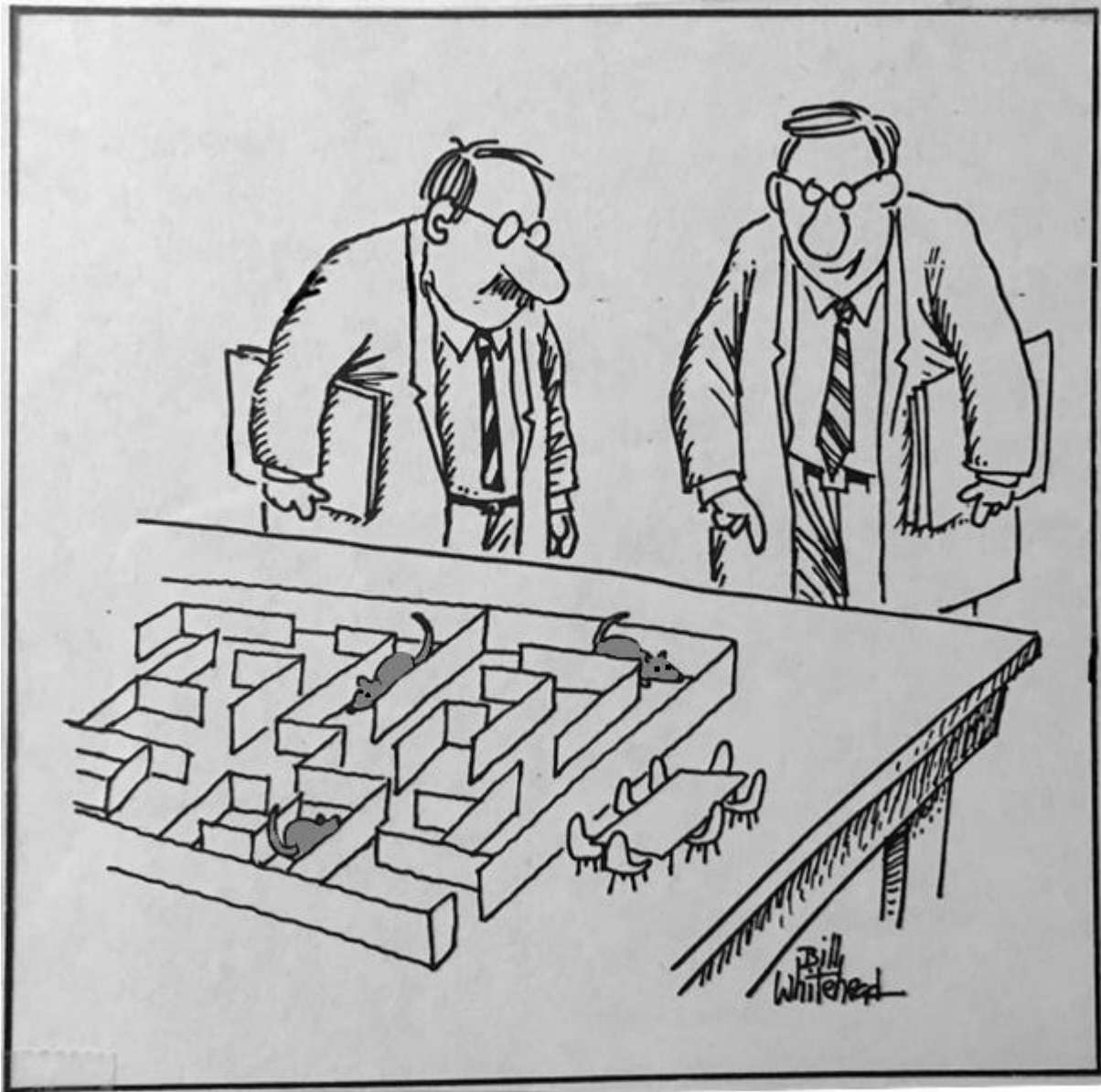
Qualitative vs. Quantitative

1. Which do you prefer, Apple pie or Chocolate cake?
 - a. Apple pie
 - b. Chocolate cake

Qualitative Research

▸ Focus Groups





“...And then we assemble all the mice at this little table for a focus group.”

Focus Groups: April 2014 - February 2015

▶ Total of 11 focus groups (N=62)

- 3 Groups: **Healthy participants**
- 2 Groups: **Recovered from serious infections**
- 2 Groups: **At-risk for hospitalizations and infections**
- 4 Groups: **Caregivers of recovered and at-risk patients**

Research Goals

- Understand the public's perceptions and beliefs about infections, antibiotics.
- Assess reactions to an FDA streamlined development approach to bringing new antibiotics to market sooner.
- Gain insight into their comfort level for taking antibiotics developed through a streamlined approach.

Mindset about Prescription Medications

- ▶ Most preferred not to take them unless necessary
 - Biggest fear = associated side effects
 - Approved drugs pulled from the market due to serious side effects
 - DTC TV
 - TV ads for class action suits for people harmed by medications

Mindset about Prescription Medications

▶ But all
medic

"I think medication is a necessary evil. But there is always a catch. Whether it's an antibiotic or cold medication, you are taking a chance, because there can be side effects."

[caregiver of recovered patient]

Patients at-risk for recurrent infections were more positive about medications.

- Theoretically, they preferred non-medication approaches but recognized the lifesaving role prescription medications have played in their lives.
- Feared dying of infection not chronic illness

“For me, a cold can turn life-threatening, and medication has helped me tremendously! I’d rather not spend the money or put those things in my body, but I realize that ‘better living through chemistry’ is working.” [recovered & at-risk patient]

Perceptions of Antibiotics

- ▶ “Wonder drugs” or “miracle drugs” = words to describe antibiotics that cure infections that once were deadly
- ▶ Antibiotics viewed as safer than many other prescription drugs:
 - Short-term nature of most antibiotic regimens
 - Positive experiences using antibiotics
 - Infections resolved
 - Few to no serious side effects

More Beliefs about Antibiotics

➤ Newer ≠ better

➤ Newer = not fully tested yet

“When my doctor needs to prescribe a medication for me, I ask for the oldest one which will work.” [recovered patient]

Beliefs about Antibiotic Resistance

- Doctors have been too quick to give antibiotics historically
- Excessive use of antibiotics in humans and livestock has contributed to the proliferation of superbugs
- When overused, antibiotics can become ineffective in treating infections they once cured
- Antibiotic resistance is a very serious problem, especially in hospitals, where these infections can run rampant

Only a few understood the mechanism of antibiotic resistance; most did not.

- Most held the mistaken assumption that individuals who take too much of a particular antibiotic will build up a tolerance to it, rendering that drug ineffective for them personally
- Even after reading an informational piece on antibiotic resistance, most were still confused

Potential Repercussion of this Misperception

- At-risk patients may hold off taking life-saving antibiotics, thinking they will preserve their future options

“You have to be careful about taking too many antibiotics because you don’t want to build up resistance to them. If you take too many, then they might not work for you when you need them.” [at-risk patient]

“I don’t mean to be morbid, but even though I have a blood cancer, I will probably die from a bacterial infection rather than my initial disease. I’ve had so many infections, and I realize that the effects of antibiotics could wear out for me with recurring use — and my condition is a lifelong thing. I don’t want to get to the last antibiotic that works when I am still in my early 50s. So I try not to take antibiotics.” [at-risk patient]

Antibiotic Resistance: Perception of the Magnitude of the Problem

- All were surprised that 2 million people in the U.S. each year contract antibiotic-resistant infections
- Healthy participants thought these resistant infections could be extremely serious — even deadly
- Recovered participants and their caregivers knew firsthand how severe infections can be and how long it can take to recover

“In 2013, I had a dental procedure, and a couple of days after that, I collapsed. I learned I had a bacterial infection in my spinal column. It took me about a year and a half to survive that episode and regain my health. I was in the hospital for two months and then in a rehab center learning to walk again for another five weeks. And then I was homebound for another two months. I was in constant pain.” [recovered patient]

Magnitude of the Problem

- ▶ All believed new antibiotics are needed ASAP to combat the growing problem of antibiotic resistance

"We're losing the battle. We're not producing [antibiotics] as much as we used to, and there's more and more bacteria resistant to the ones we have." [healthy patient]

Perceptions of the FDA Drug Review & Approval Process

- ▶ All knew that the FDA drug review process is long, but were surprised at HOW LONG
- ▶ Length of time in review didn't translate into more confidence in a drug's safety

“The FDA review process does not inspire confidence, because we see so many drugs pulled from the market because of unforeseen side effects. So, although the process is long and cumbersome, it does not necessarily result in the safest drugs coming to market.” [recovered patient]

“They study drugs for a long time, and they do the best they can, but just because it goes through all these steps doesn't guarantee that it's going to work for you. Your body is different from everybody else's body, so you never know before you take it if it's going to work for you or if you'll react to it.” [caregiver, recovered patient]

Streamlined Approach to Drug Development

- ▶ All participants reacted positively to a description of a streamlined development program.

“The problem is dire, and such a program could bring new antibiotics to market more quickly.”
[healthy patient]

▶ Advantages

- Getting new antibiotics to critically ill patients more quickly
- Saving lives

▶ Disadvantages

- Limited data on serious side effects, especially in very ill patients

All thought advantages outweigh disadvantages — especially in life-or-death situations.

“We've got so many organisms that are becoming drug resistant. This is a program to confront that. It gets the drugs to the people who really need them, and it restricts them from the general population, where they could become resistant.”
[healthy patient]

Biggest Concern about a Streamlined Development Approach

- Overuse/abuse by “profit-driven pharmaceutical companies” wanting to fast-track other medications
- Wanted safeguards to assure the streamlined development process does not become “the new normal” for other drugs

“I’d like to see that not a lot of new drugs are going through this process and that pharmaceutical companies won’t take advantage of it to make more profit quicker and put more people at risk because of side effects.”

“Antibiotics are not the only drugs that save lives, so it sets the precedent for using this process for other drugs. It’s risky, making something short this way, because it sets a precedent.”

Scenario

- ▶ “What would you do if you had a life-threatening antibiotic-resistant infection and few or no options for treatment?”
- ▶ All said they would want a new antibiotic that was approved under a streamlined development program, even though it had less data available.

“I would definitely take the drug, because what would I have to lose? It would be my last resort. ... But if I didn't have a life-threatening infection, I would take my chances and pray that my immune system would kick in.” [at-risk & recovered patient]

" It's like you're at sea, and someone throws you a life ring. You are going to grab it!"
[healthy patient]

"In that situation I would be in no shape to collect a lot of information. I would be saying, 'Bring me the pill!' not 'Bring me the iPad!' "
[healthy patient]

"If it were a life-or-death situation, I would accept more risk. If I was really sick and going to die from an infection, I would take the new antibiotic. I wouldn't say, 'Hey, I want one which has had more years of research.' "
[healthy patient]


BUT: Patients would not trust such a critical decision to only one doctor — especially one who was not conversant in the new drug.

“If you’re at that stage, you’re taking on that risk, and if you die, you die. But my question is, who makes that judgment that you are in that critical situation and that nothing else will work? Does one doctor agree with other doctors? Because these situations are never that cut and dry. That’s the problem. I think ... if somebody said, ‘You’re going to die, but take this, and there’s a chance you’ll live,’ we’d all do that. The question is who’s saying you’re going to die? And how many people agree? It’s not the premise of the drug, it’s the judgment before that that I question!” [healthy patient]

GOAL: Make sure more than one person weighs in on the decision to use a drug developed under a streamlined approach.

➤ **Some envisioned a multidisciplinary team (“The A Team”):**

- **Patient advocate**
- **Pharmacist**
- **Patient’s own doctor**
- **Physician expert**
- **ID**
- **Hospitalist**
- **Immunologist**



▶ However, participants were not well-versed in the behind-the-scenes workings of the ICU, where time is critical to outcome and where convening a large team may not be feasible.

Information Desired Regarding Drugs Approved through SDP

- ▶ Who & how many tested?
 - Population
- ▶ Side effects?
 - Common, SAEs
- ▶ Drug interactions?
- ▶ Effectiveness?
- ▶ What else is known about drug?
- ▶ How do you know the PATIENT has an antibiotic resistant infection?
- ▶ Survival odds w/o the new med?
 - What'll happen w/o it?
- ▶ Who decides?
- ▶ Are there any alternatives?

Bottom line:

- ▶ They want >1 doctor to make determination (multidisciplinary and/or expert)

At-risk patients said it would be nice to have information about drugs developed through a streamlined program when they are healthy so that their doctor knows their wishes before they are in crisis.

“I don’t want to make snap decisions after two or three days of failed treatment, when I’m slipping into a coma. Then it’s up to my family members to decide whether I’d want this or not. So I’d want as much information as possible beforehand, because you’re not just acting out of survival instinct but are making a more informed decision.” [at-risk patient]

This “advanced directive” is not feasible, according to physicians:

- PCPs are not decision-makers once patients are admitted to ICU
- It is commonplace to use treatments in the ICU that don't have a lot of data behind them
- ICU physicians don't tell patients/families that drugs are approved under a streamlined approach
- Families/patients are not asked to weigh in on which drug ICU physicians will use

This kind of “advanced directive” is not feasible, according to physicians: (cont’d)

“Families don’t weigh in very often [on the choice of antibiotics], and when they do, they probably shouldn’t, because these complicated infections are very hard even for specialists to understand, let alone a family member. I don’t want them making a decision about a complicated intra-abdominal medication in the hospital. But I do want to know if their loved one is allergic to penicillin, or if they’ve ever had a bad reaction to a sulfa drug. That’s where the family can really be of help.” [physician]

“The family never weighs in on treatment. It’s rare that a patient would have any idea about what the spectrum of an antibiotic is or why we use a certain antibiotic. I may explain that this one treats a certain bacteria that we think you have. But I would say that most patients’ knowledge of antibiotics is ‘it’s a strong one,’ or ‘it’s not a strong one.’ ” [physician]

The Bottom Line - Participants Believed:

- Antibiotic-resistant infections represent a growing crisis and that superbugs pose a serious — even deadly — threat.
- Because of the overuse of antibiotics in humans and livestock, many are now ineffective.
- The fact that there are few or no new antibiotics coming down the pike is more cause for fear.
- We need new antibiotics ASAP.

The Bottom Line (cont'd)

- All favored the creation of streamlined development programs, given the dire nature of the crisis.
- The following *new information* surprised participants and were compelling reasons to institute streamlined development programs:
 - Two million people in the U.S. contract antibiotic resistant infections every year
 - Superbugs can be passed from person to person
 - It can take as long as 15 years to bring a new drug to market

The Bottom Line (cont'd)

- ▶ If they were critically ill with a resistant infection, all would take a new drug developed under a streamlined approach. However they want more than one doctor to weigh in on the decision.
- ▶ They want mechanisms in place to assure that a streamlined development approach does not become “the new normal” for the development of other drugs.

Thank you.



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