

# Research Results

Communicating the value of innovation in personalized medicine in the context of deficit reduction and cost containment



March 2013



# Table of Contents

## *Report Outline*

	Page
<b>Background &amp; Method</b>	<b>3</b>
Background	4
Research Objectives	5
Research Method	6
Moderator Guide Outline	7
<b>Snapshot</b>	<b>8</b>
Snapshot	9
<b>Detailed Findings</b>	<b>10</b>
Awareness and Impressions	11
Definition	14
Examples	18
Hopes and Fears	22
Messages	25
Naming	28
Policy and Coverage Issues	31
Conclusions	40
<b>Appendix</b>	<b>41</b>

# BACKGROUND & METHOD

# Background

## *About this initiative*

- In April 2010, KRC Research conducted formative qualitative research about personalized medicine.
- Today, the opportunities and the challenges remain breathtaking. Yet, the opportunities come at a time when the primary policy focus in Washington, D.C. is on deficit reduction and cost containment in health care.
- Given the current climate, the Personalized Medicine Coalition (PMC) sought to conduct follow up research to identify the most current approaches for communicating the value of innovation in personalized medicine.



# Research Objectives

## *What we set out to learn*

The overarching goal of this research was to identify approaches for effectively communicating the value of innovation in personalized medicine approaches from within the context of national conversations about deficit reduction and cost containment by:

- Gauging current awareness of and perceptions about personalized medicine;
- Understanding opinions, hopes, and concerns related to personalized medicine once the idea is described;
- Identifying which facts and examples generate the greatest excitement about personalized medicine; and
- Understanding how to make the case for covering personalized medicine.



# Research Method

## *Qualitative research*

**We conducted six focus groups on February 12-19, 2013.**

**Three locations:**

- Washington, DC (Bethesda)
- Chicago, IL (Skokie)
- Dallas, TX

**Half Democrats, half Republicans**

- 27 Democrats
- 25 Republicans

**Opinion-leading news-attentive consumers:**

- Ages 30-64
- Hold at least a 4-year college degree
- Annual household over \$75,000
- Registered to vote
- Above average consumers of news and information
- Regularly discuss politics and current events

**52 opinion-leading consumers**

**Two focus groups in each location:**



# Moderator Guide Outline

## *Topics discussed*

### **Awareness and Impressions (Unaided)**

Determine unaided awareness of “personalized medicine” and associated ideas.

### **Impressions (Aided): Definition**

Evaluate reactions to the description, learn what questions the description prompts

### **Impressions (Aided): Examples**

Evaluate reactions to specific examples designed to excite and create demand/support for personalized medicine; determine how to improve examples; identify any weaknesses or sources of confusion.

### **Hopes and Fears**

Determine underlying mindset associated with personalized medicine, including people’s hopes, fears, and attitudes.

### **Messages**

Identify and strengthen most compelling messages to use in advocating in support of personalized medicine.

### **What to Call “Personalized Medicine”**

### **Policy and Coverage Issues**

Explore if and how to make the value case in the context of personalized medicine within an environment in which cost containment is a key decision driver.



# SNAPSHOT



# Snapshot

## *Major takeaways*

1. People feel good when they hear the term, “personalized medicine”—it’s a warm fuzzy term, but almost nobody has heard of it.
2. The way you define and describe personalized medicine matters—we showed two accurate but different definitions and the reactions were almost the opposite.
3. Examples are the best way to get people to think about personalized medicine in a personal way—examples generate excitement.
4. What excites people about personalized medicine is that it offers more control and has a preventive focus. The fears are that it could be used to take away covered choices or it will be out of reach for regular people.
5. The most powerful messages highlight better information and more control for decision-making with less trial and error and fewer adverse effects—now and not decades away.
6. People like the term “individualized medicine” to describe the practice area.
7. Most expect the topic to prompt debates about privacy, cost, and coverage—and most expect it to open up difficult but important ethical questions.
8. People want access to personalized medicine if their doctor says they need it—even if it costs a lot. Thus, messages in support of why personalized diagnostics and treatments should be covered by payers revolve around the doctor/patient relationship.

# DETAILED FINDINGS

# Awareness and Impressions

Unaided reactions from participants



**Key Finding:** The term “Personalized Medicine” evokes positive feelings, but... few have heard of it and it does not yet convey the intent of using diagnostic tools to identify individualized biological markers to help assess personal treatment options. Because the term has not yet been popularly adapted, there remains the opportunity to adjust or modify the term if desired.

*The term, Personalized Medicine remains new to most people.*

Just **eight out of 52** news-attentive consumers had heard the term. Out of those eight, only **one or two were able to describe the concept correctly**. This is similar to what we observed in 2010.

Unaware:   
 Aware: 

- *Most have not heard the term—there is virtually no awareness.*
- *Even most of those who have heard the term don’t know what it is.*
- *Most like the term and the associated imagery.*
- *But what they imagine is not very well aligned with the meaning. Rarely do people associate it with genetic science or to specific types of treatments.*

# Awareness and Impressions

## Top of mind impressions of “Personalized Medicine”



***When asked what comes to mind,  
the term evokes three key ideas:***

- Highly **individualized** and **proactive “concierge”** medical care.
- Having **more choices** and control over one’s medical care and the ability to **customize care or insurance** based on specific family and medical history and personal needs.
- Having access to a **personally preferred doctor** family doctor.

# Awareness and Impressions

*In their own words...*



*"The first thing that popped in my mind was my family doctor and I'm thinking old doctor, Marcus Wellby, MD or someone like that, that has been around for years and years and years."*



*"...something more focused on the individual. Not one size fits all. Very individualized. Very highly private, customizable for the individual."*



*"I just thought of, like a type of drug or treatment plan developed and prescribed based on a specific illness, symptom, ailment, and highly individualized."*



*"...something where each individual was responsible and involved and accountable for their medical care and the financial aspects of it."*



# Definition

## *Words matter*

- In the Washington, DC area, we showed participants the PCAST definition. After the Washington groups, we revised the definition based on what we had learned in 2010 research and we tested the new one in Chicago and Dallas.

<u><b>PCAST Definition:</b></u>	<u><b>Revised Definition:</b></u>
<p>“Personalized Medicine” refers to the tailoring of medical treatment to the individual characteristics of each patient...to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventative or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not.</p>	<p>“Personalized medicine” is an emerging field of medicine that uses diagnostic tools to identify specific biological markers, often genetic, and help assess which medical treatments and procedures will be best for each patient. By combining this information with the individual’s medical history and circumstances, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.</p>

# Definition

## *Reactions to official and revised definitions*



**Key Finding: Words matter.** In describing the new field of Personalized Medicine it is important to use plain language that conveys a consistent and believable description of the practice area and what consumers value about it. Some definitions scare people and are counterproductive. That said, a definition alone doesn't get you very far.

*Consumers have drastically differing sentiments depending on the definition they are shown.*

Consumers felt tricked and manipulated by the definition shown in Washington, DC because they feel it does not match what they imagined the term to mean. The definition used in Chicago and Dallas generated a much more positive reaction.

*The original definition used in Washington made consumers feel **tricked** and **manipulated***

Both Democrats and Republicans respond negatively to the official definition.

Many say the definition sounds like segmented and pigeon-holed medicine and point out that the definition and term sound contradictory to one another.

*Respondents reacted to the new definition in a very **positive** and **receptive** way*

Nearly all respondents in Chicago and Dallas felt the (revised) definition was consistent with the term.

They feel that Personalized Medicine is step in the right direction for health care and that it would produce real and direct benefits to the individual.

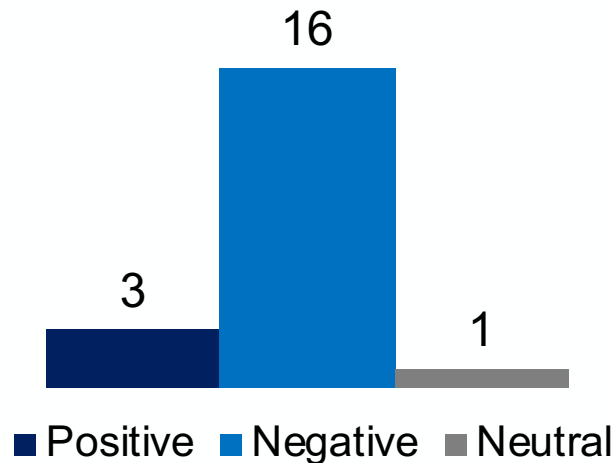




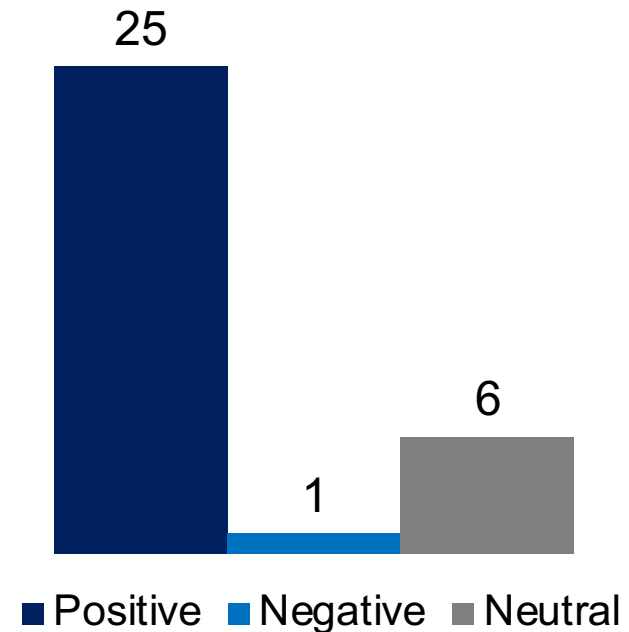
# Different Definitions, Different Reactions

*Reactions to official and revised definitions*

Impression of PCAST  
Definition



Impression of Revised  
Definition

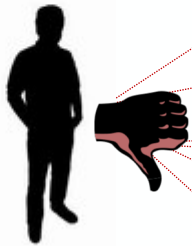




# Definition

*In their own words...*

## PCAST Definition



...it starts out saying you're going to tailor medical treatment to my characteristics but then you're going to take me from being an individual and put me in a population. So you just completely wiped out your main statement that you're going to do. You have just **contradicted** everything you said."

*Who does the classifying to determine the population? And if you're not in that **subpopulation** but you end up with something else, are you going to be **denied** coverage?"*

"I'm going to paint this wonderful, rosy picture but the pages that you don't read, you're going to see that they're **sparing expenses** and if you will benefit from it, okay. But if you won't, I'm going to kind of push you here off to the side."

"It's almost like it's **customizable** – that aspect of it. They're customizing this for you – these treatments for your specific needs, whatever they may be."

"In my opinion, I think one of the problems we have in our healthcare system today is a lack of sharing of information among doctors...So for me, this sounds kind of **positive**..."

"I think it's really **exciting**. I think looking for specific biological markers..."

"I love the fact that they're looking at **prevention**. That word really stands out for me"



## New Definition

# Examples

*Reactions to examples of how Personalized Medicine is being used today*



**Key Finding:** Examples take Personalized Medicine from an abstraction to a reality. Examples describing in clear terms how Personalized Medicine is currently being used effectively communicates value and generates excitement. Respondents personalized the examples to relate what these advances could mean to them and their family. The examples took the concept from abstraction to reality.

*Almost all*

*Most had a positive impression of Personalized Medicine after reading examples of how it's being used today. People liked:*

- **Proactive** rather than reactive
- Useful diagnostic information
- Less invasive procedures, avoid side effects
- Clear-cut data-backed research so there is less guessing

Altogether, people feel this could save lives, time and money.

*A handful*

*Those who feel neutral are not sure that the benefits to the individual patient will outweigh potential liabilities.*

They worry that this approach embodies a philosophy of solving problems with drugs rather than encouraging lifestyle changes and prevention when possible.

*Very few*

*Those who feel negative say they worry about privacy issues.*

A common concern is that if one has a “high genetic risk” for something, it might automatically label them as a liability and it **could take away choices**.

There is also some discomfort with the possibility that something as personal as genetic information could be shared with others without consent.

# The Power of Examples

*Familiar experience + less intrusion or pain + helpful information + my choice = good example*

- Specific examples of how personalized medicine benefits people now are far more powerful in establishing interest, excitement, and a sense of personal relevance than an abstract definition.
- Examples that work best...
  1. Refer to diseases with which people are familiar and have personal experience;
  2. Are associated with clear-cut information to guide decisions, faster diagnosis, less intrusive diagnostics, less difficult treatment, or greater effectiveness;
  3. Establish that there are choices in treatment, and that personalized medicine can guide people, in consultation with their doctor, to the best choice.

# The Power of Examples

## Four Examples Today

All examples were **more positive than negative**. With that in mind, some examples triggered more ambivalence than others.

Example	Reaction
Whether Herceptin is the right treatment for breast cancer	Very positive example because it seems clear cut. As long as it doesn't mean that over-expression of HER-2 means you will be denied treatment. In other words, the message is that personalized medicine helps your doctor choose <u>which</u> treatment is right, rather than decide <u>whether</u> treatment is right.
Test to determine risk of organ rejection	Also a very positive example because the test is less invasive (blood draw vs. heart biopsy). Some didn't like the reference to cost savings because it seemed to diminish the value to the person, showing once again that the cost issue is complex.
Tests for the risk of breast cancer recurrence	Mixed reactions, reflecting the fact that the outcome is less clear cut as well as participants' ambivalence about testing for risk, as well as reluctance to close the door on any treatment option. As long as it is simply to help the patient make choices, not take them away.
The right dosage for Warfarin	Most negative reactions. Without explanation of the drug's use and importance, participants fixated on the high risks associated with Warfarin and missed the point that the test helps regulate the dose. This was the least effective example because it raised a lot of skepticism.

# The Power of Examples

*The examples prompted people to tell their own personal stories*

**"I have a few friends** who have gone through some treatments for cancer. And what I like about that is that they say here that if you're low risk, you might be able to avoid the side effects of chemotherapy. **I like the idea that you're not treating everybody the same... because everyone's body is different. Everyone's physical makeup is different.**"

**"I know a story of a guy.** He had a liver transplant and they were trying all kinds of different medicines. He almost died a couple of times because the doctors had no idea how the medicines would react with each other or react with his particular genetic makeup."

**"My dad** had a heart attack and he lived on blood thinners. I feel like we're making the public paranoid saying, 'Okay, your family has a history of heart attack, so now we should test your blood thinner.'"

**"My girlfriend** had breast cancer and started this drug. Her doctor said the tumor is not responding the way that it should be. Well, come to find out she was one of 10% of that made a protein that prevented this drug from working. So they were able to stop that drug and start a drug that was effective."

**"My grandmother** had issues with her blood thinner medicine and it's eventually the poison that was in what she had that contributed to her passing."



# Hopes and Fears

*People can imagine many benefits but remain cautious*



**Key Finding:** After seeing the new definition and the examples, the majority feel excited because it may provide consumers more control over their health by taking a more proactive approach. Some fear high costs could make it a luxury. Others worry that information might be used to *take away choices*.

*Many believe Personalized Medicine would **benefit** both the individual, as well as society.*

Those who feel excited say it is because it may lead to individuals having **more control** over their own health because it is a **more proactive and preventive** way of thinking.

There is hope for **cost savings**; the combination of preventative care and **reducing waste** would ideally mean fewer costs.

*The more **cautious** express feelings of **neutrality** associated with uncertainty over promises*

Some say they **need more data** and information to determine how effective tests and treatments are.

Others express concerns over **confidentiality** and whether the trade off of privacy in return for more individualized care would be worth it.

*Those who feel **worried** say it is because Personalized Medicine could potentially reduce choices for patients.*

There are fears that individuals' treatment plans may be **limited** due to the results of genetic tests.

Also a point of concern is **cost**, some feel that would only be **available** to the **wealthy**, or lead to increase health care costs for all

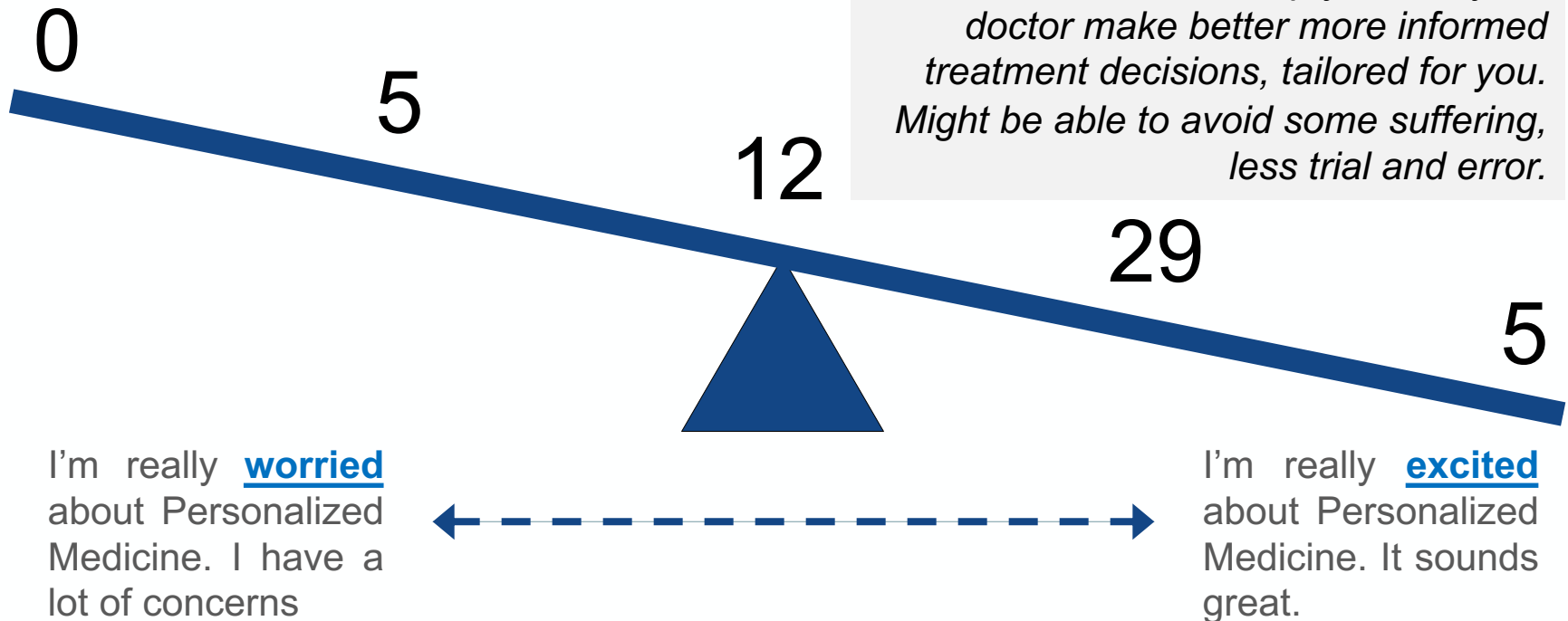
# Hopes and Fears

*The majority feel excited about personalized medicine*



**Scariest ideas:** Cost; they take away your choices; they don't cover treatments you need and want; only the rich have access.

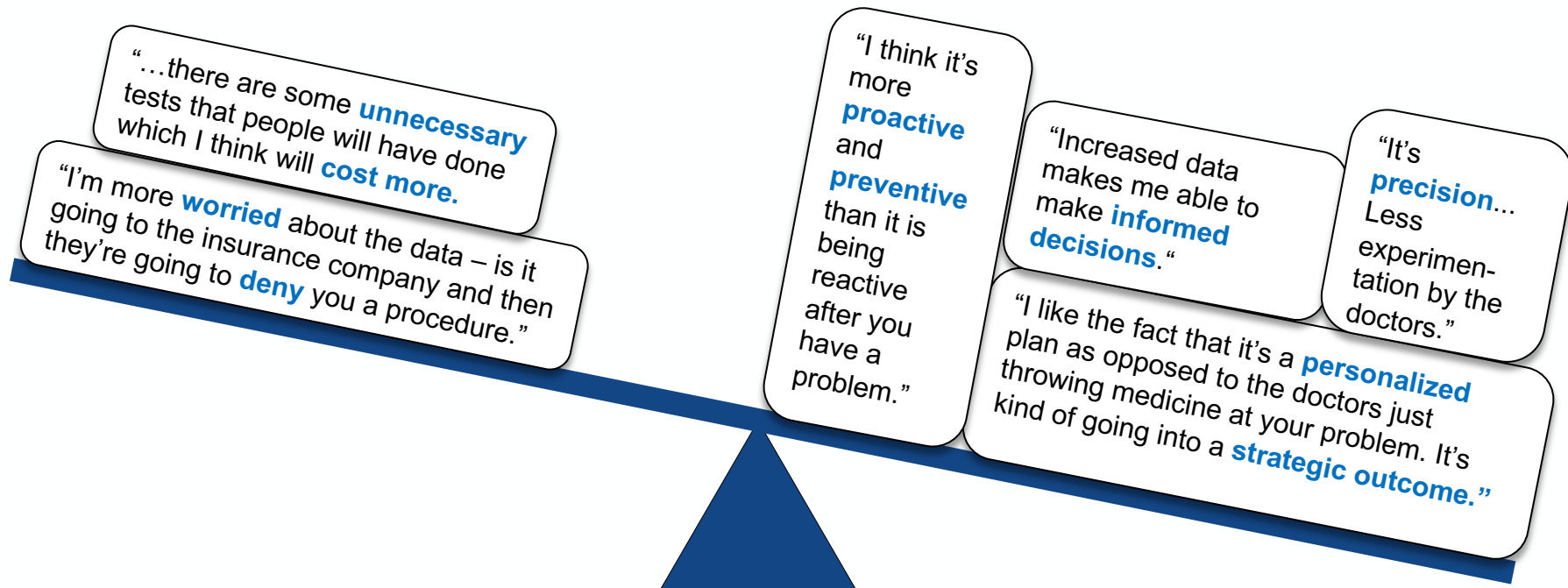
**Most exciting ideas:** More information that can help you and your doctor make better more informed treatment decisions, tailored for you. Might be able to avoid some suffering, less trial and error.





# Hopes and Fears

*The majority feel excited about personalized medicine*



I’m really **worried** about Personalized Medicine. I have a lot of concerns

I’m really **excited** about Personalized Medicine. It sounds great.



# Messages

*Key points to communicate value of personalized medicine*



**Key Finding:** The most powerful messages highlight more control over prevention and treatment choices, less trial and error, and fewer adverse effects. The fact that up to 50% of drugs in the biopharmaceutical pipeline are targeted and a description of new diagnostics and personalized medicines communicates that it is here now. Although many are skeptical that it will reduce health care costs, the message is at least plausible in the long-run.

## *More than eight in ten respondents have a positive reaction to the messages*

Several value propositions stand above others as being very important:

- ✓ **More proactive: better detection, prevention, and earlier intervention**
- ✓ **Reducing the amount of trial and error and getting the most effective treatment to patients sooner**
- ✓ **Less invasive procedures and reducing adverse side effects**

## *The biggest concerns relate to potential lack of access and the price tag.*

A number of people worry that Personalized Medicine will be covered by insurance and, if not, will it be a luxury medicine that only the rich can afford.

There is also a fear that widespread use of Personalized Medicine could drive up overall health care costs.

Some wonder what research might be left out of the pipeline if the big focus is on Personalized Medicine.

# Messages

## *Key points and reactions*

Rank	Message	Reaction
1	Better prevention and more control over your health	<ul style="list-style-type: none"> <li>• People agree that every person is different</li> <li>• They want more prevention and control by having more data, more options, and more choices</li> </ul>
2	Avoid trial and error	<ul style="list-style-type: none"> <li>• Less guessing means saving time and money</li> <li>• Getting to a solution faster, less pain and suffering, and better outcomes</li> </ul>
3	Reduce adverse effects	<ul style="list-style-type: none"> <li>• Smarter choices to avoid side effects</li> </ul>
4	Personalized Medicine is here today	<ul style="list-style-type: none"> <li>• Approvals in the last couple years means it is not just a dream</li> <li>• The 4% cystic fibrosis example raises some questions—good for those with CF but must you test everyone to find the 4%?</li> </ul>
5	It could reduce healthcare costs in the long run	<ul style="list-style-type: none"> <li>• People like this idea and many WANT to believe it—they can see a “silver lining;” but some say that costs never go down—only up; until there is evidence, this is aspirational</li> </ul>
6	Researchers are advancing this new approach	<ul style="list-style-type: none"> <li>• Most view Personalized Medicine as a step in the right direction which builds on the past; some feel that to say it will “transform” health care is overstated</li> </ul>

# Messages

*In their own words...*

- ✓ Reducing the amount of trial and error to get the most effective treatment to patients sooner means potentially better outcomes
- ✓ Less invasive procedures and fewer side effects means less pain and suffering
- ✓ Better detection, prevention, and earlier intervention means more proactive and less reactive



"I see **avoiding trial and error** as addressing an immediate, very significant problem we have in the country and the world. "



"...based off of a blood draw as opposed to having to open up or an actual biopsy off of the heart. You're talking about something way **less invasive**. So that would be a positive."



"The most exciting thing was **preventive** in the first one. They will be able to take preventive action sooner and detect diseases earlier. **Early detection** is everything. So to me, that's huge."

# Naming

*Preferred name for “Personalized Medicine”*



**Key Finding:** “Individualized Medicine” is the preferred term by more than half. Many respondents also like “Personalized Medicine” and “Targeted Therapies.”

*From beginning to end, many participants discussed how the individual should be the center of focus.*

The most popular term is “**Individualized Medicine**” because it feels like the best fit for what respondents read and discussed during the focus groups.

Although we used the term, “**Personalized Medicine**” throughout the discussion, and it was considered positive, nearly 8 in 10 chose a different term when asked which one they liked best.

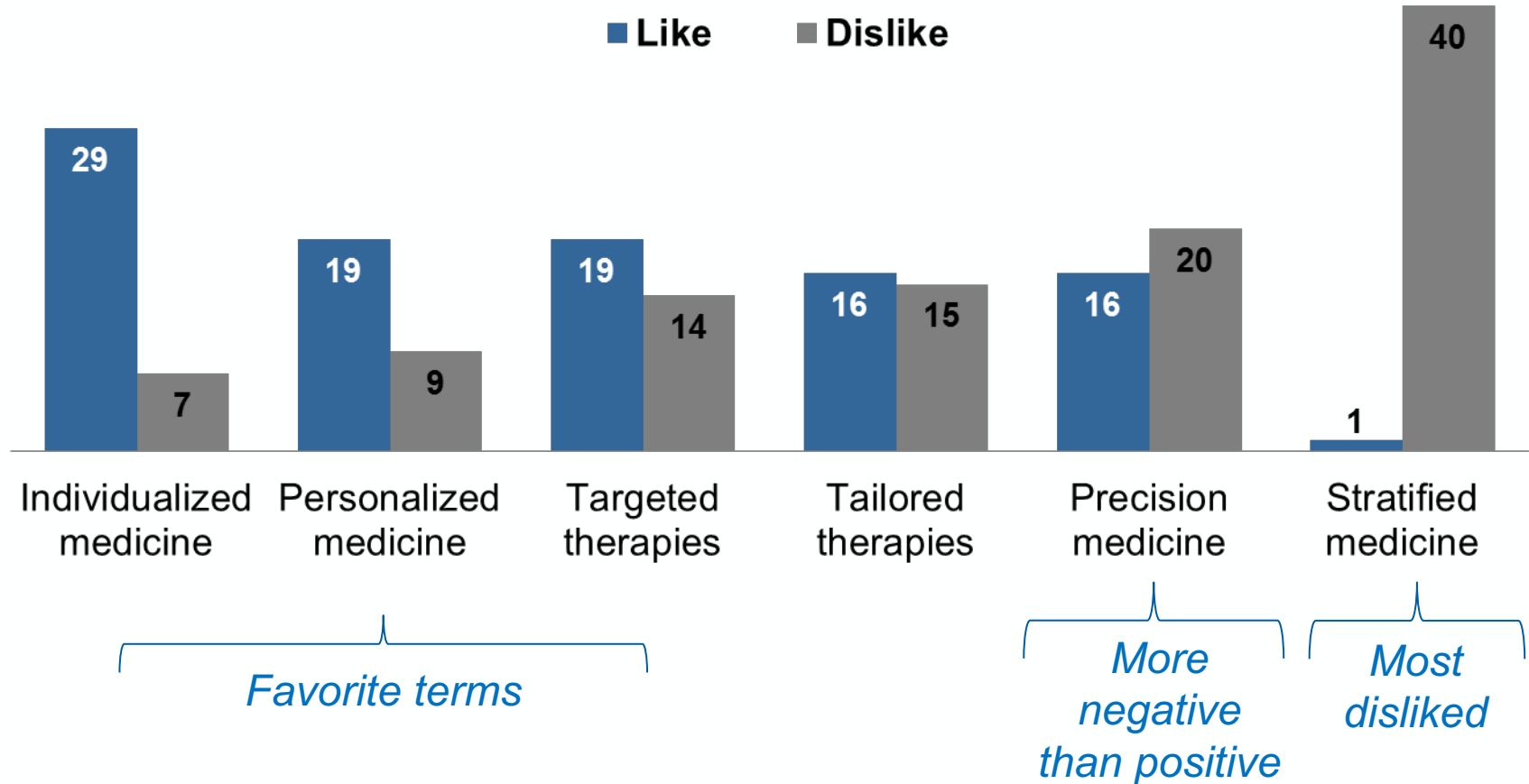
“**Targeted**” is also well liked, but some feel the word “therapies” is too narrow.

*The term, “Stratified Medicine” is universally unpopular and raises red flags because it suggests classifying people into groups and using a “cookie cutter” approach, the opposite of individualized care.*

*“Precision Medicine” is also more negative than positive.*

# Naming

*Preferred name for “Personalized Medicine”*



# Naming

## *Participants' reactions to terms*

Rank	Term	Positive	Negative
1	<b>Individualized Medicine</b>	<ul style="list-style-type: none"> <li>• Not mass produced; custom</li> <li>• Describes practice; true definition</li> <li>• Patients want to be treated as people</li> <li>• Takes into account specific needs</li> </ul>	
2	<b>Personalized Medicine</b>	<ul style="list-style-type: none"> <li>• Importance of the person</li> <li>• Clear and concise</li> <li>• Catered to individual, not "cookie-cutter"</li> <li>• Sounds customizable</li> </ul>	
3	<b>Targeted Therapies</b>	<ul style="list-style-type: none"> <li>• Specific</li> <li>• "Targeted" is a good word choice</li> </ul>	<ul style="list-style-type: none"> <li>• Counseling</li> <li>• Therapy=physical type care</li> </ul>
4	<b>Tailored Therapies</b>	<ul style="list-style-type: none"> <li>• Denotes Consideration</li> <li>• Made to fit my personal needs</li> </ul>	<ul style="list-style-type: none"> <li>• Counseling</li> <li>• Therapy=physical type care</li> </ul>
5	<b>Precision Medicine</b>	<ul style="list-style-type: none"> <li>• Pinpointing specific diseases/ issues</li> <li>• Precision = best</li> <li>• Efficient, accurate</li> </ul>	
6	<b>Stratified Medicine</b>	<ul style="list-style-type: none"> <li>• True definition</li> </ul>	<ul style="list-style-type: none"> <li>• Different layers of care</li> <li>• Rigid, not friendly or helpful</li> <li>• Segmentation; segregation</li> <li>• Opposite of what is wanted</li> </ul>

# Policy and Coverage Issues

*Thoughts on potential hurdles for Personalized Medicine*



**Key Finding:** Most expect the field of Personalized Medicine to prompt societal debates about privacy and cost—and many fear that insurance companies may not cover this type of medicine. The policy arena opens up difficult ethical questions associated with dying and end of life, and prompts personal “what if it was me?” thoughts and accompanying empathy.

## ***Key questions center around access, coverage and cost:***

- ? Is this something that insurance companies will cover, or is it a luxury only for the wealthy?
- ? Will performing additional tests run up the cost of coverage for everyone?
- ? Are diagnostic and pharmaceutical companies pushing this approach to make money?

## ***Key questions related to privacy and pre-existing conditions:***

- ? Who will have access to the information provided by genetic testing?
- ? Will health insurance companies be able to obtain this information and use it against me when it comes to covering further tests, procedures and/or treatments?

# Policy and Coverage Issues

*Should insurance companies cover Personalized Medicine?*



**Key Finding:** People want access to Personalized Medicines. When given two options (forced choice), the large majority believe that health insurance companies should cover Personalized Medicine tests and treatments if the doctor orders it—even if they are expensive.

***Participants feel strongly that the reason they pay for health insurance coverage is to have access to coverage and appropriate treatments if and when needed.***

Nearly everyone agrees that medical decisions should not be made by insurance companies. If the FDA has approved it and the doctor prescribes it, they believe insurance companies should cover it.

Many want to believe that this approach could reduce costs in the long run, but many also express doubt.

***Those who think insurance companies should not provide coverage are skeptical about costs and effectiveness.***

Some fear that the large upfront investment may not pay off in the end and that it would make sense to collect more data and information before moving forward with coverage.

One participant suggested that the statement for why Personalized Medicine should be covered sounded too much like a marketing ploy, or a political campaign for it to be true.



# Policy and Coverage Issues

*Which is closer to your own opinion?*

## SHOULD COVER

Because they only target a small number of patients, personalized diagnostics and treatments are more expensive, but they **deliver more value to patients and can help control overall health spending**. Health insurance companies should cover these tests and treatments, even if they have a high up-front cost.

## SHOULD NOT COVER

Personalized medicine sounds promising, but **it is too expensive**. Health care costs are already high, and some of these new tests and treatments can cost tens of thousands of dollars. In order to keep health care affordable, health insurance companies should not cover these tests and treatments if they are costly.

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# Policy and Coverage Issues

*Potential approaches to coverage*



**Key Finding:** There is overwhelming agreement that insurance companies should provide guidelines and the latest information to physicians, but ultimately the doctor with the patient should decide what tests and treatments are best for the patient.

***Most fear insurance companies are driven by the “bottom-line” and not the individual’s health.***

Most believe insurance companies should have a limited role to play in personalized medicine decisions. There is a feeling that insurance companies take the vital “human-based” aspect out of health care.

Ultimately, there is agreement that patients and doctors would make the best decisions.

***In an ideal world, participants would like to see insurance companies cover the “latest and greatest” tests and treatments.***

However, most don’t see this as a realistic option. They point out that it could be cost prohibitive.

Others express concern that while there are clear benefits to moving quickly in health care, moving before there is clear evidence has drawbacks as well. Nonetheless, most want access if this is their best hope.

***There is a clear belief that low cost does not always equal best option.***

Participants are not comfortable with coverage decisions being heavily influenced by cost differences between treatments.

However, they feel this is the reality in the current system.

# Policy and Coverage Issues

## *Potential approaches to coverage*

Rank	Approach (See Appendix for Full Statements)	Reaction
1	Health insurance companies should provide tools and information to help doctors tailor—but ultimately should cover what the doctor decides is best.	<ul style="list-style-type: none"> <li>• Doctors make the best decisions with their patients—providing information is good</li> <li>• But insurance companies should play a limited role in health decisions</li> <li>• Insurance companies take out the “human-based” aspect</li> </ul>
2	Health insurance companies should cover the costs of more complex diagnostics as soon as they are available, and over time gather more research.	<ul style="list-style-type: none"> <li>• Ideally, insurance companies should cover modern tests and treatments</li> <li>• Could be cost prohibitive</li> <li>• Moving before there is clear evidence has drawbacks but there need to be exceptions</li> </ul>
3	Health insurance companies should decide which treatments are similar in cost and outcome, and pay only for the least expensive.	<ul style="list-style-type: none"> <li>• This is the reality in our current system</li> <li>• Low cost is not always best option</li> <li>• Not comfortable with decisions being heavily influenced by cost</li> </ul>
4	Health insurance companies should set a cost-effectiveness standard to decide whether to cover expensive medicines and diagnostics.	<ul style="list-style-type: none"> <li>• Standardizing the cost of tests and treatments would simplify the system</li> <li>• Depends on what “cost-effectiveness” standard means</li> </ul>

# Policy and Coverage Issues

*In their own words*



"You will have **more control** over your own destiny as well as the person who is choosing the medication for you as opposed to the insurance."

You lose the **humanity** of it and all you do is just look at numbers."

"...having the **doctor perform** medicine and not the health insurance perform medicine. That the health insurance company is really just a **facilitator** ."



# Policy and Coverage Issues

*Why health insurance companies should cover Personalized Medicine*



**Key Finding:** The doctor-patient relationship is sacred. The best messages in support of covering personalized diagnostics and treatments are those that revolve around the doctor and patient making informed decisions using the latest technology to tailor care to individual needs.

***Most persuasive is that these new tools will allow patients and doctors to take more individualized approaches to care.***

Participants believe that current approaches to health care and coverage are out of date, inefficient and sometimes ineffective.

They also believe the current health care system treats patients in a way that assumes they are “average” and not a unique person.

***Participants like the idea that increased information may promote advancements in the health field.***

Most believe that increased health care data will lead to a greater ability to tailor care.

There are some reservations with medical records and patient privacy, but not enough to slow progress in this promising field.

***Some are frightened by the idea that developers could cut back investments.***

A few worry that if insurance companies decide not to cover “Personalized Medicine” that developers may lose interest and put a halt to new financing.

However, many do not believe the assertion and feel that companies would find other investors for their plan.

# Policy and Coverage Issues

*Why health insurance companies should cover Personalized Medicine*

Rank	Reason (Top 3) (See Appendix for Full Statements)	Reaction
1	Health information technology is giving doctors new tools for rapid, ongoing learning about what works best for different patients. Instead of making “yes/no” coverage decisions, we should encourage doctors to use these tools to tailor care for patients.	<ul style="list-style-type: none"> <li>• New tools will allow patients and doctors to take more individualized approaches</li> <li>• Increased information could promote advancements</li> </ul>
2	Current approaches to coverage rely on what works for the average patient. Personalized medicine is leading to new tools that will give doctors and patients the ability to tailor care to meet individual needs. As personalized medicine develops, coverage policy must be reformed to give physicians and patients more flexibility to tailor care.	<ul style="list-style-type: none"> <li>• Current system treats patients as “average,” not as individuals</li> <li>• Current approaches are out of date, inefficient and ineffective—should be reformed</li> <li>• Increased data will lead to a greater ability to tailor care, but some have privacy concerns</li> </ul>
3	If insurance companies do not cover personalized tests and treatments, companies that develop personalized tests and treatments will pull back their investment and this will stunt the promise of finding breakthroughs and developing new treatments.	<ul style="list-style-type: none"> <li>• Some think this might be true and are frightened by the idea (more seemed concerned in this context than in others)</li> <li>• Others don’t believe it</li> </ul>

# Policy and Coverage Issues

*In their own words*

- ✓ Insurance companies need to keep pace

"I circled policies that **keep pace** with the changes that are going on. I mean, science keeps moving forward but the policies don't. And if the insurance companies don't move along with it, it's not going to work."

- ✓ The patient should be the center of decision-making

"...when they talk about **controlling costs**. It isn't usually from the patient's perspective. The patient is probably the last one that's really considered."

- ✓ Care should be tailored to individual needs

"...I liked flexibility to **tailored care**. I liked that specifically. I think that that's a real good way of describing personalized medicine."

- ✓ Coverage decisions should be flexible

"...coverage policy, must be reformed to give **flexibility**. They need to work together. They need to find a way so that insurance companies can cover these types. They can't just say it's a pre-existing, or turn their back. It's too important"

# Conclusions

- Do not assume anyone knows what “personalized medicine” is.
  - Use the term “individualized” or “targeted” medicine often, but avoid “stratified” or “precision” medicine or therapies.
- Use a plain-language consumer-friendly definition—but realize a definition only gets you so far and doesn’t generate much excitement.
  - Avoid scary terms like “genetic testing” and ones that seem to exaggerate like “transforming” healthcare.
- Use good messages about how the practice is here now—and advancing:
  - **Individualized care:** Every person responds differently to different treatments, and so patient-centered care is best.
  - **Proactive care:** More information means better control over your health, less trial and error, finding solutions faster for better outcomes with fewer side effects. The silver lining is that this could reduce healthcare costs in the long run.
- To get people engaged and excited, give a couple examples that offer clear benefits.
  - Stay away from scary or muddled examples that remind people about loss of control or suffering.
- To foster a winning policy agenda, frame talking points around access to diagnostic tests and treatment options, doctor-patient decision-making, and continuous learning.
  - Encourage reform coverage and payment to keep pace with need and innovation.



# **APPENDIX: Test Materials**

# Examples

## *Examples of personalized medicine*

- A. There is a breast cancer treatment called Herceptin that is very effective for women whose tumors "over-express" a certain type of protein called "HER-2" protein, which can be identified through a genetic test. 25% of women with breast cancer have this form. As a result, for these women, Herceptin dramatically improves their odds of survival and reduces the chances of disease recurrence. For other women, this specific drug does not have a beneficial effect; therefore their doctors can recommend different treatment regimens instead.
- B. Physicians now can use a genetic test to help them determine the right dose of the blood thinner Warfarin, which is used to prevent strokes and heart attacks, for each of their patients. Doctors can determine if the patient metabolizes the drug more quickly or slowly than average. People who metabolize it more quickly eliminate the drug from their body before it has a chance to work, and therefore require a higher dose. People who metabolize it more slowly build the drug up in their bloodstream, leading to an over-dose. It is important to get the right dose of this drug for each patient to avoid complications from too low a dose (like blood clotting) and too high a dose (like internal bleeding).
- C. There is a multi-gene test available that allows heart transplant patients to know if they are at risk of organ rejection. This test requires only a blood draw as compared with heart biopsy, which is an invasive, procedure that carries significant health risks. Knowing their risk of organ rejection can help patients and their doctors best manage their health, resulting in improvement to the quality of their lives.
- D. A new genetic test can determine whether women with certain types of breast cancer are more likely to have the disease recur after treatment, which helps the doctor determine whether the patient would benefit from chemotherapy to prevent the cancer from reappearing. A patient determined to be at low risk might choose to be treated with other medicines, thereby avoiding the side effects of chemotherapy. Patients with a high risk of recurrence, on the other hand, might choose to be treated with chemotherapy because the probability of benefit would be greater.

# Key Value Messages

## *Messages about personalized medicine*

### **Better Prevention and More Control Over Your Health**

As scientists learn which genetic patterns are associated with certain diseases, people will be able to have more control over their own prevention and treatment choices for specific diseases. They will be able to take preventive action sooner, monitor for potential dangers, and may be more able to detect diseases earlier.

### **Avoiding Trial and Error Medicine**

Every person is different and medicines work differently in every person. As a result, doctors and patients often must try numerous treatment options before finding the right treatment at the right dose. Personalized medicine could reduce the amount of trial-and-error and get the right treatment to patients more quickly.

### **Reducing Adverse Effects**

Every medicine has risks. Many adverse drug reactions are the result of variations in genes. Personalized medicine can help doctors assess which patients have the genetic variations associated with certain side effects and make it possible to avoid these reactions.

### **Reducing Healthcare Costs**

Personalized medicine can help manage healthcare costs in the long run. By increasing the likelihood that patients receive the most effective treatment from the beginning, it will lead to better health outcomes and prevent the need for future care. Personalized medicines often treat a smaller, specific group of patients more effectively. Although the cost of developing a personalized medicine may be more costly than the development of other drugs, their greater effectiveness means they will be a better value in the long run.

### **Personalized Medicine Today**

In just the last two years several exciting new personalized medicines and diagnostics have been approved. For example, the first medicine to target the underlying causes of cystic fibrosis became available in 2012. The drug helps the 4% of cystic fibrosis patients who have a rare genetic mutation. Another new medicine treats a subset of patients with a dangerous form of skin cancer that expresses a specific genetic mutation.

### **The Future of Personalized Medicine**

We are entering a new era of personalized medicine. Researchers around the country are focused on advancing this new approach. In fact, a survey of biopharmaceutical companies found that up to 50% of drugs in the pipeline are targeted. Personalized medicine has the promise to transform health care in unprecedented ways.

# Approaches to Coverage Decisions

*Ways health insurance companies could make decisions about covering personalized medicine*

1. Health insurance companies should set a cost-effectiveness standard to use in deciding whether expensive new personalized medicines and diagnostics are worth the cost and should be covered.
2. Health insurance companies should decide which treatments are similar in cost and outcome, and pay only for the least expensive option.
3. Health insurance companies should provide tools and current information on studies and genetic test results to help doctors and clinicians tailor care to the needs of individual patients, but ultimately health insurance companies should cover what the doctor and patient decide is best.
4. Health insurance companies should cover the costs of more complex diagnostics, like those used to test for multiple genetic variations, as soon as they are available to doctors, and over time gather more research on them.

# Reasons to Cover

## *Reasons to cover personalized medicine*

1. As the science of personalized medicine advances, we are continually identifying newer, better approaches to disease prevention and patient care. But insurers' policies on which treatments and tests they will cover often don't keep up with this change. Health insurance companies must ensure their policies keep pace with rapid changes in medical care.
2. Current approaches to coverage rely on what works for the average patient. Personalized medicine shows how every patient is different, and is leading to new tools that will give doctors and patients the ability to tailor care to meet individual needs. As personalized medicine develops, coverage policy must be reformed to give physicians and patients more flexibility to tailor care.
3. When people talk about controlling cost, it isn't usually from the patient's perspective. Assessments of a treatment's value need to focus on what matters to patients, and should help doctors deliver care that patients' value.
4. As new research is performed, the role and value of personalized medicines continually changes. One treatment for leukemia, for example, was approved based on a reduction of cancer cells. Six years later, research showed that it was virtually a cure for a subset of patients. Insurance companies will deny patients access to valuable tests and treatment options if they set the bar too high for new medical technologies.
5. Health information technology is giving doctors new tools for rapid, ongoing learning about what works best for different patients. Instead of making "yes/no" coverage decisions for new tests and treatments, we should encourage doctors to use these tools to continuously learn how best to tailor care for patients.
6. If insurance companies do not cover personalized tests and treatments, companies that develop personalized tests and treatments will pull back their investment and this will stunt the promise of finding breakthroughs and developing new treatments.

# Questions?

*We're here to help*

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