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Redirecting Innovation in U.S. Health Care: Options to Decrease Spending and Increase Value

Interview Protocols

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RAND Health

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Project Description Used in Soliciting Interviews

Medical Technology Development: Creating a Roadmap to Achieve Better Value for the United States

RAND Health, June 2013

Among the most important challenges facing the United States is limiting the growth of spending on health care while improving population health. New medical technology—drugs, biologics, devices, diagnostic tools, and health information technology—can be viewed as both a source of the problem and as a potential solution. Some medical technologies offer dramatic improvements to health compared with available alternatives, while others provide little, if any, improvement. To make matters worse, spending increases often bear little relationship to the benefits of a new technology.

RAND Health, a research unit of the nonprofit RAND Corporation, is studying the development and adoption of new medical technologies and how these processes affect the health and spending consequences of medical-product innovation. The goal of the study is to identify public policies that could slow the growth of spending on health care—or even reduce health care spending per capita—while preserving or improving the health benefits of new technology. The policy challenges are identifying and implementing policies that will encourage development and adoption of technologies that will enhance aggregate value—namely, health benefits per dollar spent—and discourage development and adoption of technologies that will undermine value.

To assess candidate policies, RAND is developing a framework for predicting effects of promising policy options on the value of new medical technologies. This framework will highlight the key factors influencing medical-product innovation and how they affect value in the U.S. health care system. Our review will consider major aspects of the health care system that potentially influence innovation, including regulation, coverage and payment policies, utilization management, and the behavior of clinicians and facility managers. The framework will be based on information gathered through literature review and one-on-one interviews with highly knowledgeable individuals, including experts on health policy, health care industries, medical technology development, health care payers and insurers, and venture capital. The information we gather will pertain to key processes generally and how they have played out in the cases of eight specific medical technologies.

Our findings will be peer-reviewed, published, widely discussed in a public forum, and made available to all.

Interview Protocol: Broad Questions for Technology Development and Policy Experts

Numerous studies have pointed to the rapid adoption and diffusion of very expensive health care technologies as a major driver of the growth of health care spending in the United States. However, in some instances, we've seen the development of technologies that have substantially lowered health care spending by producing substantial benefits at a relatively modest price or profoundly changing the course of disease. The goal of this project is to identify policy levers that might encourage America's most innovative inventors and medical product developers to focus their efforts on creating high-value technologies. The purpose of this interview is to get your expert perspective on these important issues.

The research is being funded by a major philanthropic foundation. Our findings will be peer-reviewed, published, and made available to all.

RAND will use the information you provide for research purposes only. Your participation is completely voluntary. If you are uncomfortable responding to any question or discussing any topic, just say so, and we'll move on.

What you tell us will be kept confidential. RAND staff will be taking notes during the interview, but only summary information will be included in our final report. We will not identify you by name or affiliation without your permission. We will not share your responses with anyone outside the project team except as required by law.

Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

Examples (to get the speaker thinking)

1. In your opinion, what are one or two examples of innovative drugs, devices, diagnostics, or health IT that have generated *large health benefits per dollar spent* in the United States, while lowering overall health care spending? Why, in your opinion, do developers try to develop such products?
2. Conversely, can you identify one or two examples of innovations that have rapidly penetrated the U.S. marketplace but have produced, at best, only *small benefits*, but led to *very large spending*? Why, in your opinion, do developers try to create such products?

Current Incentives and Barriers to High-Value Innovation

3. Thinking for a moment about the *latter group*—drugs, diagnostics, devices, or health IT that substantially increased spending while producing only small benefits, what aspects of current policy *incentivize* inventors and developers to create and market such products?
4. Thinking now about the *former group*—health care technologies that produced substantial health benefits for individuals, or the U.S. population at large, while lowering overall spending, what aspects of current policy *deter or discourage* inventors and developers from creating such products and bringing them to market?

Future Options

5. Now for the most important question, and the goal of our project. In your view, what *policy options should be considered to encourage inventors and developers to create products* that improve health and would substantially lower spending in our health care system?
6. If incentives *were* altered through such policy options, are there specific, potentially game-changing technologies (in terms of providing substantial health benefits with limited or no increase in spending in our health care system) that you'd like developers to focus on?
7. Which of these options, if any, are *politically feasible* over the next three to five years? Why?
8. Why are the other options *less politically feasible*? Who would oppose them, and why?
9. What else *can or should be done* to encourage innovators to focus their efforts on creating *health care technologies* that can produce better health at lower cost?
10. Optional question: What will *have to change* for less-feasible options to become more politically viable in the years to come?

Coverage Policy Expert Interview Protocol

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Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

Coverage Policy Motivation

1. Under what circumstances [does your company/do payers] formally review a new *drug* for coverage? At whose request does such a review typically take place? Under what circumstances [does your company/do payers] decline to conduct such a review?

Begin unprompted, then if not mentioned, probe on:

PI: To what extent [does your company/do payers] follow the lead of competitors and/or other payers in making coverage decisions?

Follow up: Does the coverage review process differ substantially for expensive medical devices and associated procedures?

2. How are the amounts insurers pay for drugs and devices determined? How does this process relate to the coverage review process that we just discussed?
3. How often and under what circumstances do you **re-evaluate** coverage for a drug? [Examples: *New clinical or comparative effectiveness research, new or improved alternative technology, new indications or dosage forms, generic entry, fixed review periods, coverage change by other payers.*]

Follow up: Does coverage re-evaluation differ substantially for medical devices and associated procedures from that for drugs?

4. In general, what factors most influence coverage decisions?

Begin unprompted, then if not mentioned, probe on:

P1: Medical benefit

P2: Costs

P3: Balance of costs and benefits

P4: Availability of substitutes

P5: Do these factors differ significantly among drugs, devices, and procedures?

5. In general, what factors most influence payment amounts?

P1: Do these factors differ significantly among drugs, devices, and procedures?

6. How often and under what circumstances are health technology assessments (HTAs) of drugs, devices, and/or associated procedures used to inform coverage and/or payment decisions by [your company/payers]?

Follow up: When HTAs are considered, what are the sources of the HTAs?

Begin unprompted, then if not mentioned, probe on:

P1: In-house

P2: Government entities, such as AHRQ

P3: Other organizations, such as Blue Cross, Blue Shield TEC, or ECRI

Coverage and Payment Policy Implementation: Overview of Utilization Management

7. [Does your company/Do payers] manage utilization of some drugs or devices to match them with specific patient groups or clinical conditions?
 - a. If yes, what are the most important reasons for doing this?

Begin unprompted, then if not mentioned, probe on:

P1: Quality of care

P2: Costs

Follow-up 1: What are the major differences in utilization management between drugs and devices?

Follow-up 2: For drugs, does your answer apply to both self-administered and physician-administered drugs?

Follow-up 3: For devices, does your answer apply to utilization management of both implantable devices and expensive equipment?

Follow-up 4: Has drug or device utilization management changed recently in important ways? Are there any major, ongoing trends?

8. Which two or three tools at [your/payers'] disposal are the most effective to matching the right **drugs** to the right patients?

Follow up: Are these tools different for medical devices and associated procedures? If so, how?

Coverage and Payment Policy Implementation: Off-Label Use

I'd like to turn now to some questions about off-label use.

9. Do [your/payers'] coverage policies allow coverage for off-label use of any kind? If so, for what kinds of drugs or devices and under what circumstances?
10. What are the major challenges in enforcing limitations on payment for off-label use?

Coverage and Payment Policy Implementation: Interactions with Manufacturers

I'd like to turn now to some questions about your interactions with drug and device manufacturers.

11. Tell us about [your/payers'] interactions with *drug* manufacturers. In what ways do they try to influence coverage and payment decisions? Under what circumstances do they succeed in influencing these decisions?
12. Tell us about [your/payers'] interactions with *device* manufacturers. In what ways do they try to influence coverage and payment decisions? Under what circumstances do they succeed in influencing these decisions?

Coverage and Payment Policy Implementation: Wrap-Up

13. What are the major challenges you face in setting and implementing coverage and payment policies that promote the utilization of drugs and devices that are likely to provide sufficiently large patient health benefits for the dollars spent?

Begin unprompted, then if not mentioned, probe on:

P1: Are the challenges different from drugs and devices?

P2: Are the challenges different for generalist physicians versus specialists?

P3: For drugs, are the challenges different for self-administered and physician-administered drugs?

P4: For devices, are the challenges different for implanted devices and expensive equipment?

14. Is there anything else that I should have asked you about regarding coverage and payment?

Thank you very much for your time.

Device Developer Interview Protocol

RAND Health, a unit of the nonprofit RAND Corporation, is conducting research on the development and adoption of new medical technologies and how these processes affect the health and spending consequences of medical-product innovation. The goal of the study is to identify policies that could slow the growth of spending on health care—or even reduce health care spending per capita—while preserving or improving the health benefits of new technology. The research is being funded by a major philanthropic foundation. Our findings will be peer-reviewed, published, and made available to all.

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If you are uncomfortable responding to any question or discussing any topic, just say so, and we'll move on.

Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

1. Thinking about [your company's/a device company's] R&D expenditures, how are those expenditures allocated across the following activities;
 - a. Efforts to develop new devices?
 - b. Efforts to improve [your/their] existing devices?
 - c. Other activities, such as basic science?
2. Starting from the time when an effort to develop a new implantable device (such as a coronary stent) commences, about how many years can it take for that device to become available for use in the U.S.?

Follow-up 1: Does this timeline differ substantially for expensive medical equipment (such as imaging machines)?

Follow-up 2: What about diagnostic tests (such as PSA tests)?

3. What are the two or three most important factors that influence how [your company/device companies] target(s) investments to develop implantable devices, expensive medical equipment, and diagnostic tests?

Begin unprompted, then if not mentioned, probe on:

P1: Medical need

P2: Implications for health care spending

P3: Tax, patent, or other policy incentives

Follow-up 1: Are there substantial differences among implanted devices, expensive equipment, and diagnostic tests?

Follow-up 2: Are there substantial differences between devices primarily used by specialist versus generalist physicians?

4. What are the two or three most common reasons that efforts to develop devices are abandoned?

Follow-up 1: At what stages of the development process are go/no-go decisions typically made?

Follow-up 2: Are there substantial differences among implanted devices, expensive equipment, and diagnostic tests?

Follow-up 3: Are there substantial differences between devices primarily used by specialist versus generalist physicians?

5. Are there fairly common financial criteria or rules of thumb that investors (e.g., venture capitalists) use to decide whether to support a start-up device developer?

Follow-up 1: What do investors see as the two or three most important market or policy factors influencing whether a particular product might satisfy those criteria?

6. For devices that are likely to be marketed in the U.S., how important is sales potential in foreign markets in providing incentives for product development?

7. How often do device developers or manufacturers conduct comparative effectiveness or cost-effectiveness studies?

Follow-up 1: What are the advantages and disadvantages to companies of conducting such studies prior to FDA approval? After FDA approval?

8. At what point in the innovation process [does your company/do device companies] begin to analyze the coverage and payment environment in which a new device will be launched?

Follow-up: What are the major issues that are analyzed, and how does that influence [your/their] development decisions?

9. Besides profits, what do device companies consider in pricing?

10. What one or two policy changes during the last decade have had the most significant influence on the incentives and behavior of device developers?

P1: How did these influence incentives or behavior?

11. What changes in public policy do you think would be most helpful in influencing device companies to focus more heavily on developing products for common diseases that might provide much larger health benefits for patients than currently available therapies?
12. Is there anything else that I should have asked you about device development?

Thank you very much for your time.

Drug Developer Interview Protocol

RAND Health, a unit of the nonprofit RAND Corporation, is conducting research on the development and adoption of new medical technologies and how these processes affect the health and spending consequences of medical-product innovation. The goal of the study is to identify policies that could slow the growth of spending on health care—or even reduce health care spending per capita—while preserving or improving the health benefits of new technology. The research is being funded by a major philanthropic foundation. Our findings will be peer-reviewed, published, and made available to all.

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If you are uncomfortable responding to any question or discussing any topic, just say so, and we'll move on.

Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

1. Thinking about [your company's/drug companies'] R&D expenditures, how are those expenditures allocated across the following activities:
 - a. Efforts to discover new drug candidates?
 - b. Development of candidates into FDA-approved drugs?
 - c. Modifying or expanding use of existing drugs?
 - d. Other activities, such as basic science?

2. What are the two or three most important factors that influence how [your company/drug companies] target(s) investments to discover of new drugs?
Begin unprompted, then if not mentioned, probe on:
P1: Medical need
P2: Implications for health care spending
P3: Tax, patent, exclusivity, or other policy incentives

Follow-up 1: Are there substantial differences between small molecule drugs and biologics?

Follow-up 2: Are there substantial differences between drugs that are typically prescribed by specialist versus generalist physicians?

3. What are the two or three most common reasons that efforts to develop new drugs are abandoned?

Follow-up 1: At what stage(s) in the innovation process are go/no-go decisions typically made?

Follow-up 2: Are there substantial differences between small molecule drugs and biologics?

Follow-up 3: Are there substantial differences between drugs that are typically prescribed by specialist versus generalist physicians?

4. For drugs that are likely to be marketed in the U.S., how important is sales potential in foreign markets in providing incentives to invest in R&D?

5. How often do drug developers or manufacturers conduct comparative effectiveness or cost-effectiveness studies?

Follow-up 1: What are the advantages and disadvantages to companies of conducting such studies prior to FDA approval? After FDA approval?

6. At what point in the innovation process [does your company/do drug companies] begin to analyze the coverage and payment environment in which a new drug will be launched?

Follow-up 1: What are the major issues that are analyzed, and how does that influence [your/their] development decisions?

7. Besides profits, what do drug companies consider in pricing?

8. What one or two policy changes during the last decade have had the most significant influence on the incentives and behavior of drug developers?

PI: How did these influence incentives or behavior?

9. What changes in public policy do you think would be most helpful in influencing drug companies to focus more heavily on developing products for common diseases that might provide much larger health benefits for patients than currently available therapies?

10. Is there anything else that I should have asked you about drug development?

Thank you very much for your time.

Health Information Technology Developer Interview Protocol

RAND Health, a unit of the nonprofit RAND Corporation, is conducting research on the development and adoption of new medical technologies and how these processes affect the health and spending consequences of medical-product innovation. The goal of the study is to identify policies that could slow the growth of spending on health care—or even reduce health care spending per capita—while preserving or improving the health benefits of new technology. The research is being funded by a major philanthropic foundation. Our findings will be peer-reviewed, published, and made available to all.

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If you are uncomfortable responding to any question or discussing any topic, just say so, and we'll move on.

Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

1. Thinking about [your company's/a health IT company's] R&D expenditures, how are those expenditures allocated across HIT targeting different end users:
 - a. Patients
 - b. Providers
 - c. Other
2. What are the two or three most important factors that influence how [your company/HIT companies] target(s) investments to develop HIT?
Begin unprompted, then if not mentioned, probe on:
P1: Medical need
P2: Implications for health care spending
P3: Tax, patent, or other policy incentives
P4: Potential customers/ revenue options
P5: Access to data or data networks

Follow-up 1: Are technologies focusing on particular groups of end users more or less attractive?

Follow-up 2: Are technologies focused on particular payers or revenue strategies more or less attractive?

3. What are the two or three most common reasons that efforts to develop new HIT products are abandoned?

Follow-up 1: At what stages of the development process are go/no-go decisions typically made?

4. Are there fairly common financial criteria or rules of thumb that investors (e.g., venture capitalists) use to decide whether to support a start-up HIT developer?

Follow-up 1: What do investors see as the two or three most important commercial or policy factors influencing whether a particular product might satisfy those criteria?

5. For what types of HIT is FDA approval an issue for developers?

6. How often do HIT developers conduct comparative effectiveness or cost-effectiveness studies?

Follow-up 1: To what extent is this information used by potential payers?

7. At what point in the innovation process [does your company/do HIT companies] begin to analyze the commercial environment in which a new product will be launched?

Follow-up: What are the major issues that are analyzed, and how does that influence [your/their] development decisions?

8. What are the key factors that drive pricing decisions and (more generally) revenue generation strategies for HIT companies?

Follow-up: To what extent do these factors either promote or deter the development of technologies that could reduce costs to the health care system or improve outcomes?

9. What are the key factors that influence end user adoption of a new HIT?

- a. Patients
- b. Providers
- c. Other

10. What one or two policy changes during the last decade have had the most significant influence on the incentives and behavior of HIT developers?

P1: How did these influence incentives or behavior?

11. What changes in public policy do you think would be most helpful in influencing HIT companies to focus more heavily on developing products that might provide significant health benefits for patients per dollar of spending?

12. Where do you see the greatest opportunities for HIT to advance value and improve outcomes and lower costs for the U.S. health care system?
13. Is there anything else that I should have asked you about HIT development?

Thank you very much for your time.

Investor in Innovative Health Technologies Interview Protocol

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Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

1. Thinking about [your company's/your organization's] investments in health care–related companies, how are those investments allocated across the following activities;
 - a. Efforts to develop new devices?
 - b. Efforts to improve existing devices?
 - c. Efforts to develop new drugs?
 - d. Efforts to improve existing drugs?
 - e. Efforts to develop HIT?
 - f. Other activities, such as basic science?
2. The time frame between initial development efforts and market launch can vary dramatically across potential investments. How do these differences influence your investment strategies?

Begin unprompted, then if not mentioned, probe on:

P1: The stage at which you are willing to make an initial investment

P2: The relative sizes of investment at different stages

P3 (if applicable): Differences across categories—drugs, devices, HIT

3. What are the two or three most important factors that influence how [your company/your organization] allocates investments to particular technologies and stages of investment?

Begin unprompted, then if not mentioned, probe on:

P1: Medical need

P2: Implications for health care spending

P3: Tax, patent, or other policy incentives

P4: Product's market potential

P5: Characteristics of the developing company or the developer

P6: Existence of multiple exit options for the investor

Follow-up 1 (if applicable): Are there substantial differences in those driving factors among drugs, devices, and HIT?

4. How does the product's future regulatory environment (and uncertainty about it) factor into your investment decisions?
5. How does the product's future market environment (and uncertainty about it) into your investment decisions?

Follow-up 1: What aspects of the future market environment are most important?

Begin unprompted, then if not mentioned, probe on:

P1: Coverage and payment expectations

P2: Sales potential in foreign markets

6. What are the two or three most common reasons that you abandon investments or that investments do not succeed?

Follow-up 1: Are investments made at particular stages or in particular market segments more risky or susceptible to failure than others?

Follow-up 2: At what stage of the development or commercialization does an acknowledgement of failure most typically occur?

7. What role, if any, do investors play in the pricing or other market-related decisions?
8. What one or two policy changes during the last decade have had the most significant influence on the types of companies you are willing to invest in?
P1: How did these influence incentives or behavior?
9. What changes in public policy do you think would be most helpful in influencing innovative health care companies to focus more heavily on developing products that

might provide much larger health benefits for patients or lead to substantial reductions in overall health expenditures?

10. Is there anything else that I should have asked you about investments in health care companies?

Thank you very much for your time.

Provider Interview Protocol

RAND Health, a unit of the nonprofit RAND Corporation, is conducting research on the development and adoption of new medical technologies and how these processes affect the health and spending consequences of medical-product innovation. The goal of the study is to identify policies that could slow the growth of spending on health care—or even reduce health care spending per capita—while preserving or improving the health benefits of new technology. The research is being funded by a major philanthropic foundation. Our findings will be peer-reviewed, published, and made available to all.

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If you are uncomfortable responding to any question or discussing any topic, just say so, and we'll move on.

Do you have any questions about the study or our confidentiality procedures?

Do you agree to participate in the interview?

1. To what extent [does your organization/do you/do providers] consider cost when deciding whether to:
 - a. Use a new drug
 - b. Use a particular implantable device
 - c. Purchase expensive medical equipment?
[If asked for clarification on “expensive,” clarify meaning as tens of thousands of dollars or more; could also suggest an example such as imaging equipment.]
 - d. Invest in health information technology?
*Begin unprompted, then if not mentioned, probe on:
P1: In answering this question, were you thinking about cost to patients or to payers or to providers or to the health system?*

Follow-up: Does your answer differ substantially for drugs, implantable devices, medical equipment, and health IT?

2. What information [does your organization/do facilities] use in deciding whether to purchase expensive equipment?
3. What information [does your organization/do you/do providers] use to inform their decisions about which drug to prescribe for or administer to a particular patient?
4. What information [does your organization/do you/do providers] use to inform their decisions about whether to use a particular implantable device for a particular patient?
5. What information [does your organization/do you/do providers] use to inform their decisions about whether to invest in health information technology?
 - a. What role do payer policies play in these decisions?
- 6a. To what extent do hospitals influence utilization decisions of admitting physicians about implantable and disposable devices that hospitals purchase for their use?

Follow-up: What about drug utilization?
- 6b. For employed physicians, to what extent do employers influence physicians' device utilization decisions?

Follow-up: What about drug utilization?
7. To what extent does a patient's insurance coverage influence clinical decisions regarding:
 - a. Use of a particular drug
 - b. Use of a particular implantable device
 - c. Use of expensive medical equipment

Follow-up: If insurance coverage does affect clinical decisions, does this influence typically result in better outcomes? Less spending?
8. Tell us about providers' interactions with drug manufacturers. In what ways do manufacturers try to influence coverage and payment decisions—directly and/or indirectly?
9. Tell us about providers' interactions with device manufacturers. In what ways do manufacturers try to influence utilization decisions—directly and/or indirectly?
10. Tell us about providers' interactions with developers of health information technology. In what ways do manufacturers try to influence adoption decisions—directly and/or indirectly?
11. What resources or incentives could aid hospitals, medical systems, and clinicians in making decisions that would lead to better outcomes and/or lower spending?
12. Is there anything that I should have asked you about regarding utilization of medical technologies?

Thank you very much for your time.