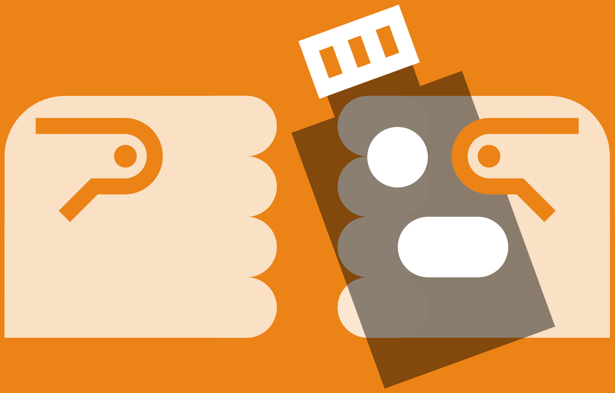

A Risky Business

Saving money and improving global health through better demand forecasts

The report of the
Center for Global Development
Global Health Forecasting Working Group

A Risky Business Saving money and improving global health through better demand forecasts Center for Global Development

Center for Global Development

Contents at a glance

1 Better demand forecasting saves lives 8

2 Risky business: who's on the line in the value chain for essential health products? 22

3 Recommendation 1: if you play in the market, take demand forecasting seriously 38

4 Recommendation 2: break boundaries and create a global health infomediary 48

5 Recommendation 3: share risks and align incentives for better forecasting 62

6 An agenda for stakeholders 68

Center for Global Development

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Advance praise for **A Risky Business: Saving money and improving global health through better demand forecasts**

"The ability to improve the forecasting of demand for medicines that are needed urgently is a critical key to building a strong and responsive health system. This Working Group has shown that we could make tremendous progress by taking specific steps, with our international partners. Now that the main analyses are complete, it is imperative that we move toward implementing the recommendations so that we will see sustained health benefits from new resources and new technologies."

Dr. Hetherwick Ntaba
former Minister of Health, Malawi

"There is an urgent need for development of new treatments for developing world diseases. Lack of new drugs has often been attributed to issues related to intellectual property and lack of financial incentives; however, the biggest disincentive to developing new drugs is the failure of making existing drugs matter. While there are many 'bottlenecks' that help explain the limited use of existing drugs in resource poor settings, none are bigger than those related to improving the capacity to develop credible forecasts. This complex area has received little attention and is poorly understood by most. If implemented, the recommendations made in the new report of the Global Health Forecasting Working Group of the Center for Global Development will go a long way to improve access to existing medicines and will lower the barriers to the development and delivery of new therapies."

Dr. Gail Cassell
Vice President for Scientific Affairs and
Distinguished Lilly Research Scholar for
Infectious Diseases, Eli Lilly and Company

"This report addresses the critical challenge of all donor agencies engaged in global health—how to improve our ability to forecast demand for essential medicines and diagnostics, with an aim of creating greater access to them in the poorest countries. We at USAID welcome this new and insightful analysis as a means to further healthy and fruitful dialogue about how to work together more effectively with all stakeholders and partners."

Dr. Kent Hill
Assistant Administrator, Bureau for Global Health,
U.S. Agency for International Development

"Scientific progress is critical to developing new technologies, but so, too, is the policy framework that facilitates science. Accurate, robust and dynamic demand forecasting is a key element of this framework that can help drive policy making, funding and research and development. The Center for Global Development and its Global Health Forecasting Working Group have done an outstanding job of conducting a thorough analysis of the present situation, identifying shortcomings and, perhaps most important, developing practical solutions—solutions that can lead to accelerated product development, improved supply chain management and more cost-effective donor aid. Technologies can only improve public health if they are available when and where they are needed, and CGD has again led the way in demonstrating just how policy analysis can help to save lives."

Mitchell Warren
Executive Director, AIDS Vaccine Advocacy Coalition

"Finally, this call for global action to address the bottlenecks in the supply chain of essential health products comes as a welcome relief to all stakeholders. The increased investments in global aid in developing countries has unfortunately not provided universal and sustainable access to required essential health products to control the major public health problems of AIDS, tuberculosis and malaria. This has been dramatically demonstrated by the escalation of drug resistance such as the recent emergence of extensively drug-resistant tuberculosis (XDR-TB) spawned by shortages of drugs. The recommended road map toward improving the demand forecasts essential to an efficient supply chain details the roles of all stakeholders in a true spirit of partnership that is urgently needed to maximize aid effectiveness and enhance the impact of Global Fund to Fight AIDS, Tuberculosis and Malaria and others. The stakes are much too high for the world to ignore. The time to act is now."

Dr. Thelma Tupasi
President, Tropical Disease Foundation

“Practical as a good recipe book, with the intensity and determination of a rallying cry and the thoroughness of a wining battle plan, this book’s suggestions seem so doable that many readers will be tempted to join the fight. After reading this book, one has the feeling that, by following its advice, the simple yet elusive goal of coordinating our efforts to attack disease in developing countries is within reach.”

Dr. Santiago Kraiselburd

Executive Director, Zaragoza Logistics Center

“Getting life-saving medicines to those who need them requires far more than money. Improving demand forecasting is an essential and urgent task as we strengthen the supply chain and the broader health system. This report, which takes a fresh look at the problem of demand forecasting, shows clearly how actions at the international level could genuinely facilitate improvements at the country level. I look forward to seeing the recommendations taken forward.”

Dr. Simon Mphuka

Executive Director, Churches Health
Association of Zambia

“The road to providing access to new vaccines, drugs and diagnostics to all who need them is a rocky one. Now, new sources of funding are paving the way as are advances in understanding of molecular immunology and mechanisms of disease. However, the need to improve demand forecasting remains a clear stumbling block. This book beautifully clears the path for credible forecasts, a means for sharing them and thus a reduction in risk for those of us who are struggling to bring the new technologies to the developing world.”

Dr. Una Ryan

President and Chief Executive Officer,
AVANT Immunotherapeutics, Inc.

“Accurate demand forecasts are the foundation of successful immunization efforts in poor countries: improvements in the current system will allow us to realize the full potential of the many new products that will soon be available. The Center for Global Development report drives home the true significance of this critical function and puts forth clear, practical solutions for how donors can come together with developing countries and private industry to effectively increase access to vaccines and other health technologies.”

Alice Albright

Chief Financial and Investment Officer, GAVI

“Ensuring an effective and responsive supply chain is essential to achieving widespread access to life-saving medicines across the developing world. The authors bring unique multidisciplinary experience and research to formulate practical solutions to this serious problem—a real demonstration of Scholarship in Action.”

Dr. Yossi Sheffi

Director, MIT Center for Transportation and Logistics

“The efforts of the Global Health Forecasting Working Group should be applauded for showing how better forecasting together with an understanding of market-related risks can impact patient morbidity and mortality and promote better health for everyone living in the developing world.”

Silvio Gabriel

Executive Vice President, Malaria
Initiatives, Novartis Pharma AG

“I hope all supply chain academics and practitioners take the problems described in this book seriously; it is our opportunity to make a real difference to one of the most important supply chain problems in the world today. This book has done an excellent job of documenting problems from the world of public health and showing how these problems can draw upon our vast experience managing similar problems in myriad supply chains. Appropriately, the book takes a close look at contracting arrangements and risk-sharing arrangements and demonstrates some ‘low-hanging fruit’ too. I hope this project continues to gather momentum and draw support appropriately; our children need this project!”

Dr. Ananth Raman

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Members of the Working Group were invited to join in a personal capacity and on a voluntary basis. The report of the Working Group reflects a consensus among the members listed above. This report does not necessarily represent the views of the organizations with which the Working Group members are affiliated, the Center for Global Development's funders or its Board of Directors.

Table of contents

Preface x
Acknowledgments xi

Executive summary 1

1 Better demand forecasting saves lives 8
Focus of the Global Health Forecasting Working Group 11
The new world of global health 12
Demand forecasting within the value chain 17
The critical and evolving role of demand forecasting 19

2 Risky business: who's on the line in the value chain for essential health products? 22
A way to look at the risks 24
Consequences of the risks 25
Those who bear the consequences cannot reduce the risks 26
What lopsided risks mean for forecasting 27
The artemisinin-based combination therapy supply chain 28

3 Recommendation 1: if you play in the market, take demand forecasting seriously 38
Distinguishing forecasting demand from stimulating demand 40
Applying basic principles of demand forecasting 41
Investing in technical forecasting capacity 43
Conclusion 46

4 Recommendation 2: break boundaries and create a global health infomediary 48
What information is needed and who has it? 50
The need for a global health infomediary 53
Implementation considerations for a global health infomediary 54
Conclusion 60

5 Recommendation 3: share risks and align incentives for better forecasting 62

Aligning incentives among stakeholders 64
Selecting from a wider menu of contracting options 64
Conclusion 66

6 An agenda for stakeholders 68

Toward implementation 70
Looking ahead: building a foundation for long-term access 72

Abbreviations 76
Glossary 77
Notes 78
References 80

Appendix A Profiles of Working Group members 83
Appendix B Individuals consulted 90
Appendix C Uncertainty and risk: using economic concepts to identify the role of forecasting 93
Appendix D Supply chains for developing country health products 99
Appendix E Forecasting principles 105
Appendix F Information sharing and gathering as a public good 113
Appendix G Supplier needs 123

Boxes

Box 1.1 Different approaches to procurement 16
Box 1.2 Who are the stakeholders? Examples from the HIV/AIDS market 18
Box 2.1 Contrasting supply chains in developed and developing country markets 35
Box 3.1 Examples of partnerships for training and research in forecasting 43
Box 3.2 Many ways to forecast 45
Box 4.1 How an infomediary helps take forecasting seriously 59
Box 5.1 Rolling-horizon forecast commitments 65
Box 5.2 Pooled procurement 67
Box 6.1 Future policy research agenda 75

Box E1 Coordination of demand forecasting at the country level 108
Box E2 The use of banding in immunization forecasts 109
Box E3 Demand forecasting in health programs 110
Box E4 International AIDS Vaccine Initiative: determining drivers 111
Box E5 Continual updating of data and assumptions 112

Figures

Figure 1.1 Funding for AIDS, tuberculosis and malaria 12
Figure 1.2 Technology traffic jam: the future vaccine pipeline 14
Figure 1.3 Demand forecasting along the value chain 20
Figure 2.1 Levels and sources of malaria funding 29
Figure 2.2 Projected stakeholder map of the supply chain for artemisinin-based combination therapies 30
Figure 3.1 From need to demand 41
Figure 3.2 Selection tree for forecasting methods 44
Figure 4.1 Approaching the information gap 51
Figure 4.2 Schematic of a global health infomediary 54
Figure 4.3 Spectrum of governance options for a global health infomediary 56
Figure 6.1 Recommendations at a glance 71
Figure 6.2 Push-pull boundary 73
Figure C1 Supply-demand relationship at equilibrium 95
Figure C2 Supply-demand relationship with shift in demand 95
Figure C3 Short-run and long-run supply 96
Figure C4 Supply and demand with uncertainty 96
Figure D1 Product supply chains in the United Kingdom and for developing countries 100
Figure D2 Commodity logistics system in Kenya 102
Figure E1 Forecasting accuracy and investment risk 110
Figure F1 Overall importance and performance of information categories 118
Figure F2 Information sharing in developed markets 121

Tables

Table 2.1 Risk allocation for artemisinin-based combination therapies 31
Table 2.2 Risk allocation for the U.S. pharmaceutical market 32
Table 2.3 Supply chain incentives for artemisinin-based combination therapies 34
Table 4.1 Incentives and benefits for stakeholders 57
Table 4.2 Preliminary institutional assessment and tradeoffs 58
Table C1 Incentives and benefits for stakeholders 97
Table F1 Information used most frequently by forecast developers 114
Table F2 Information sources, users and gaps 119
Table G1 Key supplier needs from the global health community 124

Preface

Access to medicines is an issue of life or death for millions of people in poor countries. Compared with a decade ago, huge amounts of new aid funding are available for drugs to treat AIDS and malaria, for vaccines previously unavailable in developing countries and for other essential medical supplies. The Global Fund to Fight AIDS, Tuberculosis and Malaria, the Global Alliance for Vaccines and Immunization and the U.S. President's Emergency Plan for AIDS Relief are only a few of many new funds that buy medicines and vaccines. In addition, Novartis, Merck and other pharmaceutical firms indirectly contribute through concessionary pricing of medicines destined for use in low-income countries.

But the global supply chain that connects the dots—production to people—does not work well. A key problem is poor forecasting of effective demand for products. Good forecasting is fundamental for critical decisions, such as how much production capacity to build, that must be made years in advance of products being delivered. But donors that provide much of the money to purchase drugs, and a whole range of technical agencies and intermediaries, have yet to devise and coordinate credible forecasts among themselves—or with developing country governments. The lack of a demand forecasting system undermines the best intentions of those working to make life-saving products widely available.

No one wins when forecasts are off: not the manufacturers, who may face the unhappy prospect of having to dispose of unsold drugs; not the donors or ministries of health, who face uncertain prices and availability of essential products; and certainly not the patients and their communities, who face the prospect of shortages, incomplete treatments and the emergence of drug resistance. If everyone is losing, a win-win solution seems possible.

Finding that win-win solution, based on a careful diagnosis of the problem, is just the sort of challenge that attracts the attention of Ruth Levine and her colleagues who work on global health policy at the Center for Global Development. In early 2006 Levine convened the Global Health Forecasting Working Group to sort out why demand forecasting has been so problematic—it's about who bears the risk when things go wrong—and to develop practical, forward-thinking options. The group focused on developing specific recommendations that apply across a range of products and that can be implemented by identifiable public and private organizations. Experts from donor agencies, the pharmaceutical industry and procurement and delivery organizations looked at how forecasting challenges are related to how donors give money, how manufacturers make decisions about R&D spending and installing manufacturing capacity, and how incentives affect the actions of all players, from in-country supply chain managers to pharmaceutical industry chief executive officers.

Among their "do it now" recommendations is the creation of an "infomediary"—a neutral third party to collect and disseminate essential data for forecasting demand. Industry players or interested foundations must take the leadership in creating such a coordination mechanism. Another recommendation is that donors who are the major purchasers should accept more of the risks associated with unforeseen shocks to actual demand—internalizing at least the shock that their own lack of predictable financing creates. This implies, for example, that for some products donors move to contracts with manufacturers that include minimum quantity (as well as price) guarantees.

This report provides an elegant analysis of the problem and a sensible agenda for action. If its recommendations are implemented, millions of families in developing countries will benefit—from reduced disease and deaths and the personal agony those entail. At the Center we will consider this report a success only when we see those actions being taken.

Nancy Birdsall
President
Center for Global Development

Acknowledgments

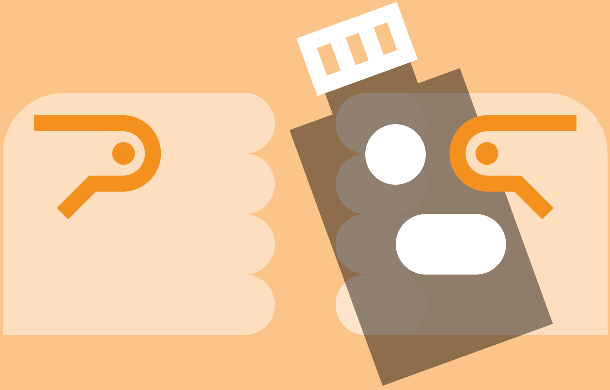
Many individuals contributed information, ideas and inspiration for this report. We thank, first, members of the Global Health Forecasting Working Group, who devoted many hours of their valuable time to thinking through the key constraints to good demand forecasting and to shaping a set of practical solutions to recommend. Throughout, all members excelled in balancing the interests they were closest to—be they those of the public-private partnerships, industry or funding agencies—with the imperative to develop solutions that work for all.

The content of the report draws heavily from a set of background papers that represent contributions to the field in their own right. Early on, Owen Barder shared insights about concepts of the influence of risk in decisionmaking. Daniella Ballou-Aares and Priya Mehta from Dalberg Global Development Advisors organized thinking and data about information needs and weaknesses in information sharing; Michelle Lee later built on that framework to identify specific publicly available data sources and analyze their strengths and weaknesses. Prashant Yadav and Kirsten Curtis of the Massachusetts Institute of Technology–Zaragoza International Logistics Program provided deep insights about the misalignment of incentives across players in the supply chain, drawing on broad knowledge of other sectors and new observations about the global health field. We further laude the generosity and leadership of Santiago Kraiselburd and others at the Zaragoza Logistics Center in moving the recommendations forward through the establishment of a scholarship for developing country nationals studying global health supply chain management—a very valuable immediate outcome of the Working Group's efforts. Presentations by Scott Armstrong of the University of Pennsylvania Wharton School and Yvette Madrid also helped to inform and enrich the group's deliberations.

Many, many experts in related fields provided in-person and written comments on earlier versions of this report. We are particularly grateful to Miloud Kaddar for organizing a briefing at the World Health Organization; Mark Rilling for convening a consultation among U.S. Agency for International Development staff and contractors; Michael Borowitz for including us in a U.K. Department for International Development workshop for developing country stakeholders; and Harvey Bale, Cinthya Ramirez and others at the International Federation of Pharmaceutical Manufacturers and Associations for organizing a side meeting of supplier representatives to provide input on industry needs. (See appendix B for a full list of individuals consulted.) Novartis was kind enough to lend us the use of their facilities for a Working Group meeting.

We would also like to thank Nancy Birdsall, Lawrence MacDonald and colleagues at the Center for Global Development for comments and critiques, and Aaron Pied for his cheerful assistance throughout the Working Group process.

Finally, we are grateful to Blair Sachs, Girindre Beeharry, Daniel Kress, Gargee Ghosh and others at the Bill & Melinda Gates Foundation for intellectual contributions during the course of this project, which was supported by a grant from the Foundation to the Center for Global Development for work on global health policy.



Executive summary

Today's global health programs will attain their objectives only if products appropriate to the health problems in low- and middle-income countries are developed, manufactured and made available when and where they are needed. Achieving this requires mobilizing public and charitable money for more and better products to diagnose, prevent and treat HIV/AIDS, tuberculosis, malaria, reproductive health problems and childhood killers. But more money is only one part of the story. Weak links in the global health value chain—from research and development (R&D) through service delivery—are constraining on-the-ground access to essential products. The consequences of those weak links are many: supply shortages, inefficient use of scarce funding, reluctance to invest in R&D for developing country needs and, most important, the loss of life among those who need essential products.

One of the weakest links—and one of the most vital for achieving both short- and long-term gains in global health—is the forecasting of demand for critical medical technologies, including vaccines, medicines and diagnostic products. Demand forecasting, which may seem at first glance to be a small piece of the very large puzzle of access to medical products, is of central importance. Many of the shortcomings in funding and functioning of health systems impede accurate forecasting of demand—and without the ability to forecast demand with reasonable certainty and some assurance of a viable market, manufacturers cannot scale production capacity, make commitments to suppliers of raw materials or justify a business case for investing in costly clinical trials and other activities to develop future products. National governments and international funders rely on demand forecasts for budgeting, while health programs and implementing agencies depend on forecasts to plan their supply chain logistics. Thus, in the high-level policy debates about the volume, duration and use of donor funds to support R&D and purchase essential health products, one key fact has often been overlooked: if actions by the international community do not increase the ability to generate credible forecasts of demand—if, in fact, those actions contribute to a situation of greater uncertainty, with higher stakes—efforts to achieve greater access to life-saving and life-extending medicines will be undermined.

The challenge is urgent. The past several years have seen an influx of new funds, new products, new suppliers and new organizations providing technical services in global health, making the flow of money and information far more complex than it was in the past. In the foreseeable future we will see more financial resources devoted to product procurement for AIDS, tuberculosis, malaria, vaccine-preventable diseases and other conditions as well as a significant number of new products licensed and available in the market. New resources will be devoted to R&D for products further upstream in the development process, such as a vaccine against HIV. While this rapid evolution represents a tremendous achievement, the ability of all the new funding, products and technical resources to achieve their full potential and to be sustained depends on far more serious and successful efforts to provide credible and accurate forecasts of demand to key players as a way to reduce risk and increase efficiencies. Moreover, it requires efforts to share the remaining risk in a way that encourages all parties—on both the supply and demand sides—to work together toward broad and equitable access to essential medical technologies.

The demand forecasting challenge

Aggregate demand forecasting is a lynchpin of supply, serving five critical functions in the market for global health products and the effective delivery of medicines and supplies; together, combined with the resources for R&D and procurement, these five functions add up to lives saved:

- *Essential products are available because there is enough supply to meet demand.* Demand forecasts allow manufacturers to plan and invest in manufacturing capacity, ensuring enough supply to meet demand and taking advantage of production efficiencies.
- *New products are developed because the picture of future markets is realistic.* Demand forecasts provide manufacturers information about new market potential, permitting them to efficiently allocate resources to develop, produce and commercialize new products that respond to developing country opportunities, thereby accelerating the pace of product availability.
- *Supply chain capacity is increased so products can get to people who need them.* Demand forecasts enable health systems in developing countries to plan expansion of their capacity to deliver products to more patients, matched to the scale and mix of products required.

- *Funders plan purchases and make the most of the money available.* Demand forecasts allow donors and national governments to efficiently allocate their resources by fostering appropriate prices and adequate supplies of products.
- *The public health community sees bottlenecks and understands opportunities to expand use.* Demand forecasts highlight key demand- and supply-side constraints and can guide policy and advocacy efforts to reduce those constraints and achieve broader access; this can even include influencing the characteristics of future products to respond to potential demand.

The heart of the matter: misaligned incentives

Better forecasting would benefit many stakeholders. So why hasn't forecasting been improved? Part of the explanation is that the major changes in funding, products and other factors are recent, but improvements in forecasting methods and institutional roles have not yet caught up. The rest lies in the fact that risks in the current market are unequally distributed across key actors whose decisions affect supply of and demand for products. Patients, who directly suffer the consequences of the risks, are not in a position to reduce them, and the consequences are felt only indirectly by the funders and intermediaries who could take specific actions to reduce the underlying budgetary, policy-related and logistics risks. The vast majority of the financial risk is borne by developers and manufacturers of products.

The result: not all stakeholders have incentives aligned toward better forecasts and greater access to critical medical technologies. Moreover, because of the limited market potential in developing countries, the private sector invests little in market research and other sources of information that are common in developed country markets. Understanding and correcting the misaligned incentives are core challenges that the recommendations below address. If not dealt with, the misalignment of incentives will continue to constitute a major barrier to equitable and sustainable access to essential medicines.

Global solutions

Improvements in demand forecasting require better sharing of risk and aligning incentives among the actors who influence market dynamics. This can be achieved by three mutually reinforcing actions:

- Improving the capacity to develop credible forecasts by taking forecasting seriously.
- Mobilizing and sharing information in a coordinated way through the establishment of an "infomediary."
- Sharing risks and aligning incentives through a broader range of contractual arrangements.

Implementing these recommendations will greatly enhance the relationship among funders, suppliers, intermediaries and users of health products and go a significant distance toward achieving the alignment across participants in the global health value chain that is essential for long-term improvements in access to quality products. Far from being small technical patches, these recommendations would help the global health supply chain function more efficiently, allowing the new funds and products to realize their potential in better health outcomes in developing countries.

The recommendations are mutually reinforcing. Armed with better information from a credible infomediary and the adoption of key principles of forecasting, funders will be able to assume more of the risk currently borne by suppliers, allowing for a greater return on donor spending in the form of improved public health outcomes. Efficient contracting arrangements, in turn, will create the incentives to improve the forecasting process itself, creating a virtuous cycle. Fully implemented, these recommendations can save lives by dramatically improving aggregate demand forecasts for critical medical technologies at the global level.[1]

Taking forecasting seriously

Demand forecasting must become imbedded in all global efforts to increase access to essential medicines and technologies. This requires:

- A clear understanding of what is meant by "demand forecasting" and how it differs from estimating needs and from advocacy and demand creation activities.
- Universal adoption of basic principles for good forecasting to increase market understanding and credibility, better understand and mitigate systemwide risk, and increase value for money.
- Investing in technical forecasting capacity and creating models specific to forecasting for developing country health products.

The Working Group recommends 10 basic principles in three categories:

- *Customer-focused principles* ensure that forecasts will meet the needs of customers and have the greatest impact on the decisions they are intended to inform.
    1. Identify the principal customers or decisionmakers of the forecast and clearly understand their needs.
    2. Understand and clearly communicate the purpose of the forecast and the decisions that it will affect.
    3. Create a forecasting process that is independent of planning and target setting.
    4. Protect the forecasting process from political interference and ensure it is transparent.
- *Process- and context-focused principles* create a credible forecasting process and help develop, present and explain the forecast in relation to the overall market and public policy environment.
    5. Embed the forecast into the broader environment taking into account market conditions, public policy, competitive forces, regulatory changes, health program guidelines and the like.
    6. Create a dynamic forecasting process that continually incorporates and reflects changes in the market, public policy and health program capabilities.
- *Methodology- and data-focused principles* select the right methods for the nature of the forecast being developed and effectively incorporate qualitative and quantitative information.
    7. Choose the methodologies most appropriate to the data and market environment and obtain customers' and decisionmakers' agreement on the methodologies.
    8. Keep the methodologies simple and appropriate to the situation, but include enough detail to address the level of investment risk and accuracy required.
    9. Make forecast assumptions clear and explicit.
    10. Understand data and their limitations, using creativity and intelligence in gathering and introducing data into forecasts.

Create a global health infomediary

Up-to-date, credible and comprehensive information is essential to good forecasting, but requires that key organizations and individuals collect and share high-quality data. Currently, funding agencies, procurement agents, technical agencies, product development and other global health partnerships and national buyers each have access to several important data elements but do not systematically share them with others in the value chain—or invest enough in the focused market research required to build the most accurate forecasts possible.

The shortcomings in the systems to collect, share and assure data quality are clear. In large measure they can be traced to the current allocation of risk in the market for critical medical technologies. On the demand side for funders, technical agencies, procurement agents, global health partnerships and in-country supply chain managers, all of which have critical data elements, there are few if any consequences for poor forecasting; thus, there is no incentive to share information or to ensure its quality. On the supply side manufacturers may directly bear a financial risk for inadequate forecasting, particularly for excess capacity, but they have a disincentive to share individually identified supply information that could make them vulnerable to competitors or to antitrust allegations.

The resulting opacity of data increases both demand uncertainty and its associated risks. This suggests the need for an information intermediary, or infomediary, for global health to effectively gather and analyze data to forecast demand across a variety of diseases and products and to make information available to all stakeholders.

The key functions of the infomediary would be to:

- Serve as central repository of all relevant demand and supply data by collecting, synthesizing and disseminating information related to forecasting that individual organizations may not be willing or able to share independently.
- Ensure data integrity and perform the labor-intensive tasks of cleaning and analyzing data received from multiple sources.
- Establish a mechanism for ongoing, continual gathering and updating of core forecasting information.
- Generate transparent baseline aggregate forecasts by product category based on the information sets provided to serve as the common starting point for stakeholders to produce their own forecasts, and build aggregate and country-level models for generating demand forecasts that consider the unique developing country environment.

- Incorporate information from specific market research studies that are conducted by the infomediary or other market research firms and stakeholders to provide a more complete data repository and refine assumptions for forecasts.
- Serve as a neutral party responsible only for collecting information and generating baseline forecasts and remain uninvolved in demand generation, advocacy, target setting or other functions that could compromise the integrity and independence of activities, while maintaining strong relationships with public and private supply chain partners and establishing credibility with stakeholders.

Sharing risk and aligning incentives through a broader menu of contracting options

While not all of the misalignments in incentives across key players can be corrected in the short term—and some are a structural feature of donor funding that is divorced from accountability to beneficiary communities—an important and immediate opportunity exists to better align incentives and share risks by restructuring contractual arrangements. Effective contracting is also critical for ensuring that pooled purchasing mechanisms, which are being considered by many funders, achieve their objectives. However, global health funders in general have made only limited use of the wide range of risk-sharing arrangements, such as minimum purchase commitments, quantity flexibility contracts, buyback contracts, revenue sharing and real options.

No single contracting option is optimal across all types of products and situations. Rather, a range of approaches could and should be considered to shift the current risk allocation in which funders, procurement agents and national buyers accept little or no risk, while suppliers gear their decisions about pricing and investments in capacity to a market in which they face significant, unshared risk.

Toward implementation

Achieving better demand forecasts for—and better access to—critical medical technologies in developing countries requires collaboration and investment from all the key stakeholders in the value chain for these products and will benefit each of them in turn. While the broader global health community plays a critical role in advocating for taking forecasting seriously, coordinating information and sharing risk, success ultimately depends on the actions of donors, industry national health programs and those charged with generating aggregate demand forecasts.

Donors and funding agencies

Donors and funding agencies such as the U.S. Agency for International Development (USAID), the U.K. Department for International Development and the Bill & Melinda Gates Foundation, as well as their beneficiaries such as the GAVI Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria, are fundamentally in the business of saving lives and so place great value on using their aid dollars effectively. But only with better forecasting and efficient contracting will existing efforts to develop new products actually lead to a return on donors' aid investment in the form of improved public health outcomes.

In the realm of demand forecasting donors face innovative opportunities to support work across product streams by committing startup funding to a global health infomediary. These funds would go toward developing a repository structure to gather and house data, providing initial analyses and forecasts, populating the repository with available data and creating interfaces to update this data on an ongoing basis, and incorporating new data and market research studies into the repository as they are conducted. An immediate step would be to develop a request for proposals that would outline the key functions of the infomediary, its business model and the qualifications of a host institution.[2]

Armed with better information from this infomediary, funders could then increase access to critical medical technologies—and reduce their hidden costs—by assuming a greater share of the financial risk currently borne by suppliers; this can be achieved through the adoption of efficient contracting mechanisms.

Suppliers

Suppliers of drugs, vaccines, diagnostics and other critical medical technologies value opportunities to serve as good global citizens by providing access to life-saving health interventions in developing countries, while also exploring new markets and protecting their corporate interests. Through collaboration with international donors and technical agencies, it would be possible to produce better demand forecasts that could reduce and share risk in these markets, which in turn could support better business cases for investing in developing country products and making them available for those who need them most.

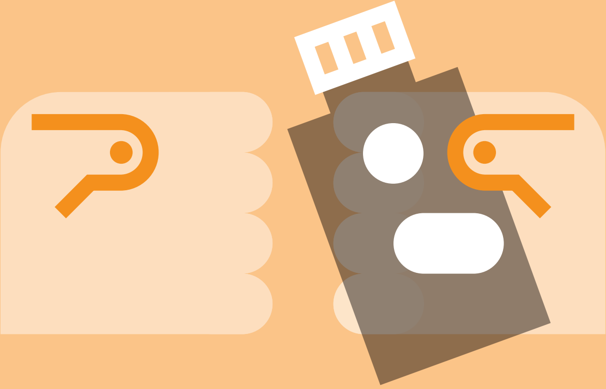
Supporting the funding, creation and widespread use of an infomediary that would generate better forecasts is both good for health and good for business. Specifically, individual suppliers could move toward better forecasts by providing both public and proprietary data to a global health infomediary; in turn, they could commit to purchase information and baseline forecasts to inform their internal decisionmaking processes. Suppliers could also contribute by sharing their technical forecasting expertise with other global health stakeholders through forums, online tutorials or other platforms.

National health programs

Developing country governments—and ministries of health in particular—are charged with delivering essential health products to as many of their citizens as possible given constrained health system capacity and limited financial resources. Getting district- and country-level demand forecasts right is critical to both the availability and affordability of these products by eliminating shortages and waste at delivery and by informing decisionmaking further upstream in the supply chain. To achieve this, national program managers must take forecasting seriously, adopting principles of good demand forecasting—including increased transparency of the demand forecasting process in countries and globally. Above all, the forecasting process must be independent, free from political interference and separate from advocacy and target setting.

Global technical agencies and intermediaries

Many organizations have recently emerged with the purpose of generating demand forecasts as part of their broader mandate to improve access to medical products. To ensure that their forecasts reduce overall market uncertainty and contribute to better matching of supply and demand, they can adopt principles of good demand forecasting, including ensuring transparency and political independence of forecasting processes and clearly separating forecasting activities from advocacy and target setting.



1

Better demand forecasting saves lives

Chapter at a glance

- Good demand forecasting is essential for ensuring broad access to new, life-saving global health products. Poor demand forecasts contribute to high costs, insecure supply of essential products and the development of drug resistance.
- Demand forecasting is the ongoing process of projecting which products will be purchased, where, when, in what quantities and by whom.
- Demand forecasting serves five critical functions in the market for global health products and the effective delivery of medicines and supplies:
  - Matching supply to demand.
  - Stimulating development and manufacture of new, much needed products for which a viable market exists.
  - Expanding supply chain capacity to enhance delivery to patients.
  - Planning and executing procurement efficiently.
  - Identifying leverage points for the public health community to stimulate demand and expand use of products.
- Recent changes in global health have made demand forecasting both more important and more difficult: new amounts and sources of money, new and future products, new buyers, new suppliers and business models, and new intermediaries. These have created a challenging environment that needs innovative approaches.

Lack of accurate and credible information about effective demand for critical medical technologies costs lives. Crucial decisions about which vaccines, medicines and diagnostics to produce and to buy hinge on realistic projections of the future market—not on what ideally would be required to meet the potential need. Gaps and weaknesses in demand forecasting result in a mismatch between supply and demand. If forecasts are off, so are the outcomes: limited funds to purchase products do not stretch as far, and the chance of shortages is higher than would otherwise be the case. The most important consequences are to health: children fail to get malaria medicines and vaccines that will save their lives, pregnant mothers and their babies go unprotected from exposure to malaria and the transmission of HIV, and AIDS patients miss their medicine cycles, jeopardizing their lives and adding to the threat of drug resistance within their community.

The negative economic effects are profound as well and exacerbate the problem of small markets. Uncertainties about demand significantly weaken the business case for branded and generics manufacturers' involvement in developing countries and have both immediate and long-term impacts on access to life-saving products. In fact, when listing their biggest problems in serving the global health community, many pharmaceutical company executives cite poor demand forecasting as the most important one. In short, ensuring better demand forecasts is at the heart of the global health agenda and merits attention from all who are involved in funding, purchasing, setting specifications for, developing, supplying and distributing global health products.

Demand forecasting is defined as the ongoing process of projecting which products will be purchased, where, when, in what quantities and by whom. Demand forecasts measure effective demand in the market—that is, product needs that have or will have purchasing power behind them and will result in actual orders. Ultimately, effective demand can serve as a metric for assessing actual access to essential medical technologies at the patient level.

Demand forecasting is hardly a new challenge. But the need for better forecasting has become acute in the context of current efforts to increase access to essential medical technologies. Without the ability to generate realistic estimates of effective demand—as opposed to needs or aspirational targets—manufacturers cannot scale production capacity, make commitments to suppliers of raw materials or justify a business case for investment in costly clinical trials and other activities to develop future products. Similarly, national governments and international funders rely on demand forecasts for budgeting, while health programs and implementing agencies rely on forecasts for planning their supply chain logistics.

Traditionally, demand forecasting for health products in developing country markets was seen as a relatively low-level function, to be left to firms with particular business interests, using some basic information about health conditions and health system coverage provided by technical agencies. In developing countries themselves demand forecasting has been viewed as one of the many functions required of overburdened technical personnel within ministries of health or particular dedicated units, such as those that manage national immunization programs.

More recently, with increased attention on getting new products into broad use to address highly visible public health priorities such as HIV/AIDS—and with significantly increased funding from governments and consumers in middle-income countries, plus new donor funding mechanisms for low-income countries—creating good demand forecasts that can be agreed to by multiple stakeholders has taken on a new and fundamentally different level of importance. In a piecemeal fashion, for specific products, the global health community has responded. For example, WHO has taken responsibility for developing forecasts for some products, and public-private partnerships have made impressive efforts for others. However, relatively little has been done to address the weaknesses in data, methods and institutional incentives that are common to virtually all products and that severely constrain good decisionmaking.

The need to take demand forecasting seriously and to improve forecasts is urgent because the stakes are far higher than they have ever been. Recognizing the importance of demand forecasting and believing that improvements are possible through "win-win" solutions, the Center for Global Development convened the Global Health Forecasting Working Group in early 2006, after a six-month consultation with knowledgeable individuals to define the nature of the problem and sketch out potential solutions.[1]

The Working Group, consisting of 26 individuals with a range of expertise from industry, public-private partnerships, funding agencies and other backgrounds (see appendix A for the list of Working Group members) who met several times over the course of one year, found that demand forecasting can and must be improved for current global health investments to realize their potential. The group concluded that forecasting challenges can be understood only by looking at the nature and distribution of underlying risks faced by the pharmaceutical industry, national buyers, regulatory and purchasing intermediaries, and funders, particularly in light of the new global health environment of more money, new products and a more complex international market. Those risks, and their asymmetric distribution, confer distinct and misaligned incentives across important players in the global health market. Under current arrangements, those misaligned incentives impair demand forecasting and, more important, hamper broader access to critical medical technologies.

The group determined that the near-term solutions—not only to the technical issue of better forecasting, but to the big-picture concerns about reliable and increased access to essential products—lie in mutually reinforcing strategies designed to break the cycle of bad information, inaccurate forecasts and lack of incentives to do better. These strategies include taking forecasting seriously and adopting principles of good forecasting; reducing risk through better mobilization, sharing and generation of information; and aligning incentives by sharing risk between funders and manufacturers. The Working Group developed an action agenda for key funders, technical agencies, national buyers, procurement organizations and manufacturers. Taken together, the group's recommendations will improve forecasting and generate more informed and efficient decisionmaking across a range of life-saving products. Recognizing that forecasting challenges are linked to structural problems in global health, these solutions fit within a broader and longer term policy agenda of greater health system capacity, improved regulatory and post-regulatory processes at the global and national levels, more market-oriented research funding and increased predictability of international finance for health.

Focus of the Global Health Forecasting Working Group

The Working Group concentrated on aggregate demand forecasts at the global level (rather than country-specific ones) for "new products and new markets"—that is, products that are newly licensed or new entrants into use in developing countries, in contrast to currently available and widely distributed therapies. This scope was adopted because the challenges of demand forecasting and the consequences of demand uncertainty are most pronounced for these products. Such products tend to be manufactured or made available in countries by only a limited number of quality manufacturers, and manufacturing processes and regulatory factors may be less predictable than those for products that have a long track record. Newer products are generally offered at higher unit prices than are off-patent products, and donor funds are used to purchase them for use in low-income countries; this introduces additional risks and forecasting challenges not necessarily faced when national governments are payers. Future usage patterns are difficult to project because of limited historical consumption data. While demand forecasting for many medical products is challenging, it is the "new products and new markets" for which the hurdles are highest and for which donor actions can have the greatest impact.

This report focuses on similarities across products and product categories but recognizes that each type of new product faces a unique manifestation of a core set of risks, depending on the characteristics and dynamics of the market, including level of competition, affordability and other factors. For example, antiretroviral drugs were originally developed in response to needs and demand in developed countries, and the lion's share of the R&D investments were recouped through those markets; although use in developing countries is still limited, several first-line therapies are being produced by generics manufacturers and, because of this supply situation and the impressive negotiations at the international level, are offered at a far lower price than was the case only a few years ago. At the same time, second-line antiretroviral drugs are offered by a small number of multinational suppliers at relatively high (albeit concessional) prices.

By contrast, antimalaria drugs have little or no developed country market. The market in malaria-endemic countries is divided between high quality artemisinin-based combination therapies (ACTs), which are produced by a small number of suppliers and subject to price and procurement scrutiny, and low-efficacy products, based on older drug classes and often produced in endemic countries. Suppliers in the malaria field require clarity on both these markets to improve supply of effective antimalaria medicines.

Most vaccines, beyond traditional products that are now largely off patent, are produced by a few multinational manufacturers, are offered at prices substantially higher than "commodity-type" products and have both developed and developing country markets. With its diverse representation, the Working Group was able to reflect on the varied market situation in the conduct of its deliberations, while looking for solutions that spanned products and diseases.

The rest of this chapter provides an overview of the new global health context, with a focus on how recent changes have dramatically increased the challenge as well as the importance of good demand forecasting. It also highlights the role of demand forecasting within the value chain for medical products. Chapter 2 focuses on the underlying risks and misaligned incentives that contribute to the challenges of demand forecasting; without addressing these any solutions are likely to be superficial and of limited success. Chapter 3 presents the Working Group's first recommendation—to take demand forecasting seriously—spelling out the core principles of good demand forecasting that are accepted across a range of sectors and discussing the implications of adopting those principles in global health. Chapter 4 focuses on the Working Group's second recommendation, describing how strategic investments could be used to create a global health infomediary that would address—in a coordinated way—the gaps in the information base required to generate credible forecasts. Chapter 5 focuses on the third recommendation, providing a menu of new ways to better share risk and align incentives for better forecasting across suppliers, funders and actors throughout the supply chain that are affected by funders' policies and practices. Finally, chapter 6 places these near-term actions within the longer term policy agenda, lending the Working Group's voice to calls for important progress on health systems strengthening, regulation, and development and financing of critical medical technologies.

The new world of global health

Understanding why demand forecasting is key to future progress in global health requires a look at five recent changes: new amounts and sources of money, new and future products, new buyers, new suppliers and business models, and new intermediaries.

New amounts and sources of money

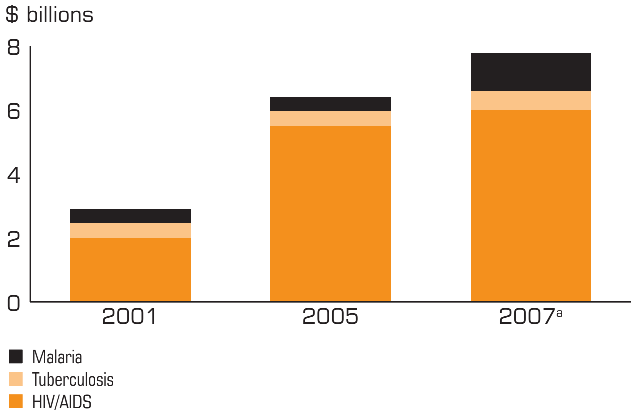
The three main sources of finance for health products in developing countries are private, out-of-pocket spending; national or subnational public sector payers, typically channeled through ministries of health; and international public and private donors. Although expenditures by all three sources have been gradually increasing in most countries, the expansion in international public sector donor funds is creating a discontinuity in the resources available, particularly in the lowest income countries. As this has happened, the policies and practices of both traditional and new donor agencies have become a driving force in the market.

Donor funding for global health has increased substantially in the past five years, particularly for HIV/AIDS, tuberculosis, malaria and vaccines. The United States alone authorized up to $15 billion for HIV/AIDS through the President's Emergency Plan for AIDS Relief in 2003–08 and $1.2 billion for malaria through the President's Malaria Initiative in 2005–10.[2] The Global Fund to Fight AIDS, Tuberculosis and Malaria has over $10 billion in assets today and has already committed $6.6 billion to programs. Globally, annual funding for AIDS, tuberculosis and malaria has more than doubled from 2001 to 2005 (figure 1.1); by 2007 the funding target is $15 billion for the three diseases, with at least $8.7 billion already committed by major donors.

The situation for vaccines is similar. In 2004 the United Nations Children's Fund (UNICEF) alone purchased 2.8 billion

Figure 1.1
Funding for AIDS, tuberculosis and malaria

Global grant agreements funding, 2001–07



Note: Funding estimates are for all activities, not just procurement of products. However, at least half of spending is likely to be devoted to critical medical technologies (drugs, diagnostics, bednets and the like).

a. Projected.

Source: President's Emergency Plan for AIDS Relief, World Bank and Global Fund to Fight AIDS, Tuberculosis and Malaria.

doses of vaccines worth a total of $374 million, compared with only 969 million doses worth $55 million in 1990—an almost 600% increase in spending.[3] In addition to increases for polio eradication, much of this new money has come through the GAVI Fund (formerly the Vaccine Fund), which has received $3 billion in commitments over the next 10 years. The International Finance Facility for Immunization was also launched with the expectation of generating an additional $4 billion over the next 10 years to purchase vaccines through GAVI.[4]

These new funds are being channeled through new mechanisms. Beyond the Global Fund and GAVI, which are now reasonably well established players in global health funding, newer approaches are being launched. In 2006 the International Drug Purchase Facility (UNITAID) was created to channel new funds from the French airline ticket levy and other donors. UNITAID is expected to mobilize at least $300 million a year, to be dedicated specifically to health products. Several donors, including Canada, Italy, Norway, Russia, the United Kingdom and the Bill & Melinda Gates Foundation, have joined forces to fund a pilot advance market commitment, which has mobilized $1.5 billion for the procurement of pneumococcal conjugate vaccine for low-income countries if and when an appropriate product is deemed eligible for purchase.[5] A global subsidy program for ACTs for malaria is under development by the World Bank, which would create a separate, product-specific funding stream. Other proposals are in the offing.

The increase in funds and funders has had significant impacts on the overall supply chain that affect demand forecasting. First, donor funding is notoriously unpredictable and tends to be more subject to rapid fluctuations than the national public finance base in developing countries is.[6] Commitments are not always reflected in disbursements, and funding can be cut off instantly when there are allegations of corrupt practices or other major governance concerns. While several of the new funding instruments are designed to create a more predictable flow of funding, the risks associated with relying on donor funds are a major challenge for forecasting demand.

Second, the increase in demand for products is a major step change for global capacity, not an incremental one. From its launch in 2002 through March 2007 the Global Fund disbursed $3.5 billion, with grant agreements for an additional $2.19 billion.[7] About half these funds are committed for the purchase of drugs and supplies.[8] The majority of UNITAID's annual funding will also be committed to buying drugs and commodities for AIDS, tuberculosis and malaria.[9]

If the money is there, will the products be, too? The major increase in funding and subsequently in demand for products requires large investments by manufacturers to scale up production capacity. Within countries it implies the need for greatly expanded procurement, warehousing, storage and logistics capabilities. Both require accurate forecasts to plan and justify investments.

New aid instruments, through which much of the new funding is being channeled, assume that developing country supply chains can deliver products quickly, efficiently and at a large scale. These new funding instruments, all of which cite performance as a criterion for continued funding, require countries to show measurable results in a short period of time to justify continued disbursements. For example, Global Fund grants are initially approved for five years, but after the first two years of the grant cycle recipients must meet performance targets to continue receiving funds. According to the Global Fund's estimates, the procurement process alone for medicines and supplies can take up to 18 months during its first round,[10] a figure consistent with experience from the World Bank.[11] Thus, to meet the requirements of these new aid instruments, procurement mechanisms and supply chain processes must be greatly streamlined and strengthened, requiring investment in skilled staff and infrastructure.

New and future products

As a beneficial result of recent investments in global health, including both the large appetite of donors to purchase global health products and the growing support for global health R&D, many new products for developing country markets are available or in development. The array of new products has many payoffs for health. For example, new products containing artemisinin are effective against malaria that is resistant to traditional chloroquine products, and the dozens of antiretroviral medicines in use in developing countries are needed for the clinical management of AIDS patients. However, the emergence of so many products creates challenges for funders, intermediaries and consumers, who are all accustomed to having only a few commodity-type products with quite well established supply and procurement relationships. Those challenges will be exacerbated as the late-stage products—new vaccines, antimalaria drugs and tuberculosis drugs, in particular—are licensed and brought to market.

Over the next five years 15–20 new vaccines with significant value to developing countries are expected to be prequalified by WHO (figure 1.2). These products enter a supply chain that has struggled in recent years with new vaccines against two antigens, *Haemophilus influenzae* type b and hepatitis B, following decades when immunization programs in developing countries were focused on delivering just six relatively low-cost vaccines. Beyond vaccines, those who follow the pipeline of tuberculosis products expect to see 12 new diagnostic products and 7 new therapeutics by 2013. And one of the public-private partnerships, the Medicines for Malaria Venture, anticipates four new antimalaria drugs in the next two years alone. In short: excellent news about bringing new science into the service of global health, but major hurdles and questions as the fruits of recent investments come to market.

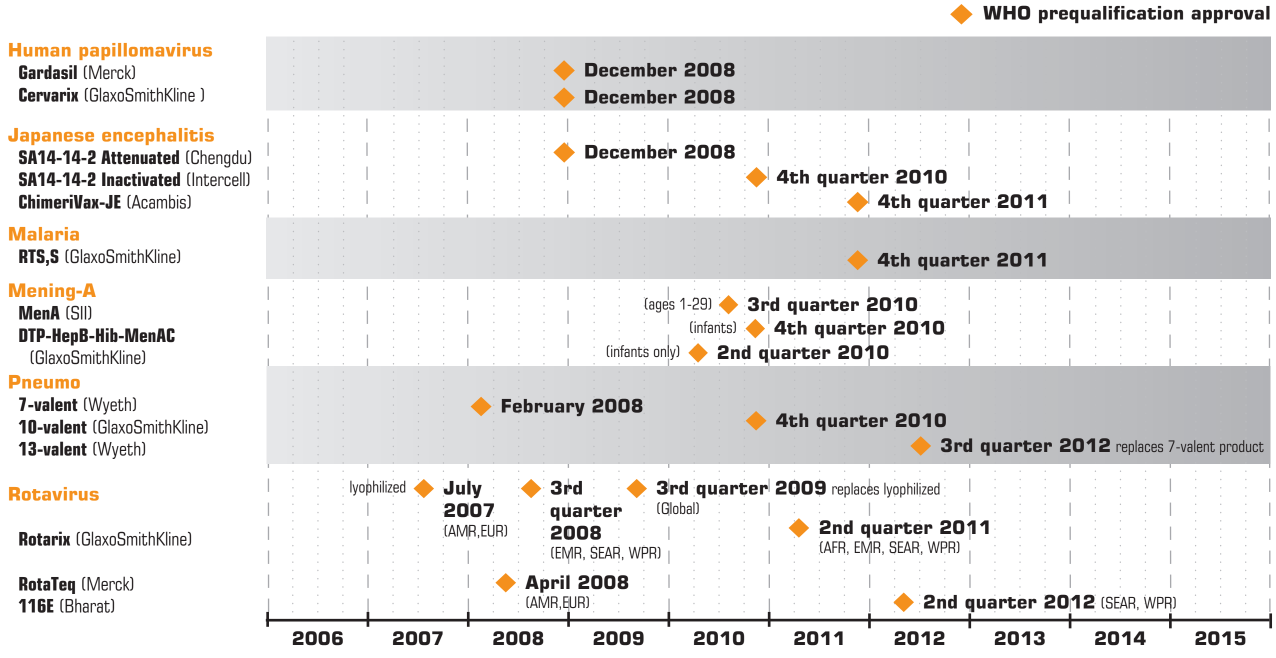
Beyond simple numbers of new entrants, the pharmaceuticals, biologicals and diagnostics now available and soon to come to the market differ from their older generation therapies. These differences highlight why the stakes for good demand forecasting are high, and particularly why manufacturers who are engaging in the global health market are keen to see major progress in forecasting accuracy.

First, many products are still on patent. As a result, their prices reflect manufacturers' business need to recoup R&D investments. Consequently, the unit prices are higher than for earlier generation products that are now off patent.

Second, some products have short shelf lives, long production cycles and a limited number of global suppliers. Production from raw materials to finished ACTs averages almost 18 months, for example, and building and accrediting manufacturing facilities takes at least three years.

Third, for some key products supply shortages or stockouts at any point in the distribution chain generate major negative public

Figure 1.2
Technology traffic jam: the future vaccine pipeline



Source: Applied Strategies.

health consequences. For antiretroviral drugs, for example, an interruption in a patient's treatment can quickly lead to death for the patient or viral drug resistance in the community. For tuberculosis drugs stockouts bring the possibility of developing multidrug resistance. Some 420,000 new cases of multidrug resistant tuberculosis are diagnosed around the world each year, and 7% of them show resistance to three or more drugs.[12, 13]

Fourth, the technology behind many of these products is very complex, which makes the possibility of low-cost generics less likely in the short term. For example, conjugate vaccines require advanced technology and production know-how that are still out of the reach of most emerging manufacturers; future products are likely to rely on even more complex recombinant processes.

Fifth, many of the new products—particularly those emerging as a result of specific global health research subsidies from foundations and other funders—have little or no market in developed countries. Thus, unlike for earlier generation products, manufacturers cannot expect to recoup costs from lucrative markets. All costs will have to be recouped from sales in developing countries, creating the potential for a long delay before significant decreases in prices.

Finally, some products are provided by a limited number of quality suppliers or produced only by generics manufacturers in developing countries. These suppliers may find it prohibitive or impossible (for example, if the drug is still under patent) to apply for approval through an established regulatory authority. To respond to these issues, WHO has set up a new prequalification system for the approval of safe, high-quality drugs for developing countries. However, so far the approval process for a single drug has averaged two years, which has further limited the number of qualified suppliers on the market for a variety of products.[14]

New buyers

With new funds have come new buyers, some with limited experience in international pharmaceutical procurement. This has consequences for forecasting the volume and timing of purchases. The most prominent example is in the grants provided by the Global Fund, which has decentralized purchasing power to more than 400 buyers in 132 countries, including public entities, nongovernmental organizations and faith-based organizations.[15] The original intent of the Global Fund's procurement design was to promote country ownership and improve local capacity in purchasing and supply chain management. In practice, however, this approach has significantly burdened in-country supply chains by creating a market of small, disaggregated buyers with limited ability and experience to influence product quality, price, packaging, shelf life, availability or delivery times.

Many of these smaller new buyers have little capacity and experience in demand forecasting, negotiation, procurement and contract management. Their decision processes, price sensitivities, competing priorities and political realities are poorly understood by suppliers and others in the market. This makes it difficult to accurately predict their demand and costly to forge the partnerships required to generate trust among participants in the market, on both the supply and demand sides. Disaggregated purchasing has consequences: the Global Fund's price-reporting mechanism shows an almost eightfold difference across countries in the price paid for Nevirapine, a common first-line antiretroviral drug, in 2006; purchase prices in low-income African countries ranged from $58 per patient per year to $438.[16]

In contrast to the Global Fund's approach, the GAVI Fund, which provides grants to countries for vaccines, injection supplies and immunization programs, has traditionally used UNICEF procurement arrangements (box 1.1). Because the GAVI Fund has a longer funding horizon than the bilateral donors that have traditionally financed UNICEF vaccine purchases, it has been possible to engage in longer term procurement arrangements. This has clear benefits but makes it essential to make good medium- and long-term forecasts of demand.

New suppliers and business models

The number of suppliers continues to grow, in part because some multinational companies are showing a willingness to license production in developing countries to respond to urgent public health needs. However, this does not necessarily guarantee more access; bottlenecks are seen in the regulatory and post-regulatory steps established to ensure the safety and quality of medicines and vaccines. For example, Cosmos, a producer in Kenya, has received voluntary licenses from Roche and Boehringer Ingeheim to produce two AIDS drugs. Because it has not completed the WHO prequalification process, however, Cosmos is unable to bid for government tenders to provide antiretroviral drugs through donor-funded programs.[17] Although more than four suppliers have been deemed qualified to provide the common first-line antiretroviral drugs, problems with prequalification and cumbersome national registration processes have led to a situation in which only one or two suppliers are registered in any given country.[18] Countries are vulnerable to suppliers' production or delivery problems.

Box 1.1
Different approaches to procurement

> We found that most of the problems in achieving our Global Fund performance targets were directly caused by difficulties with procurement.
>
> —Dr. Simon Mphuka
> Churches Health Association of Zambia

GAVI and the Global Fund approach their intervention in the supply chain and in product procurement very differently. GAVI centralizes procurement of vaccines through a single procurement agent, UNICEF, which negotiates framework contracts with suppliers for the entire market of grantees. Grantees can either buy through UNICEF or procure products independently. However, GAVI only reimburses grantees up to the amount that they would have paid through UNICEF. As a result, all countries procure through the centralized UNICEF contracts. In essence this means that GAVI delivers products directly to countries rather than giving them money to buy products.

The Global Fund, in keeping with its principle of country ownership, provides money rather than products to grantees. Recipients procure products individually using their own processes. While this arrangement provides maximum flexibility, it also increases price and currency risks, does not leverage the Global Fund's huge purchasing power and contributes to long delays in procuring essential products.

A recent Global Fund study evaluating this design found that recipients would welcome a more managed approach to procurement and recommended that the Global Fund pursue a voluntary pooled procurement mechanism where recipients could ask the Global Fund to establish framework contracts on their behalf and pool procurement activities.[1] The Global Fund's board endorsed these recommendations in November 2006.

[1] McKinsey & Company 2006.

Even as the number of developing country suppliers expands, recent changes in developed country markets may actually decrease the security of supplies in developing countries. Several countries belonging to the Organisation for Economic Co-operation and Development (OECD) have introduced initiatives to reduce the rate of increase in drug costs and expand markets for generics; these actions increase the attractiveness of OECD markets for generics manufacturers in developing countries. For example, patents for several of the most common antiretroviral drugs are due to expire over the next five years. Even today, HIV/AIDS drugs are estimated to contribute only 10%–15% of the profit margin of the two largest Indian generics manufacturers, Cipla and Ranbaxy, both of which already sell a wide range of generics to OECD countries.

As with new buyers, new suppliers in developing countries often lack expertise in forecasting demand, negotiation and procurement. Their motivations, decision processes and internal realities are not well understood by buyers or international agencies, and partnerships based on trust are still being formed with these new suppliers. At the same time, the stakes are even higher for these suppliers than for traditional manufacturers because they lack the resources to bear the financial risks of poor forecasting.

For traditional multinational manufacturers, the situation is complicated by the fact that prices in some low-income countries are set to recover costs rather than to generate profit. Faced with vast public health needs and the threat of reputational damage, suppliers have been willing to accept low or even zero margins, but this greatly impedes their willingness and ability to invest in production capabilities without some assurance of demand and to spend large sums to obtain market intelligence. In some cases, the low returns compared with other markets mean that suppliers' sales objectives are to make the drug available but not necessarily to promote sales. At the same time, the costs of doing business in developing countries tend to be higher than in developed country markets because of supply chain complexities, country-specific packaging in multiple languages and other registration requirements, and uncertainty of funding.

Further complicating the picture is competition in the market between quality pharmaceutical products (from both multinationals and emerging suppliers) and counterfeits. As the healthcare market in developing countries has grown, often without parallel strengthening of the regulatory framework and enforcement, low-quality and counterfeit products have taken a firm foothold in many countries. According to WHO, about a quarter of the medicines consumed in developing countries are counterfeit; in some countries nearly half are.[19] One study, for example, found that up to 40% of products that were supposed to contain artusenate antimalarial in fact contained no active ingredients at all.[20]

New intermediaries and public-private partnerships

In addition to more funders, buyers and suppliers, many new intermediary organizations have entered the global health products market, each to play a particular role—albeit not always in coordination with other players (box 1.2). Some of these organizations have novel structures involving relationships between the public and private sectors, and these institutions are characterized by evolving management and governance. For example, over the past few years several public-private partnerships have been created to encourage the development and introduction of specific new products for neglected diseases (most with significant funding from the Bill & Melinda Gates Foundation); these include the Foundation for Innovative Diagnostics, International Partnership for Microbicides, Aeras Global TB Vaccine Foundation, PneumoADIP, International AIDS Vaccine Initiative, Medicines for Malaria Venture, Malaria Vaccine Initiative, Institute for OneWorld Health, Rotavirus Vaccine Program and the Global Alliance for TB Drug Development.[21]

In addition to managing or facilitating product development, several of these partnerships have taken responsibility for creating demand forecasts through the product development phase and for managing the introduction of new products into the market. Recently, the Clinton Foundation HIV/AIDS Initiative has become a central player in the antiretroviral drug supply chain by negotiating prices with suppliers and active pharmaceutical ingredient manufacturers, preparing demand forecasts and advising countries on procurement and supply management. It will soon expand its role to include similar functions for ACT for malaria.

As new entities have sprung up, agencies with longer histories have expanded or deepened their involvement in health product markets and supply chains as well. WHO is involved in prequalifying a wide range of products and procures specific drugs, in addition to its normative role of establishing treatment guidelines and proposing essential drugs lists. Public-private partnerships have been established under the WHO umbrella, such as Roll Back Malaria and the Stop TB Partnership, which are involved in drug policy, forecasting and procurement. The Joint United Nations Programme on HIV/AIDS has also created an Accelerated Access Initiative with major antiretroviral drug manufacturers to increase availability of these products.

Demand forecasting within the value chain

The “supply chain” refers to the flow of materials, information and financing as they move in a process, virtually or physically, from supplier to manufacturer to wholesaler to retailer to consumer. Supply chain activities transform raw materials and components into a finished product, delivered to the end consumer. The “value chain” encompasses the supply chain but also includes the R&D process.

At virtually each step in the supply chain and the broader value chain for pharmaceutical products decisionmakers depend on information about demand: how many units of a product will be purchased and used in the near, medium and long term?

Aggregate forecasting estimates the overall size of effective demand in the market, taking into consideration assumptions about price, funding availability, uptake rates and other key factors. Although it is only one step in the long and often complicated value chain, this process represents a key input into decisionmaking for both buyers and suppliers. For health products, demand forecasting starts when a product is first conceived during the R&D phase and continues through the lifecycle of that product and through the value chain. If not done in a way that optimally uses information and that is seen as credible by decisionmakers—particularly in newer markets, given their inherent uncertainties—the rest of the value chain cannot be efficiently mobilized to deliver.

Box 1.2
Who are the stakeholders? Examples from the HIV/AIDS market

The value chain for any global health product involves multiple stakeholders, each with its own role, governance, financial and other incentives, and sets of relationships with other players. To give a sense of the diversity and complexity, key stakeholders in the market for antiretroviral drugs are listed here.

Supply-side facilitators fund late-stage research, providing information pertaining to long-term market potential, funding clinical trials, helping manufacturers obtain better rates from contract research organizations and facilitating relationships between smaller manufacturers and international regulatory and technical organizations such as WHO and national health and regulatory authorities. The Clinton Foundation HIV/AIDS Initiative is one example of a supply-side facilitator in the antiretroviral drug supply chain.

Manufacturers develop, produce and sell antiretroviral drugs to the mass market. Qualified manufacturers, such as Bristol-Myers Squibb, Cipla and Ranbaxy, have products that are Pharmaceutical Inspection Cooperation Scheme approved; nonqualified manufacturers do not have approval for their products.

Quality regulators, such as the U.S. Food and Drug Administration, the European Agency for the Evaluation of Medicinal Products and the Pharmaceutical Inspection Cooperation Scheme, are responsible for ensuring drug quality. WHO prequalifies manufacturers. Funding agencies also apply internal standards that guide which manufacturers recipient countries can buy from. In addition to being approved by a quality regulator, many buying countries have their own national registration process in which drugs must be registered by a national entity.

Global technical agencies, such as WHO, set treatment norms and guidelines.

Funding agencies, including the World Bank, the Global Fund and USAID, give grants and loans for HIV/AIDS treatment programs.

Donor countries, such as the U.K. government, and **philanthropic foundations,** such as the Bill & Melinda Gates Foundation, give money to funding agencies.

Procurement agents, such as the Inter-Agency Procurement Services Office, UNICEF and WHO, assist countries in ordering and purchasing antiretroviral drugs.

Logistics providers, such as JSI Deliver, DHL and UPS, handle shipping and transport of antiretroviral drugs from the manufacturer to the buying country and assist in distributing it throughout the buying country.

National public buyers, often the ministries of health, are responsible for purchasing antiretroviral drugs for the public sector.

Aggregate demand forecasters, such as the Clinton Foundation HIV/AIDS Initiative and WHO's AIDS Medicines and Diagnostics Service, forecast demand for antiretroviral drugs on a global level.

Demand forecasting serves five critical functions in the market for global health products and the effective delivery of medicines and supplies, all of which result in lives saved:

- *Essential products are available because there is enough supply to meet demand.* Demand forecasts allow manufacturers to plan and invest in manufacturing capacity, ensuring enough supply to meet demand and taking advantage of production efficiencies.
- *New products are developed because the picture of future markets is realistic.* Demand forecasts provide manufacturers with information about new market potential, permitting them to efficiently allocate resources to develop, produce and commercialize new products that respond to developing country opportunities and accelerating the pace of product availability.
- *Supply chain capacity is increased so products can get to people who need them.* Demand forecasts enable health systems in

developing countries to plan for expansion of their capacity to deliver products to more patients, matched to the scale and mix of products required.

- *Funders plan purchases and make the most of the money available.* Demand forecasts allow donors and national governments to efficiently allocate their resources by ensuring appropriate prices and adequate supplies of products.
- *The public health community sees bottlenecks and understands opportunities to expand use.* Demand forecasts highlight key demand- and supply-side constraints and can guide policy and advocacy efforts to reduce those constraints and achieve broader access; this can even include influencing the characteristics of future products to respond to potential demand.

The critical and evolving role of demand forecasting

Demand forecasts are intended to quantify "effective demand" in the market, which means demand for products that is likely to have purchasing power behind it. A variety of organizations are involved in forecasting needs for specific drugs and products and for particular countries; some of these are also attempting to forecast effective demand as well. These organizations include WHO, various partnerships such as the TB Alliance, the Malaria Vaccine Initiative and the International AIDS Vaccine Initiative, GAVI, the Clinton Foundation HIV/AIDS Initiative, the United Nations Population Fund, UNICEF, USAID contractors such as John Snow Inc. and Management Sciences for Health, procurement agents and suppliers. These organizations prepare a range of forecasts from developing long-term scenarios to setting targets, mobilizing funding or engaging in negotiations with particular suppliers.

The demand forecasting process starts early in the product lifecycle and forecasts are continually refined as the product gets closer to launch and then to widespread usage. When a candidate is still in the development pipeline, long-term strategic forecasts are produced, assuming various product specifications. These forecasts, which are based on a set of early assumptions about product characteristics and efficacy, are used to make an R&D investment case for suppliers and funders.

Strategic forecasts present unique challenges because they are made in an environment of significant uncertainty, many years in advance of when a product may actually be available. At this stage demand forecasts can best be considered demand scenarios based on a set of assumptions about the likely product and its future uses. For products with particularly long product development cycles, such as vaccines or tuberculosis drugs, the uncertainty is even greater. Long-term strategic forecasts serve as the beginning of the forecasting process and are in a continual state of refinement as the product progresses through its lifecycle, with iterative feedback loops to other areas in the organization and the external environment, reflecting changes as they occur.

As a product becomes more clearly defined and is ready to reach the market—or in the case of existing products, when the product is entering new markets—forecasts evolve to provide greater and greater specificity to guide production investment decisions. Once a product has entered the market, demand forecasts are further refined and detailed to guide short-term production decisions and management of the supply chain.

Demand forecasts are essential for every level of the value chain and throughout the product lifecycle (figure 1.3). They are used by local health facilities, ministries of health, procurement agents, international organizations and suppliers. The forecasting process and basic principles are the same for all of these forecasts, but their specificity and accuracy change over time and differ at each level.

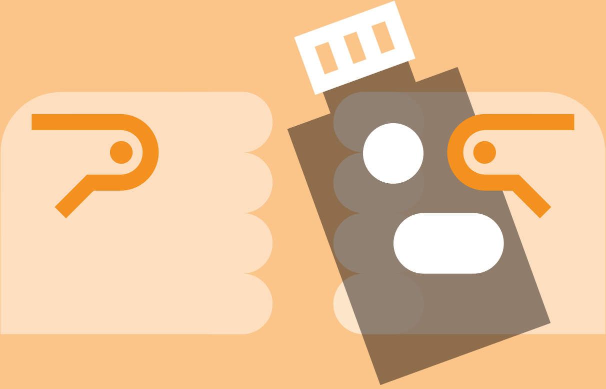
This report focuses on aggregate forecasting, which describes forecasts that are combined across regions and countries to produce an overall indication of demand for products in the market. As a product gets closer to launch and becomes available to patients, these forecasts will rely more and more on good country-level and local forecasting. In fact, short-term or supply chain forecasts depend heavily on the accuracy of country and local buyer forecasting processes. However, there is a still a need to aggregate these forecasts for suppliers to help them scale up production capacity and smooth out fluctuations in demand between countries and regions.

Given the importance of forecasting at each stage and the number of stakeholders that would benefit from better forecasts, it is initially surprising that forecasting is such a problem in global health. Why hasn't this been fixed? Part of the explanation is the recent major changes in funding, products and other factors without a corresponding improvement in forecasting methods, health system capacity or institutional accountability. The rest

Figure 1.3
Demand forecasting along the value chain

	Pre-product development	**Product development (Phases I, II)**	**Large-scale trials (Phase III)**	**Product launch and post-launch (Phase IV)**	**Product usage**
Supplier	Preliminary forecasts drive R&D investment	Product forecasts drive manufacturing and marketing	Regional and country forecasts drive sales and manufacturing	Regional and local forecasts drive sales	Regional and local forecasts drive sales
Public-private product development partnership	Preliminary forecasts drive suppliers and funders	Product forecasts drive suppliers and funders	Regional and country forecasts drive budgets and funders	Regional and local forecasts drive orders and funders	
Funder or buyer		New product forecasts drive funding projections	New product forecasts drive short-term funding	Country forecasts drive disbursements	Country forecasts drive disbursements
Global program		New product forecasts drive funders and approvals	Country forecasts drive funders and approvals	Country forecasts drive funders and suppliers	Country forecasts drive funders and suppliers
National program or country buyers		Country forecasts drive budgets and regulations	Local forecasts drive budgets, regulations and supply chains	Local forecasts drive orders and logistics	Local forecasts drive orders

lies in the fact that risks in the current market are unequally distributed across key actors whose decisions affect supply of and demand for products, and as a result not all stakeholders' incentives are aligned toward better forecasts and greater access to critical medical technologies. Moreover, because of the limited market potential in developing countries, the private sector invests little in market research and other sources of information that are common in developed country markets. While this may be partially addressed over the medium term with new efforts such as advance market commitments, understanding and correcting the misaligned incentives is—and will likely remain—a core challenge.



2

Risky business: who’s on the line in the value chain for essential health products?

Chapter at a glance

- Forecasting is about risk—and improving demand forecasting is about managing that risk well. Without underlying uncertainties on supply and demand sides, it would be possible to know precisely the effective demand for products in the future. However, because the pharmaceutical business is risky—and because aspects of the global health environment greatly increase risk—forecasting represents a major challenge.
- Key sources of risk occur in the supply of global health products, in their demand and in the regulatory and distribution components of the value chain.
- In efficient markets risk tends to be allocated across many parties, and major players on both the supply and demand sides have incentives to reduce risk.
- An audit of risks and incentives in global health, focusing on the supply chain for fixed-dose formulations of ACT antimalaria drugs, indicates that risks are highly concentrated among manufacturers and patients. Few if any risks are borne by funding agencies, technical intermediaries or procurement agents.
- The asymmetrical distribution of risks in the global health supply chain means that those who could act to reduce risk—particularly funders—have little incentive to do so.
- The consequences for demand forecasting are obvious: when incentives are misaligned, key players do not collect, share or assure the quality of essential information, and they do not act in ways that minimize overall risks.

The two-way relationship between demand forecasting and risk is clear. First, because major risks are inherent to both the supply of and demand for health products, particularly in developing countries, accurate forecasting is difficult. Second, weaknesses in demand forecasts exacerbate risks for those who are selling and buying products and those who are preparing for future engagement in the market. Patients ultimately bear the consequences for poor management of market risks.

Improving demand forecasting needs to start with an analysis of the sources and distribution of risk across players in the global health market. This chapter begins with a description of common risks in the market for critical medical technologies, with particular attention to the developing country environment. It then discusses how those risks are distributed across actors and the consequences for access and forecasting.

A way to look at the risks

The nature of the market for medical products and the functioning—or failure to function—of the value chain from R&D to consumer can be understood in part by identifying a set of common risks. Each underlying risk affects the ability of main actors (including suppliers of raw and finished products, intermediaries, consumers and others) to make economically efficient decisions and to ensure that products are available in the quantity, quality, place and at the price that yields maximum health benefits. In particular, the risks affect the ability to accurately predict the size and features of the market.

There are as many ways to describe and classify risks as there are economists or supply chain experts doing it. While not exhaustive, the list below illustrates one way to identify the core risks that affect product supply, demand and entry into the market related to regulatory factors and logistics of delivering products (see appendix C for details on the underlying economic framework.)

On the supply side risks are associated with the development and manufacture of the product, including:

- *R&D risk.* The transition from the basic scientific discovery process to viable molecules or biological agents that merit clinical studies and to the survival of those products through multiple phases of clinical studies is fraught with uncertainty. To some extent, public-private product development partnerships aim to reduce this risk though diversification: funding multiple scientific pathways to address a complex challenge, as in the search for vaccines, drugs, diagnostics and microbicides for malaria, tuberculosis and AIDS. Without public or charitable subsidies, individual manufacturers bear this risk alone.
- *Batch or production yield risk.* A firm may produce batches of products that fail tests for effectiveness, uniformity or safety because of failure in a process, component or system or because of personnel error. Products with relatively short production track records are particularly vulnerable to this type of risk, which is typically borne exclusively by the manufacturer.
- *Input risk.* A firm may face an inelastic supply of inputs required for the finished product, such as raw materials or active pharmaceutical ingredients. This is a particularly acute concern for products like ACTs, whose production requires active ingredients from agricultural materials, which are subject to a host of weather, market and other risks.

The demand side also faces multiple risks—related to the likelihood that a product will be attractive to those who might place orders and the ability to translate a desire for the product into orders to suppliers. Major risks include:

- *Competition risk.* Some products benefit from a temporary period of exclusivity through intellectual property protection; others face little competition because of complex production or regulatory barriers. But where alternative products yield health benefits, the price and availability of those substitutes can make a significant difference to demand for a company's product.
- *Obsolescence risk.* A long-term risk for some products is that they will be rendered obsolete. For example, a better alternative may be developed, or the need for a product may be eliminated or greatly reduced because of the entry of an entirely new class of products for the same condition or because underlying risk factors may change. For example, demand for treatment for diarrheal disease may be reduced by the introduction of an effective vaccine or by major improvements in water and sanitation. This is a particular problem if manufacturing assets are specific to a product that becomes obsolete.
- *Policy and preference risks.* Adoption and post-regulatory approval of medical technologies frequently depend on

a range of uncertainties, such as the availability of data about the burden of disease, public attitudes to the disease, understanding of the range of interventions and stigma and understanding about a particular product or intervention. Whether a country decides to adopt a new technology or therapy after regulatory approval as part of a national disease control program is a significant risk that can be further amplified by a lack of clarity at the country level on how such decisions are made and how long it would take to roll out a new technology, if adopted.

- *Budget and purchasing power risks.* Volatility in donor budgets for global health leads to unpredictable demand (see chapter 4). Furthermore, if developing countries pay for some or all of the costs (for example, through a co-financing mechanism), uncertainty about domestically financed health also affects demand. This risk category also includes the possibility that funding aimed at product purchase is diverted, through legal or illegal means.
- *Credit risk.* A borrower, supplier or customer might fail to honor its contractual obligations. This may be quite pronounced if the contractual obligations are weakly enforced—again, a characteristic of developing country pharmaceutical markets.
- *Price-related risk.* Key decisions are made based on particular assumptions about near- and long-term prices, which may behave differently than expected—for example, because large purchasers are in a stronger negotiating position than anticipated and able to bargain down prices.

Regulatory and quality assurance factors also convey significant risks, especially in developing country environments, where regulatory agencies may have a poorly defined role, have a shorter track record than in developed country markets and be less predictable.

- *Regulatory and post-regulatory regime risks.* Regulatory regimes change in unpredictable ways. This includes new requirements concerning manufacturing processes, changes in intellectual property regimes and new clinical trial requirements.
- *Regulatory enforcement risks.* Where enforcement of regulations is weak or changing quickly, there is the risk that poor quality or counterfeit products will enter the market and crowd out good quality or branded products.

Finally, a set of major risks associated with logistics affects decisionmaking, particularly in developing countries.

- *Nontimely delivery.* These are risks associated with unforeseen weaknesses and bottlenecks throughout the supply chain, including transportation breakdowns, leading to stockouts.
- *Losses in distribution chain.* Waste due to leakage or lack of appropriate storage (for example, breakdown of cold chain), if not predicted in placing orders, pose a risk.
- *Complementary inputs.* Human resources, accompanying products (for example, testing kits needed prior to some treatments and injection supplies) or other inputs may not available in the quantity or location needed to make use of a product. This may occur, for example, if scale-up of services occurs rapidly with inadequate ability to respond with newly trained or deployed personnel, vehicles or other complementary inputs. It may also occur if orders are placed without bundling complementary products, such those for testing and treatment.

Consequences of the risks

The consequences of these core risks are both financial and human.

Inefficient use of financial resources

Firms may manage risk by keeping prices higher than they would be otherwise, to buffer the consequences of being left with unsold inventory or of encountering other situations with negative financial implications. Although suppliers tried to keep prices as low as possible for developing country markets—typically as part of a corporate social responsibility agenda—they are rarely able to operate in a money-losing position over the medium or long term. Thus, products may be supplied to developing country markets and supply chains at higher prices than would be the case if less risk were present, meaning that donor, national government and private funds do not go as far as they otherwise would.

Excess inventory

If estimates of short-run effective demand are incorrect—for example, if expected orders do not materialize or national programs' uptake of new products is slower than hoped—the supplier is left with excess inventory. For example, GAVI initially estimated the amount of hepatitis B vaccine required based on available funding and epidemiological projections without accounting for country willingness to adopt the monovalent vaccine rather than waiting for the DTP-HepB combination vaccine. Several manufacturers, particularly in India, scaled up production, and many more entered the market to accommodate this anticipated demand. But uptake of the vaccine was much slower than predicted, with initial supply exceeding actual demand; as a result, competition drove down the price by almost 80%, causing some developing country manufacturers to go out of business and making many others nervous about future investment.

Long-term overcapacity

If a supplier's estimates of long-run effective demand are incorrect—for example, if competing technologies are licensed earlier than anticipated and capture part of the demand—the supplier is left with excess manufacturing capacity and potentially costly supply agreements with the firms that provide key inputs. This has negative financial consequences for the supplier and affects prices and willingness to continue to supply the market.

Shortages

If the supplier underestimates demand, has difficulty obtaining inputs or suffers batch failures, supply can undershoot demand. If the price is not fixed, it will rise, and only purchasers who can pay the higher price will be served. If the price is fixed, the shortage will be felt across the board as drug stockouts. This has negative financial implications for the purchaser and, more important, serious health consequences—unprotected populations and untreated individuals. This is of particular concern when interrupted treatment quickly worsens a disease process (as with antiretroviral drugs in the treatment of AIDS) or creates the risk of drug resistance (as with tuberculosis, malaria, AIDS and other viral and bacterial conditions). In addition, the supplier may suffer reputational damage from being unable to supply life-saving or life-extending medications.

Lack of investment in next generation products

The functioning of the value chain and the rewards that market engagement confers on both suppliers and donors strongly influence their interest in R&D. For example, if pharmaceutical firms face extremely high transaction costs in supplying developing countries and uncertainties around effective demand result in absolute or relative financial losses, their appetite for developing new products for that market will be weak. Inefficiencies in the existing value chain that result in higher prices or reduced access to products jeopardize the ability to consistently mobilize more funds over the long term. Moreover, investment in the public-private partnerships that are now seen as important to development of products for developing countries can be sustained only if current and near-term products are effectively moved into the market through well functioning distribution channels.

Mortality and morbidity

The most serious public health consequence of poorly managed risks is men, women and children dying or becoming incapacitated because they cannot access life-saving products. Inefficient resource allocation, shortages and insufficient R&D each constrain access in the short and long term, resulting in unnecessary illness and death.

Those who bear the consequences cannot reduce the risks

Some of the risks described above are unavoidable. But many could be avoided or reduced by the actions of buyers, sellers or intermediaries. For example, policy and preference risks are reduced when regulatory and post-regulatory bodies are transparent about the criteria and timing of decisions that have implications for the market. Budget risks are reduced when funders commit to a particular funding stream, under transparent rules, over a multiyear period. Risks related to the entry of new products are reduced if awareness about the size and characteristics of the potential market drives decisions about the publicly subsidized product development pipeline. Risks associated with logistics and distribution are reduced when those who were responsible for operating and strengthening the supply chain make sufficient and well organized investments in its smooth functioning. Clearly, these changes are parts of a long-term agenda to develop a better functioning market for global health products that is under way, but in an early stage.

In the global health environment actions to reduce risk have not systematically been taken in the past—in large measure because those who experience and suffer the consequences of the risks are not in a position to reduce them. In terms of other stakeholders, under current arrangements, most of the consequences are felt by two parties: first, manufacturers, who face the possibility of short-term excess inventory and long-term overcapacity as well as the reputational damage from being seen as responsible for shortages; second, patients and communities in developing countries, who are insufficiently protected against a lack of access to products, stock-outs of products that should be on the shelf, poor quality products and other conditions that jeopardize their health. Consequences may also be felt decisionmakers, for example, within ministries of health. Consequences are felt only indirectly by funders and intermediaries, who, paradoxically, are best positioned to reduce the underlying budgetary, policy-related and logistics risks.

The situation is particularly pronounced because so many parties in a position to reduce risks—including bilateral and multilateral funders, public-private partnerships, specialized organizations that undertake procurement such as UNICEF, international authorities such as WHO, and national buyers—are subject to a set of organizational imperatives that may conflict with taking actions to reduce risks. For example, decisionmakers in agencies that provide funding for the purchase of global health products may be responsive to the need to show success in negotiating low prices, may disburse funds only to well governed nations or may maintain year-to-year flexibility in setting priorities for the use of scarce resources. In organizations that support product development with research grants, success may be measured by the number of products in the pipeline rather than by the viability of the resulting market over the long term. Despite the potential health-related value of expanding the range of products and suppliers, procurement agents may face unwelcome costs associated with building relationships with multiple suppliers, creating information interfaces, evaluating numerous bids and administering multiple contracts. Agencies that have a role in product regulation and quality assurance may be extremely averse to implementing any acceleration or change in procedures that could increase the risk of a quality lapse, even very slightly. National buyers and health authorities may face uncompensated costs if they choose to introduce new products and thus may be inclined to rely upon older, less effective therapies.

While many of these challenges exist to some extent in developed country markets as well, historically higher levels of health spending have allowed manufacturers and buyers to develop and use responsive, higher capacity supply chains and excess inventory to buffer against market uncertainties.[1] Developed country markets are also characterized by relatively good information and market research, in part because more money has been invested for information gathering. Purchasers and suppliers have established relationships and balanced market power.[2] Both formal and informal risk sharing is a common feature of market relationships in developed countries.

Developing country markets are rapidly becoming much more complex. Data are limited and unreliable, few tools exist to gather good market research, and both money and human resources are in shorter supply. At the same time, disaggregated and small purchasers combined with multiple layers of international and national decisionmakers make the process more uncertain and expensive for manufacturers and buyers. In addition, health goods are delivered by multiple supply chains, including those in the public, nonprofit, nongovernmental organization, formal private and informal sectors. Despite a trend toward greater and more sustained demand for products through new funding and funders, the current situation still makes it unrealistic to expect manufacturers and private intermediaries alone to make significant investments in the information and supply chain infrastructure that could help reduce and manage major sources of risk, and contribute to better demand forecasting.

What lopsided risks mean for forecasting

In a well functioning supply chain, where risks are shared across stakeholders, all parties have an incentive to keeping an efficient flow of funds, information and products. In fact, the market has mechanisms (typically contracts) to distribute risks—say, between retailers and wholesalers—so that they have incentives to take actions that reduce overall risk and make it more likely for products to move efficiently to customers. When risks are distributed so that each party is better off through collaboration, that collaboration is likely to occur. But today risks are not broadly distributed across actors, and individual funding agencies, regulatory authorities, firms and intermediaries are less likely to work together to improve access. More narrowly, the misalignment in incentives may interfere with the aim of obtaining aggregate demand forecasts that are as accurate and credible as possible.

To understand how this works in practice and what might be done to correct some of these misalignments, the Global Health

Forecasting Working Group commissioned an audit of risks and incentives in the global health supply chain by Prashant Yadav and Kirsten Curtis of the Massachusetts Institute of Technology–Zaragoza International Logistics Program. The objective of the audit was to use expertise from the field of supply chain management to assess the current allocation of risks in the value chain for global health products and its impact on the incentives of different stakeholders.[3]

Because supply chains are product-specific, the audit mapped one product, fixed-dose ACTs (Coartem, produced by Novartis), and concentrated on externally funded, public sector procurement. Due to the complexity and specificity of each country-level supply chain, this study focuses only on the global actors in the supply chain and does not map the risks and incentives within each country or faced by the ultimate consumers—patients. Expanding this work to focus on the specific risks borne by patients is critical for a full understanding of the risks and incentives in the supply chain.[4]

ACTs were selected because they are among the newest drugs in the arsenal against malaria, and recent problems with their supply and demand have been well publicized. The fight against malaria has also garnered significant donor funds for the next few years, making it critical to address underlying incentive misalignments so that new funds have maximum impact. While the detailed findings from the audit are specific to ACTs, the risks and incentives identified and the methodology developed provide a tool to better understand incentive misalignments for other health products.

The artemisinin-based combination therapy supply chain

The disease and the problem

Incidence and prevalence of malaria are difficult to quantify because malaria often goes unreported and untreated.[5] Estimates of the number of people infected with malaria vary significantly—from 300 million to 660 million annually.[6] Some studies report more than 1.2 million deaths a year from malaria, most of them children under age six.[7] The health and economic toll due to malaria is tremendous, with some estimates suggesting that African countries lose $12 billion a year from direct and indirect effects.[8]

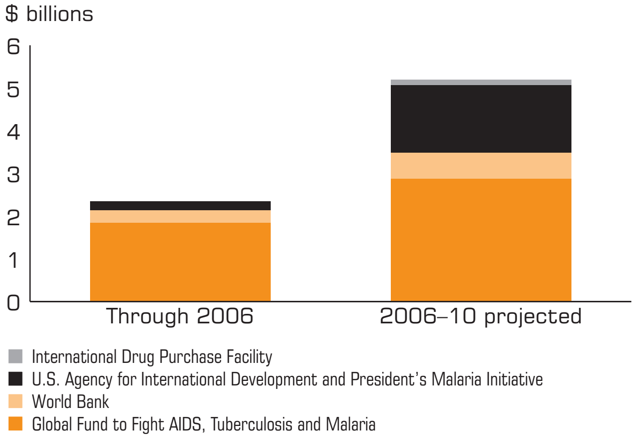
Proven methods exist to prevent and treat malaria and even to eradicate the disease in many areas of the world. In the past 50 years a variety of inexpensive antimalaria drugs, most notably chloroquine, has been used for treatment, but a high degree of drug resistance has emerged over the past 20 years in many of the most severely affected countries. As a result, in 2003 WHO recommended ACT as the preferred malaria treatment in many countries. The therapy involves a relatively new class of drugs, and Novartis, which sells the drugs under the brand name Coartem, was the only WHO-approved manufacturer for fixed-dose ACTs as of December 2006.[9]

The costs of production and hence price of Coartem and ACTs in general are significantly higher than those for traditional malaria treatments: 10 cents for an average dose for chloroquine compared with $1 for Coartem in the public sector;[10] private sector prices range from $12 to $15 per dose.[11] The high costs of the drugs stem from the long production cycle described earlier. Because of its price, affected countries cannot cover the costs of ACTs without external resources; they are increasingly relying on donors to fund malaria treatment programs. By far the largest funder of the drugs is the Global Fund to Fight AIDS, Tuberculosis and Malaria, which finances 60%–70% of all externally funded demand worldwide, followed by the World Bank, the U.S. President's Malaria Initiative and UNITAID (figure 2.1).

The long production cycle of ACTs coupled with their very short shelf life of only 24 months makes the need for accurate demand forecasts essential. Unfortunately, Coartem demand forecasts have been notoriously unreliable, with shortages in 2004 followed by large surpluses and excess inventory in 2005 and 2006.[12] Today, while Novartis has scaled up its production capacity to produce 120 million treatments (based on WHO's initial forecast in 2004), realized sales continue to be around 60 million treatments.

Some argue that this mismatch between supply and demand is a temporary consequence of the creation of a new market. For example, the introduction of ACTs as the preferred first-line therapy by WHO required new international drug protocols to be developed and then adopted and modified by individual countries. Implementing these new protocols created significant barriers on the ground, with extensive retraining of staff and development of new in-country distribution channels needed

Figure 2.1
Levels and sources of malaria funding



Source: U.S. Agency for International Development, World Bank, International Drug Purchase Facility and Global Fund to Fight AIDS, Tuberculosis and Malaria.

to prevent misuse of the drugs and onset of drug resistance. The slower than expected introduction of ACTs highlights the need to link global decisionmaking with sufficient dialogue at the country level.

Despite these concerns, the market for ACTs over the past few years has been relatively simple, characterized by essentially one large funder, the Global Fund; one WHO-approved supplier, Novartis; and one procurement agent, WHO, which negotiated prices with Novartis and has served as the only authorized procurer for public sector purchase of Coartem.

An analysis of the market for ACTs shows that the landscape is rapidly becoming much more complex, with more manufacturers, a diversity of new funders and several new procurement agents who can procure the drug on behalf of countries (figure 2.2). With these additional choices comes greater uncertainty in demand and supply, making forecasting even more challenging and increasing the risks for individual suppliers and buyers.

Who bears the risks in the supply chain for artemisinin-based combination therapy?

How risks and rewards are shared among stakeholders in a supply chain determines its effectiveness, efficiency and long-term sustainability. Poor allocation of risks leads to misaligned incentives, which leads to individual stakeholder behavior that compromises the effectiveness of the entire system. The ultimate stakeholder in a supply chain is the customer. (That the list of stakeholders in figure 2.2 does not include the customer is due only to the fact that this analysis focused on the global level, stopping at purchase of drugs by national buyers. Highlighted boxes refer to potential new entrants.)

The various types of risks in global health markets described in this chapter are all clearly manifested in the supply chain for ACTs. Some of these risks are quantifiable (for example, cost of long-term overcapacity and holding excess inventory), while others are more qualitative (for example, reputational risk).

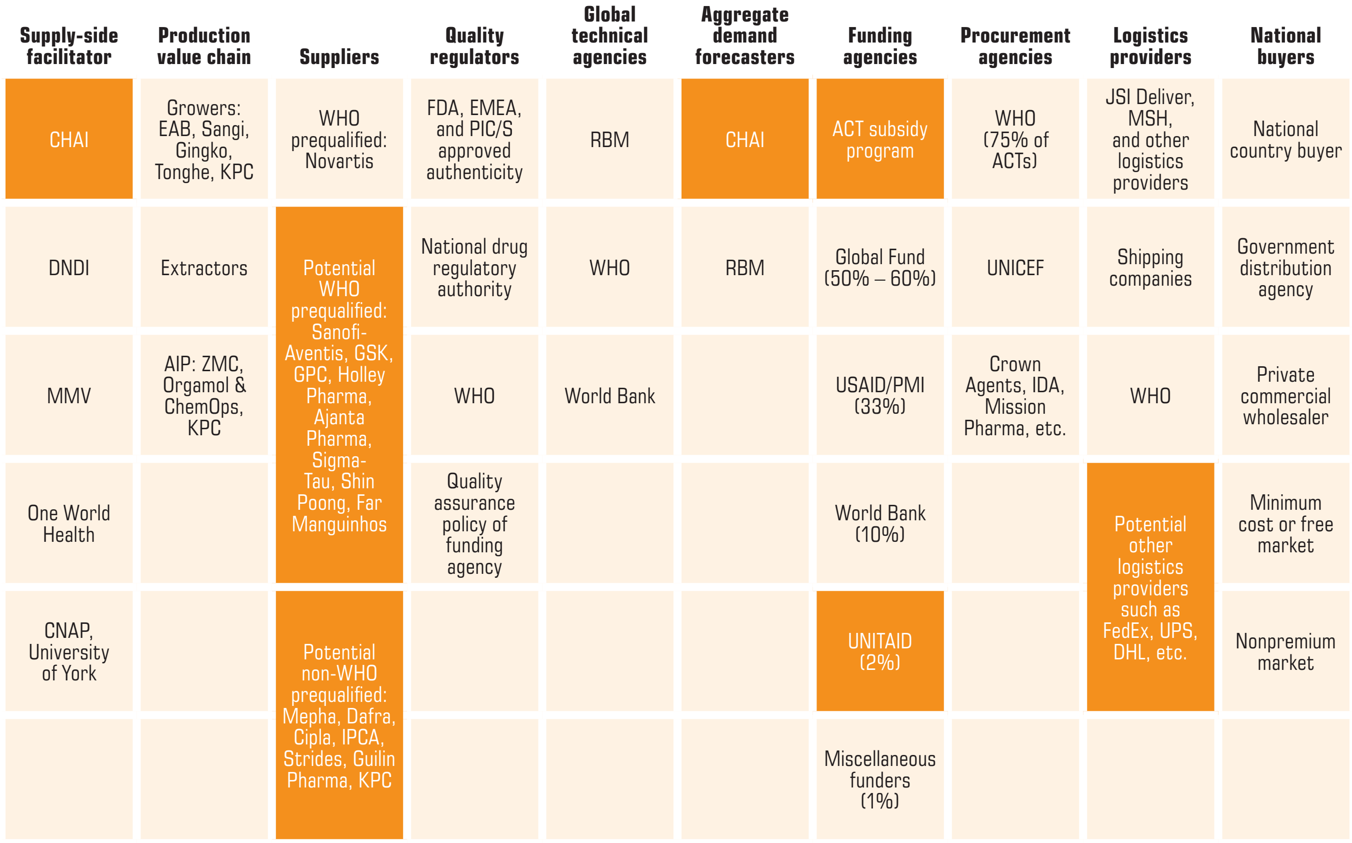
Several layers of risks are present. Some are underlying risks, such as batch failure, while others are consequences of underlying risks, such as supply shortages caused by production risks, budget or purchasing power risks, or preference and other demand risks. Each risk affects the behavior of the stakeholder that bears that risk. Appropriate allocation of risk means that stakeholders who can in some way mitigate or manage the risk bear some of the costs (economic and other) for that risk. Table 2.1 shows the major risks in the supply chain for ACTs and how they are allocated, based on interviews with key stakeholders.

The risk allocation map can be read in several ways: looking across the rows shows the extent to which each stakeholder bears some of that particular risk. Looking down the columns gives a picture of which stakeholders are bearing the most risks. The darker the square, the greater the burden of a particular risk is on that stakeholder. For example, suppliers bear the greatest burden of economic risks for excess inventory because under current contracting arrangements they receive no purchase commitments but must have inventory available to fill orders as they are placed. National buyers bear some risk for excess inventory if they order too much and products sit past their shelf life in warehouses; and funding agencies bear a lesser, indirect risk if their funds are ineffectively used when national buyers overorder, resulting in waste at the country level.

Looking at the map by stakeholder shows that most risks fall to suppliers. National buyers also bear risks, with the most acute being dependence on donors for sustainability of funding. Risks can also be lopsided; for example, quality regulators are at much higher risk if drugs they approve turn out to be

Figure 2.2

Projected stakeholder map of the supply chain for artemisinin-based combination therapies



Supply-side facilitator	Production value chain	Suppliers	Quality regulators	Global technical agencies	Aggregate demand forecasters	Funding agencies	Procurement agencies	Logistics providers	National buyers
CHAI	Growers: EAB, Sangi, Gingko, Tonghe, KPC	WHO prequalified: Novartis	FDA, EMEA, and PIC/S approved authenticity	RBM	CHAI	ACT subsidy program	WHO (75% of ACTs)	JSI Deliver, MSH, and other logistics providers	National country buyer
DNDI	Extractors	Potential WHO prequalified: Sanofi-Aventis, GSK, GPC, Holley Pharma, Ajanta Pharma, Sigma-Tau, Shin Poong, Far Manguinhos	National drug regulatory authority	WHO	RBM	Global Fund (50% – 60%)	UNICEF	Shipping companies	Government distribution agency
MMV	AIP: ZMC, Orgamol & ChemOps, KPC		WHO	World Bank		USAID/PMI (33%)	Crown Agents, IDA, Mission Pharma, etc.	WHO	Private commercial wholesaler
One World Health			Quality assurance policy of funding agency			World Bank (10%)		Potential other logistics providers such as FedEx, UPS, DHL, etc.	Minimum cost or free market
CNAP, University of York		Potential non-WHO prequalified: Mepha, Dafra, Cipla, IPCA, Strides, Guilin Pharma, KPC				UNITAID (2%)			Nonpremium market
						Miscellaneous funders (1%)			

unsafe than if drugs are not moved quickly through approval processes.

The supply chain shows significant scope for better risk sharing between stakeholders. For example, funding agencies bear very little risk in the developing country supply chain, unlike funders in developed markets, who share risk with suppliers through purchase guarantees and other contracting mechanisms. Although there are exceptions, in general the intermediaries in the global health supply chain involved in procurement and distribution bear virtually none of the risks; they make neither purchase guarantees to manufacturers nor binding commitments to supply those who are further downstream. National buyers may have some reputational stake, particularly if there are accountability mechanisms in the public sector, but they rarely face economic risk (as they would if their contracts included volume guarantees). The consequences of these risks fall to patients and communities, who bear by far the largest burden—the health consequences of unbalanced risk sharing.

By contrast, table 2.2 maps risk in a representative pharmaceutical value chain in an advanced market, in this case the United States (see also box 2.1 contrasting the implications for supply chains in developed and developing country markets). In addition to fewer stakeholders, risks are clearly more evenly distributed. For example, economic and reputational risks for shortages are borne by suppliers, procurement agents (wholesalers) and buyers (for example, pharmacies and hospitals) because wholesalers

Table 2.1
Risk allocation for artemisinin-based combination therapies

	Supply-side facilitators	Suppliers	Quality regulators	Global technical agencies	Aggregate demand forecasters	Funding agencies	Procurement agents	Logistics providers	National buyers
Supply-side risks									
Batch yield risk	No risk	Low risk	No risk	No risk	No risk	No risk	No risk	No risk	No risk
Excess inventory risk									
Economic	No risk	High risk	No risk	No risk	No risk	Low risk	No risk	No risk	Moderate risk
Reputational	No risk	No risk	No risk	No risk	Low risk	No risk	No risk	No risk	No risk
Long-term overcapacity risk									
Economic	No risk	High risk	No risk	No risk	No risk	No risk	No risk	No risk	No risk
Reputational	Low risk	No risk	No risk	No risk	Low risk	No risk	No risk	No risk	No risk
Shortage risk									
Economic	No risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk	No risk
Reputational	No risk	High risk	No risk	Low risk	Moderate risk	Low risk	No risk	No risk	Moderate risk
Demand-side risks									
Price increase	No risk	No risk	No risk	No risk	No risk	Moderate risk	No risk	No risk	Moderate risk
Price decrease	No risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk	Low risk
Budget and purchasing power risks									
Grant approval and disbursement timing	No risk	High risk	No risk	No risk	No risk	Moderate risk	No risk	No risk	High risk
Sustainability of funding	Low risk	Moderate risk	No risk	No risk	No risk	High risk	No risk	No risk	High risk
Obsolescence risk	Low risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk	Moderate risk
Regulatory and quality risks									
Lack of approved drugs	No risk	No risk	Low risk	No risk	No risk	No risk	No risk	No risk	No risk
Regulatory enforcement risks									
Counterfeit product	No risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk	Moderate risk
Safety of approved drugs	No risk	High risk	High risk	No risk	No risk	Low risk	No risk	No risk	Moderate risk
Logistical and miscellaneous risks									
Nontimely delivery	No risk	Moderate risk	No risk	No risk	No risk	No risk	Moderate risk	Moderate risk	Moderate risk
Losses in the distribution chain	No risk	No risk	No risk	No risk	No risk	Low risk	No risk	Moderate risk	Moderate risk

Table 2.2
Risk allocation for the U.S. pharmaceutical market

	Supply-side facilitators	Suppliers	Quality regulators	Aggregate demand forecasters	Funders (insurers)	Procurement agents (wholesalers)	Logistics providers	Buyers (pharmacies, hospitals)
Supply-side risks								
Batch yield risk	No risk	Low risk	No risk	No risk	No risk	No risk	No risk	No risk
Excess inventory risk								
Economic	No risk	Moderate risk	No risk	Low risk	No risk	Moderate risk	No risk	Moderate risk
Reputational	No risk	No risk	No risk	Low risk	No risk	No risk	No risk	No risk
Long-term overcapacity risk								
Economic	Low risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk
Reputational	No risk	No risk	No risk	Low risk	No risk	No risk	No risk	No risk
Shortage risk								
Economic	No risk	Moderate risk	No risk	No risk	No risk	Moderate risk	No risk	Moderate risk
Reputational	No risk	Moderate risk	No risk	No risk	No risk	Low risk	Moderate risk	Moderate risk
Demand-side risks								
Price increase	No risk	No risk	No risk	No risk	Moderate risk	No risk	No risk	Moderate risk
Price decrease	No risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk
Budgeting and purchasing power risks								
Grant approval and disbursement timing	No risk	No risk	No risk	No risk	No risk	No risk	No risk	No risk
Sustainability of funding	Low risk	Moderate risk	No risk	No risk	No risk	No risk	No risk	No risk
Regulatory and quality risks								
Lack of approved drugs	No risk	No risk	Low risk	No risk	No risk	No risk	No risk	No risk
Regulatory enforcement risks								
Counterfeit product	No risk	Moderate risk	No risk	No risk	No risk	Moderate risk	Moderate risk	Moderate risk
Safety of approved drugs	No risk	High risk	High risk	No risk	Low risk	No risk	No risk	Moderate risk
Logistical and miscellaneous risks								
Nontimely delivery	No risk	Moderate risk	No risk	No risk	No risk	Moderate risk	Moderate risk	Moderate risk
Losses in the distribution chain	No risk	No risk	No risk	No risk	No risk	No risk	Moderate risk	Moderate risk

and buyers negotiate binding purchase contracts with suppliers. The same is true of excess inventory, where both wholesalers and buyers share in the costs of holding inventory.

If suppliers are expected to provide their products at low or zero margins, and guarantee access to products when and where they are needed, it is important that funding agencies and other stakeholders share some of the risks that suppliers are currently bearing. In the long run stakeholders who bear disproportionate risk but are not adequately compensated will either leave the market or engage in behavior that will threaten the viability of the value chain.

And where are the incentives?

The extent of the risks borne by each party and whether their distribution is lopsided can lead to misaligned incentives in the supply chain. The goal of the supply chain is to provide access to products. Table 2.3 is an incentives map that shows whether each stakeholder has a definite incentive, a clear disincentive or neither to engage in a particular behavior that will promote this goal. In and of itself it is not "good" to have a positive incentive and "bad" to have a disincentive; this depends on how the incentive, disincentive or lack of incentive affects the overall goal of access.

Major misalignments in the supply chain are highlighted. Misalignments exist in several areas of forecasting. In long-term capacity forecasts suppliers' incentives are balanced: they have a disincentive to both overforecast and underforecast because they bear the costs of overcapacity but must have sufficient inventory for orders. But the incentives faced by national buyers for long-term capacity forecasts are lopsided: they have an incentive to overforecast so that they can guarantee capacity from the supplier but no incentive to underforecast, which would result in more accurate estimates of demand, because they bear no risk for overcapacity.

There is a similar mismatch for short-term forecasting. In this case, manufacturers have an incentive to underforecast because they bear the costs of holding excess inventory, while others in the supply chain—funding agencies, procurement agents and national buyers—have an incentive to overforecast because they have very limited risk for excess inventory but wish to guarantee sufficient availability of product. Experience in other industries shows that if forecasts are successively inflated, they will be ignored by suppliers, resulting in less supply rather than overproduction.

To more accurately match supply and demand, stakeholders should have balanced incentives for under- and overforecasting. This would be achieved by more evenly sharing forecasting risk among key stakeholders.

Another critical misalignment that affects forecasting is sharing supply and demand information, which serves as inputs into forecasts (such as buyer intentions, inventory levels and the like). The map shows no clear incentive for most players to share this information with others in the supply chain because they bear no risks for poor forecasting. Individual suppliers have a disincentive to share supply information if it can identify supplier-specific inventory and production capacity because it could give an unfair advantage to competitors. However, if the information is shared in aggregate and without attribution, the supplier's disincentive to share this information is removed. As discussed in chapter 4, sharing forecasting information to obtain more accurate long- and short-term forecasts requires these misalignments to be corrected.

Other areas of incentive misalignment show that national buyers lack clear incentives to rapidly adopt new therapies, such as ACTs, because they bear the costs of switching from older therapies, even though donors may provide the drugs free of charge. They also do not necessarily benefit by reducing the retail price of ACTs (for example, by providing them free at the point of treatment) if they rely on cost recovery to fund the health system's delivery capacity. If widespread adoption of ACTs at no or affordable costs to patients is a public policy objective, these misalignments need to be addressed.

While this risk analysis outlines major areas of risk, the situation is even more complicated for some stakeholders. For example, while the large R&D companies in the market may be able to absorb some of the financial risks, the fundamental maldistribution of risk makes it difficult for smaller suppliers, including many firms based in developing countries, to enter the market. The risk and analysis audit could be further expanded to include obsolescence risks for suppliers, given the increasing use of other technologies such as bednets to reduce malaria incidence as well as the potential introduction of a malaria vaccine. This adds further uncertainty to future demand and makes it less attractive for new suppliers to enter the market.

The misalignments described above and their consequences are pronounced in the case of ACTs; but they are not unique to this situation. The structural complexities of the global health market, including cases in which one agency (say, a funder) acts on behalf of another (say, a ministry of health) through a third (say, a procurement agent), combine with the asymmetrical distribution of risk to create major problems for forecasting and access to medicines. In the end, those with the least influence on how the system works—or fails to work—suffer the consequences: the patients, their families and their communities.

Against this backdrop solutions must be found to the challenge of forecasting demand. The overview of the major risks within the global health market—and their asymmetric distribution—is the starting point for the long-term agenda: more predictable funding, more efficient and transparent regulatory and post-regulatory regimes, attentiveness to the impact on the market of new products in the pipeline and a stronger supply chain all

Table 2.3

Supply chain incentives for artemisinin-based combination therapies

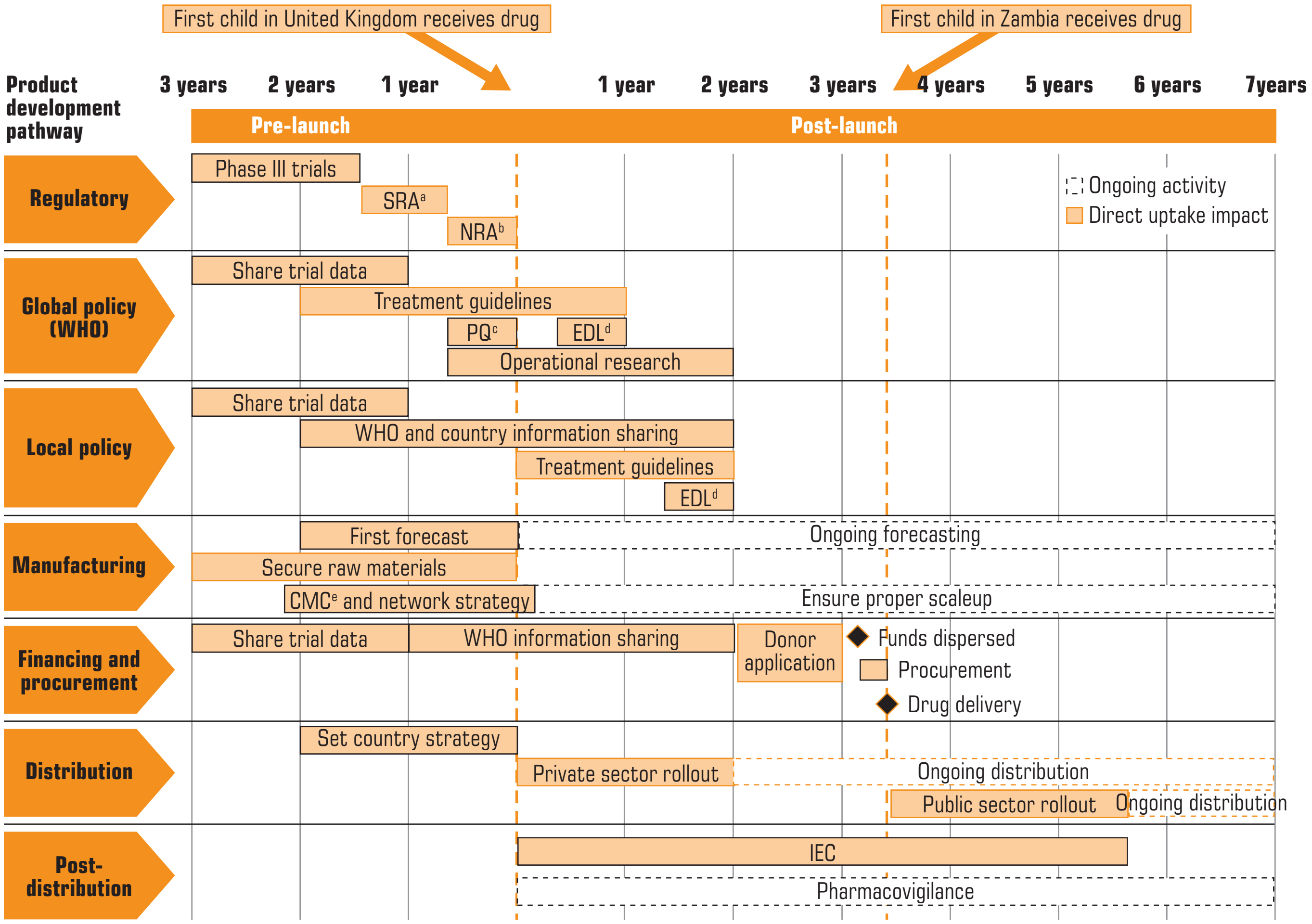
	Supply-side facilitators	Suppliers	Quality regulators	Global technical agencies	Aggregate demand forecasters	Funding agencies	Procurement agents	Logistics providers	National buyers
Supply side									
Develop innovative products	Incentive	Incentive	Indifferent	Indifferent	Indifferent	Indifferent	Indifferent	Indifferent	Indifferent
Increase size of the supply market	Incentive	**Disincentive**	Indifferent	Incentive	Indifferent	Incentive	**Disincentive**	Indifferent	Incentive
Decrease supply chain lead time	Incentive	**Indifferent**	Indifferent	Incentive	Indifferent	Indifferent	Incentive	Indifferent	Incentive
Overforecast in the short term (less than 1 year)	Indifferent	**Disincentive**	Indifferent	Indifferent	**Incentive**	**Incentive**	**Incentive**	Indifferent	**Incentive**
Underforecast in the short term (less than 1 year)	Indifferent	Indifferent	Indifferent	Indifferent	**Disincentive**	**Disincentive**	**Disincentive**	Indifferent	**Disincentive**
Overforecast in the long term (1-5 years)	**Incentive**	Disincentive	Indifferent	**Incentive**	Indifferent	**Incentive**	Indifferent	Indifferent	**Incentive**
Underforecast in the long term (1-5 years)	Disincentive	Disincentive	Indifferent	Disincentive	Indifferent	Disincentive	Indifferent	Indifferent	Disincentive
Sharing information on demand, inventory…	Incentive	**Disincentive**	**Indifferent**	**Indifferent**	Incentive	**Indifferent**	**Indifferent**	**Indifferent**	**Indifferent**
Demand side									
Decrease wholesale price of ACTs	Incentive	**Disincentive**	Indifferent	Incentive	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Decrease retail or end-customer price of ACTs	Incentive	Incentive	Indifferent	Incentive	Indifferent	Incentive	Indifferent	Indifferent	**Indifferent**
Expedite grant approval and disbursement	Indifferent	Incentive	Indifferent	Indifferent	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Rapid adoption of ACTs as a treatment option	Incentive	Incentive	Indifferent	Incentive	Indifferent	Incentive	Indifferent	Indifferent	**Indifferent**
Enhance the level and sustainability of funding	Incentive	Incentive	Indifferent	Incentive	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Regulatory and quality									
Ensure regulatory compliance and safety	Incentive	Incentive	Incentive	Indifferent	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Expedite regulatory approval of new drugs	Incentive	Incentive	**Indifferent**	Incentive	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Logitstical and miscellaneous									
Improve efficiencies in distribution chain	Indifferent	Indifferent	Indifferent	Incentive	Indifferent	**Incentive**	Indifferent	Incentive	Incentive
Ensure availability of complementary inputs	Indifferent	**Disincentive**	Indifferent	Incentive	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Achieve long lasting success (eradication)	Incentive	Indifferent	Indifferent	Incentive	Indifferent	Incentive	Indifferent	Indifferent	Incentive
Have rigorous accountability in funds usage	Indifferent	Indifferent	Indifferent	Indifferent	Indifferent	Incentive	Indifferent	Indifferent	**Incentive**

Box 2.1
Contrasting supply chains in developed and developing country markets

The additional risks faced in developing countries can be demonstrated by the differing experiences of a child in the United Kingdom and a child in Zambia when attempting to navigate the market for critical medical technologies (in this case, malaria treatment). The sad consequence is that the Zambian child must wait three years longer than her British counterpart to get access to life-saving treatment, even when the money is available (see figure).

(continued on next page)

Public sector rollout of new malaria products



Note: Assumed timeline for next generation ACT.

a. Stringent regulatory authority (for example, European Agency for the Evaluation of Medicinal Products or U.S. Food and Drug Administration). b. National regulatory authority in endemic country; may require additional small-scale local studies. c. Prequalification. d. Essential drug list. e. Chemistry manufacturing and controls.

Source: Boston Consulting Group for Medicines for Malaria Venture.

Box 2.1 (continued)
Contrasting supply chains in developed and developing country markets

If a child living in the United Kingdom fell ill with malaria, she would be assured that the major producer of ACT, the preferred treatment for malaria, would have registered her drug with the regulatory authorities and received approval for its use. In most cases the drug would have also been authorized by the National Institute of Clinical Excellence for the treatment of malaria. She would know that when she went to her doctor, the doctor would prescribe the drug and it would be paid for by the National Health Service. If she was in the hospital, availability would not be a problem because it would have been procured based on demand forecasts and framework contracts by the National Health Service's Purchasing and Supply Agency and delivered to her hospital directly by the manufacturer or DHL, the agency's logistics provider. If she was not in the hospital, she would be able to go to her local pharmacy and obtain the drug, with the bill paid directly by the National Health Service.

By contrast, if the child lived in Zambia, the necessary drug may not yet have received approval for purchase with donor funds in her country if it had not passed WHO prequalification as well her government's own national registration processes. This could be because the manufacturer had not chosen to get the drug registered, because the drug was waiting in the queue for various approvals, which can take two to three years, or because the drug was not on WHO's accepted treatment guidelines and essential drugs list, which are generated by two separate processes. If it had been approved by WHO, it still might not be on her national essential drugs list, meaning it could be ordered through the public sector.

If the drug had been through all of these approvals and was also on the required treatment guidelines and essential drug lists, she could hope that her national health system had ordered the drug and it was available in stock. But her drug may not have been ordered because there were problems with donor funding, problems with approval for accessing the funds, poor forecasting of the demand for her drug or long delays in procurement because of outdated and slow procurement procedures. Even if her drug was available in the country, she could not be assured that her drug had made it to her clinic because it would have had to go through a long and complicated distribution and logistics system made even more difficult by poor roads and communication. (Appendix D describes these two supply chains in greater detail.)

If the child in Zambia overcame all these hurdles to receive her drug where and when she needed it, it would save her life.

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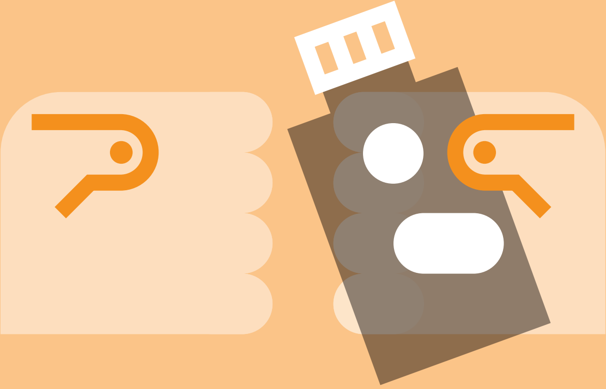
the way to the patient. It also provides the foundation for nearer term approaches to correct misaligned incentives that impede forecasting and access: taking forecasting seriously, as a core element of the value chain for global health; taking action to share information more systematically; and reducing overall market risk and better sharing the remaining risks in the market through more effective contracting methods. These are the subjects of the next three chapters.



3

Recommendation 1: if you play in the market, take demand forecasting seriously

Chapter at a glance

- Forecasting demand is not the same as estimating patient needs or establishing targets for treatment. Measuring effective demand can serve as a metric for assessing access to medical products on the ground.
- Forecasting demand requires technical expertise. Investments are needed to expand this technical expertise for developing country health products and to create new models and methods to better predict demand in these environments.
- Organizations engaged in forecasting should adopt a common set of 10 principles to ensure that forecasting processes are credible and use the most appropriate, evidence-based methodologies.

As chapter 1 shows, good demand forecasting is essential for ensuring that medicines and critical medical technologies get to the people who need them when they need them. Over the past two years several organizations have invested resources to produce credible, aggregate forecasts. At the forefront of these efforts are the public-private partnerships responsible for ensuring that new products are developed for neglected diseases and that existing products reach the developing world. The AIDS Medicines and Diagnostics Service, Clinton Foundation HIV/AIDS Initiative, International AIDS Vaccine Initiative, Medicines for Malaria Venture, PneumoADIP and Roll Back Malaria, among others, have invested both in developing demand forecasting technical skills and in gathering critical information to improve forecasting accuracy.

While these are important steps, taking forecasting seriously requires embedding demand forecasting in all global efforts to increase access to essential medicines and technologies. This requires:

- Understanding demand forecasting and how it differs from advocacy and demand creation.
- Adopting the basic principles of good forecasting.
- Investing in technical forecasting capacity and creating specific forecasting models for developing country health products.

Each of these is discussed below.

Distinguishing forecasting demand from stimulating demand

The term *demand forecasting* has often been used loosely in the global health community to define a wide range of forecasts that do not measure effective demand for health products (product needs that have or will have purchasing power behind them and can result in actual orders). For example:

- International agencies often use *demand forecasting* to mean *needs forecasting*—for example, using epidemiological data to determine the number of people affected by a disease and the proportion requiring treatment.
- Funders may use it to mean *resource forecasting,* to project needs for future financing, usually from the donor community.
- For country programs and buyers it can span a spectrum from short-term orders at one end to ambitious government targets at the other.
- In global health programs it is often used synonymously with *creating* or *generating* demand for products that can be used to address public health challenges.

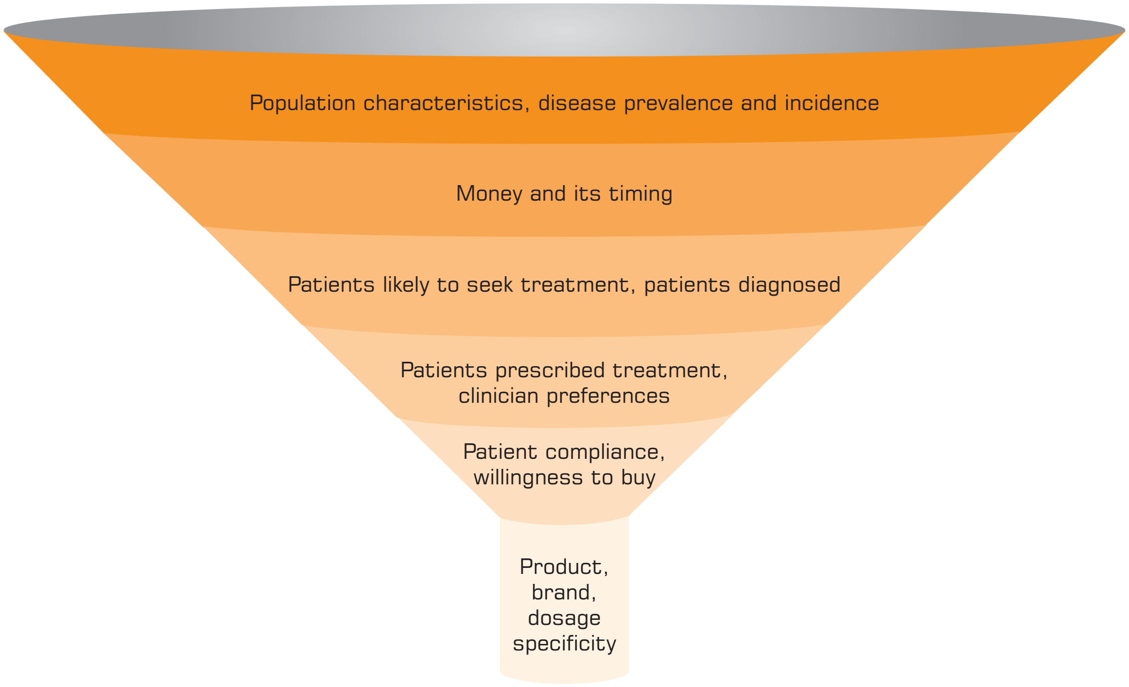
While all these forecasts are important, none describes demand forecasts. First, demand forecasts do not identify the *need* for products or resources. While disease burden, epidemiological projections and projected resources are essential inputs into demand forecasts, good forecasts refine these basic inputs to produce projections of likely effective demand in the market. For example, while it is important to know that there will be 300 million malaria cases annually or that various donor agencies have committed $2 billion to malaria control over the next two years, to scale up production suppliers need to know more than that. Suppliers must know which products will be purchased, in what quantities and when orders are likely to be received. Without this information, mismatches between supply and demand are inevitable.

Figure 3.1 shows, at a high level, how estimates of need become forecasts of demand. Ultimately, demand forecasts measure how many drugs will reach patients. Because demand forecasts represent the level of consumption that is realistically expected, they serve as a metric for actual access to essential health products.

Second, forecasts are not plans or targets. Plans show us how we want the future to look, and targets are goals to motivate performance.[1] Forecasts tell us how the future *will most likely* look based on a realistic analysis of the best data and estimates available.[2] To keep these two processes distinct, pharmaceutical firms separate marketing and forecasting. Marketing and sales staff (whose functions are analogous to those of demand stimulation in global health programs) have targets and operate at arm's length from the analysts who produce demand forecasts. While optimism may be the hallmark of target setting, realism is the watchword of demand forecasts.

Although the focus of this report is on global aggregate demand forecasting, the process nonetheless relies on accurate country-level forecasting, which in turn depends on a clear understanding of the local drivers and constraints of scaling up treatment. Investments are required to better understand barriers within countries, including on the ground access to health products, and to build models that incorporate the key drivers of local demand, such as physician and patient preferences, direct and indirect treatment costs to the patient, public and private health services capacity,

Figure 3.1
From need to demand


Population characteristics, disease prevalence and incidence
Money and its timing
Patients likely to seek treatment, patients diagnosed
Patients prescribed treatment, clinician preferences
Patient compliance, willingness to buy
Product, brand, dosage specificity

Effective demand = Actual access on the ground

distribution channels, and special relationships between distributors and providers, among others. A realistic picture of current demand, and of its critical drivers and constraints, is important for understanding what levers can be used to stimulate demand for global health products.

Applying basic principles of demand forecasting

Credibility and transparency are essential to forecasting. Forecasts are intended to drive decisions and investments by suppliers, distributors, funders and others, but this can occur only if the forecasting is independent, free of political interference and separate from advocacy and target setting. Lack of credibility will cause investors to discount forecasts, creating the potential for supply shortages and stockouts.

It is difficult to provide one answer on "how to forecast" because of the diversity of organizations involved in the value chain across numerous countries, covering various stages of a product's lifecycle, using different methodologies, with different base datasets. It is not possible, nor necessarily desirable, to strive for a single or even limited set of methods and sources for forecasting. It is possible and necessary, however, to reduce the variation in forecast outputs and increase the confidence of all players in the market in the accuracy of forecasts.

The first step is to adopt transparent evidence-based principles. The 10 demand forecasting principles described below should be adopted by organizations projecting demand for global health products. These principles are adapted from a much longer list of standards and practices for forecasting that have been tested in a variety of industries in recent decades.[3]

These fundamental principles do not describe *how* to forecast, but rather how to design and manage good forecasting processes. The principles are applicable to forecasts at all stages of the value chain, the client-care cycle (prevention, cure, prolonged treatment) and the health program lifecycle (planning, launch, expansion, scaleup, maintenance, resupply, graduation).

Outlining transparent and evidence-based principles for demand forecasting can reduce risk and uncertainty in the market and increase the chance that supply will better match demand. Specifically, these principles are intended to:

- *Increase market understanding and credibility.* Assuring forecast users that standard and transparent practices are being applied increases confidence in the forecasting process. Adopting a principles-based approach also improves consistency in forecasts across the value chain, increasing the likelihood that all stakeholders will take appropriate actions based on the demand forecasts that are produced.
- *Better understand and mitigate systemwide risk.* Reduced variation and increased credibility can lower market and value chain risks for each stakeholder.
- *Increase value for money.* A more confident market can make investment decisions in research and development, manufacturing plants and distribution that are more likely to result in products closer to the optimal quantity and price.

The demand forecasting principles are divided into three categories (see appendix E for more detail):

Customer-focused principles identify how to ensure that forecasts meet the needs of customers and have the greatest impact on the decisions they are intended to inform:

1. Identify the principal customers and decisionmakers of the forecast and clearly understand their needs.
2. Understand and clearly communicate the purpose of the forecast and the decisions that it will affect.
3. Create a forecasting process that is independent of planning and target setting.
4. Protect the forecasting process from political interference and ensure that it is transparent.

Process- and context-focused principles identify how to create a credible forecasting process and how to develop, present and understand the forecast within the context of the overall market and public policy environment:

5. Embed the forecast in the broader environment, taking into account market conditions, public policy, competitive forces, regulatory changes, health program guidelines and similar elements.
6. Create a dynamic forecasting process that continually incorporates and reflects changes in the market, public policy and health program capabilities.

Methodology- and data-focused principles identify how to select the right methods for the type of forecast being developed and effectively incorporate qualitative and quantitative information:

7. Choose the methodology most appropriate for the data and market environment. Obtain customers' and decisionmakers' agreement on the methodology.
8. Keep the methodology simple and appropriate to the situation. Avoid too much complexity, but include sufficient detail to address the level of investment risk and accuracy required.
9. Make forecast assumptions clear and explicit.
10. Understand data and their limitations. Use creativity and intelligence in gathering and introducing data into forecasts.

These principles are equally relevant for public programs and private organizations but may be applied uniquely by different organizations. National and global health programs, for example, are integrated organizations in which demand forecasting is one of many activities undertaken to generate and meet demand for health products. Though demand forecasting should be a separate activity in these programs, it will be affected by the program's policies, budgets, stakeholders, priorities, infrastructure, management and administrative systems, staffing, catchment areas and client needs and behaviors. These should serve as inputs into the forecast and not be used to change the forecast once it has been developed. As these capabilities change, the forecast will change, providing an important feedback loop to health program managers.

While all of these principles are important, most important is ensuring that the forecasting is independent, transparent and protected from political interference. Once demand forecasts become a tool of political targets and agendas, their usefulness is severely compromised.

Investing in technical forecasting capacity

Putting demand forecasting principles into practice requires technical expertise in forecasting. Adequate skilled resources must be available to manage and perform demand forecasting. This is a particular challenge in global and national health programs, where functions are integrated and disease experts are expected to create forecasts. Demand forecasting is not an activity that can simply be added to the task of those with strong domain experience. While demand forecasters need to work collaboratively with experts in the disease or product area to ensure that forecasts are valid and have real life applicability, forecasting requires specialized technical skills.

Toward this end, the Working Group recommends the following:

Developing technical forecasting capacity within the global health community

In the past two years several organizations have produced aggregate demand forecasts for particular products. However, across the wide range of global health technologies there is still a gap in forecasting capacity and in the development of credible aggregate demand forecasts that can be shared with suppliers to promote the availability of adequate and cost-effective products.

Forecasting expertise can be expanded within public-private partnerships, including public-private product development partnerships, and procurement agents. Supplier organizations also have considerable demand forecasting technical skills. But while industry forecasters may be skilled in methodologies for developed country markets, there is limited experience in forecasting for developing country markets. Some organizations bridge this gap in the short term by using consultants. Over the medium to long term, however, organizations need to move beyond building an internal, proprietary capacity based on consultants and focus on building technical capacity broadly for the global health community.

Two options for building core forecasting skills are to recruit students from graduate programs into global health and to intensively train current staff, perhaps through scholarships to international or regional supply chain and logistics programs (box 3.1). Another option is to recruit experienced forecasters from industry into national and global health programs.

Box 3.1

Examples of partnerships for training and research in forecasting

The Massachusetts Institute for Technology (MIT) has a masters program focused on supply chain management that teaches forecasting skills. Its European center, based in Zaragoza, Spain, provides opportunities and scholarships for global health students and practitioners. It recently launched a full scholarship to its program for African-based students. MIT has also collaborated with the Harvard School of Public Health and Tufts University to launch an interdisciplinary initiative in humanitarian studies that tailors their business and engineering curriculums to the needs of agencies engaged in health and humanitarian concerns.

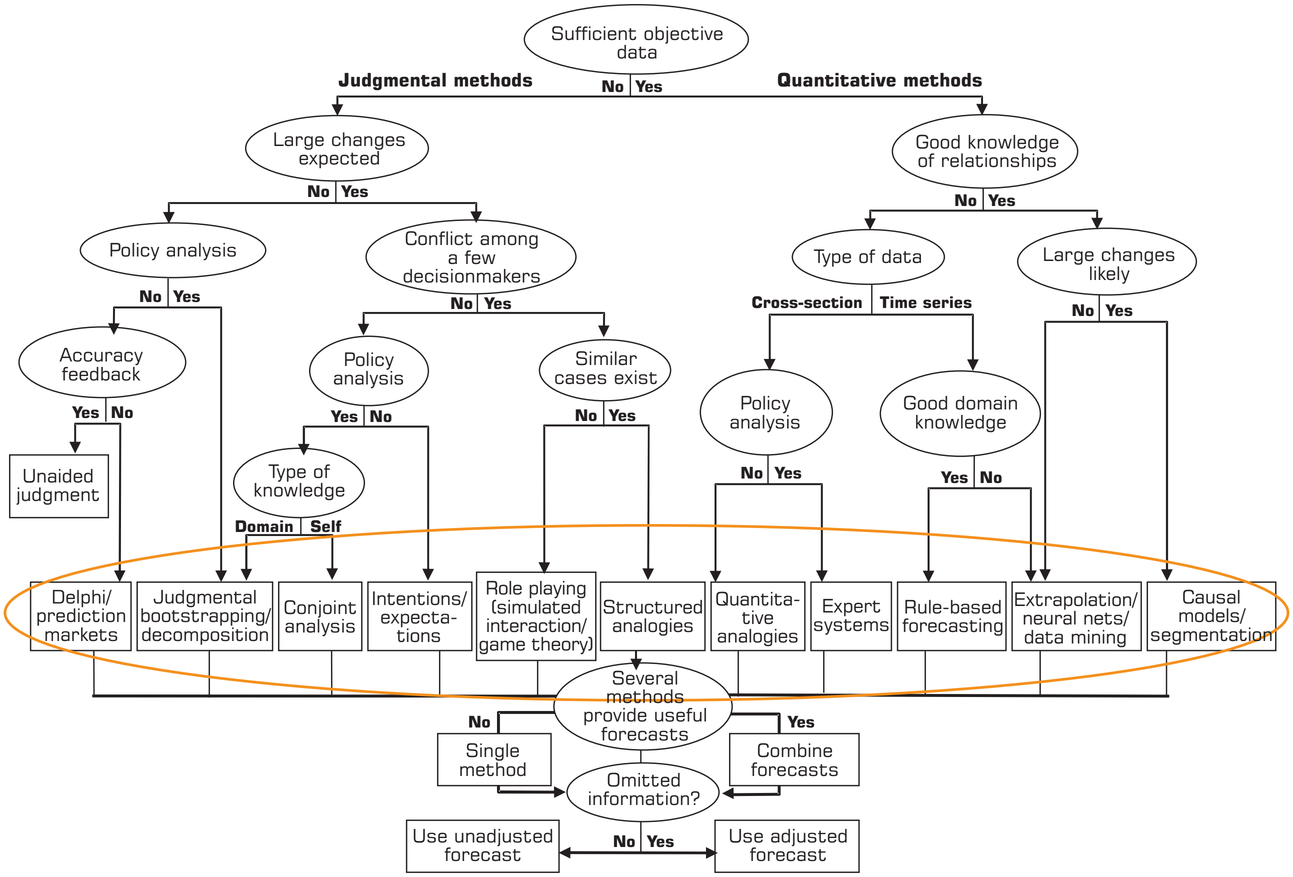
The Fritz Institute offers a program in humanitarian logistics to enable organizations around the world to strengthen their humanitarian assistance through professional training. The program teaches the base principles of logistics and supply chain operations in a humanitarian context.

In addition to basic skills a new expertise is required in applying forecasting methods to developing countries, across cultures and in resource-poor environments. Creating an international resource and knowledge base in forecasting methods for developing country health products could have substantial benefits for the global health community. By being widely available to organizations forecasting at the global level as well as to country-based programs, it could help to build capacity through training, commissioning research on forecasting and data collection, and providing consultation to forecasters.

Expanding the understanding and use of forecasting methods outside of healthcare

Despite widespread complaints about the lack of accurate quantitative data on developing country health products, the two most common methods used of forecasting demand for health products

Figure 3.2
Selection tree for forecasting methods


Sufficient objective data
Judgmental methods
No
Yes
Quantitative methods
Large changes expected
No
Yes
Good knowledge of relationships
No
Yes
Policy analysis
No
Yes
Conflict among a few decisionmakers
No
Yes
Type of data
Cross-section
Time series
Large changes likely
No
Yes
Accuracy feedback
Yes
No
Unaided judgment
Policy analysis
Yes
No
Similar cases exist
No
Yes
Policy analysis
No
Yes
Good domain knowledge
Yes
No
Type of knowledge
Domain
Self
Delphi/ prediction markets
Judgmental bootstrapping/ decomposition
Conjoint analysis
Intentions/ expecta- tions
Role playing (simulated interaction/ game theory)
Structured analogies
Quantita- tive analogies
Expert systems
Rule-based forecasting
Extrapolation/ neural nets/ data mining
Causal models/ segmentation
Several methods provide useful forecasts
No
Yes
Single method
Combine forecasts
Omitted information?
No
Yes
Use unadjusted forecast
Use adjusted forecast

Source: Armstrong 2001b.

are consumption-based and morbidity-based, both quantitative methods dependent on solid market research.[4] In other industries current conditions call for forecasting methods that encourage dialogue among a diverse set of players through systematically gathering and sharing information, creating scenarios independent of political pressure and combining forecasts from various sources for greatest accuracy.

In an environment with significant discontinuity, such as that for many global health products today, forecasting methods that use qualitative input gathered in a structured fashion or a combination of quantitative and structured inputs are more appropriate and widely used in other industries. Figure 3.2 presents a selection tree that narrows the range of possible forecasting methods based on their suitability in various environments, with additional detail in box 3.2. For example, in the case of the introduction of antiretroviral therapy into a new market, where quantitative data are limited and large changes are expected, the tree suggests "judgmental methods," which allow gathering qualitative input from a wide range of stakeholders in a structured and rigorous way. This can be combined with market research, epidemiological information and other quantitative data to provide a clearer picture of actual market demand.

Box 3.2
Many ways to forecast

The forecasting literature suggests that a product's life-stage and market conditions affect the appropriate mix of qualitative input from human "judges," structured combinations of quantitative and qualitative information and statistical techniques in each situation.[1] In general:

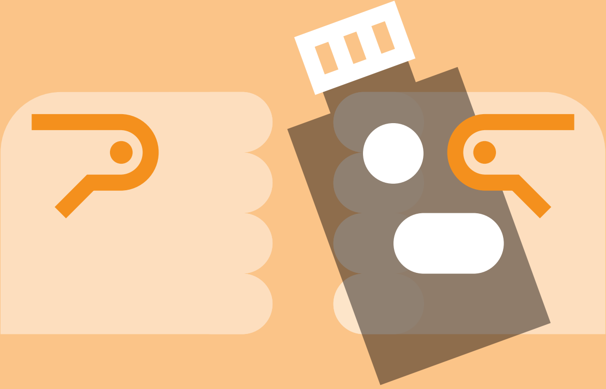
- **Methods based on judgment or qualitative forecasts** are most useful in cases of special events or discontinuities and when quantitative data are very limited. However, human judgments are subject to various errors, which may be compounded when groups meet to agree on forecasts, by dynamics such as "groupthink" and by the presence of dominating individuals or differences in power relationships. Several methods capture qualitative input more systematically than simple use of experts groups, including Delphi techniques, prediction markets, structured analogies, game theory, judgmental decomposition, judgmental bootstrapping, expert systems, simulated interaction, intentions and expectations surveys, and conjoint analysis.[2]
- As more data become available, **qualitative and quantitative information can be integrated,** but this must be done systematically to avoid adding greater inaccuracy to forecasts. **Voluntary integration**[3] methods allow the forecaster to adjust statistical forecasts based on explicit assumptions and can improve accuracy when the forecaster has specific contextual information or can affect the forecast (for example, change purchasing decisions)[4] and when the forecaster does not have predetermined or political agendas for the final forecast.[5]
- **Direct judgment,** in which experts modify forecasts based on personal knowledge, is the most frequently used method of incorporating qualitative input into forecasts. The method is seriously flawed, however, because of the variety of simplifying strategies that people employ when assessing data, including a tendency to overvalue the most recent data, underestimate the growth or decline in time-series data, see patterns in randomness and inconsistently assign relationships between variables based on personal biases.[6]
- A variety of **mechanical integration** methods are available in which statistical tools are used to integrate qualitative and quantitative judgments.[7]
- **A combination of forecasts from different methods** is used in many industries and can be useful when uncertainty is high or when it is unclear which method is best. Combining forecasts works best if forecast errors in each method are negatively correlated and will cancel each other out, but this may be difficult to achieve in practice.[8]
- As comparable time-series information becomes available and the market stabilizes, **statistical methods** are preferable for forecasting.[9] These include extrapolation, quantitative analogies, rule-based forecasting, neural networks, causal models and segmentation. Integrating human judgments for special events or circumstances into these methods will still be appropriate.

1. Armstrong and Green forthcoming. 2. Armstrong and Green forthcoming. 3. Goodwin 2000. 4. Goodwin 2000. 5. Webby, O'Conner, and Lawrence 2001. 6. Goodwin 2000. 7. Goodwin 2000. 8. Armstrong 2001a. 9. Goodwin 2000.

The science of forecasting is constantly evolving. As technical forecasting capacity in global health grows, understanding and applying forecasting methods that are being used in other industries gives greater opportunity to increase forecasting accuracy, particularly in data-poor environments.

Conclusion

Recognizing the importance of demand forecasting and investing in technical forecasting capacity will help to ensure that patients get health products when they need them. This chapter has focused on making demand forecasting an essential part of the discussion on improving access to essential medical technologies. The next chapter deals with the importance of gathering and sharing information to improve the accuracy of forecasts.



4

Recommendation 2: break boundaries and create a global health infomediary

Chapter at a glance

- Up-to-date, credible and comprehensive information is essential to good forecasting and requires key organizations and individuals to collect and share good quality data.
- The current opacity of data increases both demand uncertainty and its associated risks. This suggests the need for an information intermediary, or infomediary, for global health to effectively gather and analyze data needed for demand forecasts across a variety of diseases and products and to make this information widely available to all stakeholders.
- The key functions of the infomediary would be to:
  - Serve as central repository for all relevant demand and supply data.
  - Ensure data integrity.
  - Establish a mechanism for ongoing, continual gathering.
  - Generate transparent baseline aggregate forecasts.
  - Incorporate information from specific market research studies.
  - Serve as a neutral, trusted third party for information sharing and demand forecasting.
- An assessment of potential economies of scale and scope supports the creation of a multiproduct, central infomediary.
- The Working Group identified a set of viable options for key functions, institutional home and business model of a global health infomediary.

Taking forecasting seriously requires better information about supply and demand. In fact, the first response to "What do we need to improve demand forecasting?" is "Better information." Dig a bit deeper, and it's clear that part of the wish for better information is actually a desire for less uncertainty: "If only we knew what donors and ministries of health would do in the future, we'd be all set." But a remaining part of the focus on information simply reflects the ineffective systems in place to measure, report and share the "knowables," including those related to disease patterns, product adoption and use, funding, and other factors.

The Global Health Forecasting Working Group investigated the types of information most critical for demand forecasting from the perspectives of a wide range of stakeholders.[1] In addition, the Working Group examined best practices in forecasting, looking outside the somewhat insular world of global health to other sectors where forecasting is crucial. From that work, the Working Group developed an understanding of the information challenges in forecasting for global health products.

Central to the discussion were the incentives that various actors in the value chain have to behave in ways that would generate, share and use information to create the best aggregate forecasts. As discussed in chapter 2, the major stakeholders—funding agencies, procurement agents, global health programs and national buyers—lack clear positive incentives to share information about demand. While they would all like to have accurate forecasts and have no obvious disincentive to share information, few are willing to invest the resources for broad information gathering and sharing because they do not bear the financial risks for poor forecasting. By contrast, suppliers bear a direct economic cost for poor forecasting, particularly for capacity, but they have a disincentive to share individually identified supply information that could leave them vulnerable to competitors or to antitrust allegations.

In developed countries the challenge of sharing supply and demand information for forecasting is addressed through the use of information intermediaries, or infomediaries. While this role varies across industries, they are generally private firms that act as information brokers, providing a vehicle to share data among all stakeholders in the value chain and producing analyses and baseline forecasts that are useful to each stakeholder.

In the pharmaceutical industry core market information on drug consumption and trends is gathered across hundreds of products and a range of diseases in a common data repository operated by such firms as IMS Health, Verispan, Cegedim and NDC Health. IMS Health maintains the largest single data repository for basic drug information and is the most common source used by industry, governments, drug safety organizations and public health institutions. Data in these repositories are collected primarily from suppliers, wholesalers, insurers and to a lesser extent from governments; the data can be disaggregated by categories such as disease, product, dose, geography and time.[2]

What information is needed and who has it?

To better understand what information is needed for forecasting for global health products, what currently exists and the gap between the two, the Working Group assessed the data requirements of key stakeholders in the value chain (see appendix F). The findings highlight several important points:

- Key stakeholders across a variety of disease areas and geographies require similar types of basic information for forecasting. Product-specific and disease-specific information are also necessary, but a substantial set of shared data categories serve as the foundation for demand forecasting for health products.
- Collectively, more information is available than one might imagine. Each stakeholder has access to several important data elements, but these are not systematically shared with others in the value chain.
- In addition to available data, investment in additional data gathering through focused market research, particularly at the country level and for new products is required. Several organizations are beginning to make this investment and models are being developed, but analyses and methodologies are not widely shared.

Each of these findings is discussed below.

Common data needs and gaps exist

Several international initiatives have been recently created to collect and disseminate information relevant to forecasting, as their central function or as part of their broader mandate.[3] Most of these are focused on providing certain sets of information for specific diseases or products, and forecasters often go through similar processes to search for reliable data sources and to compare and clean data so they are usable for forecasting. Researchers often identify the same data sources, resulting in significant duplication of effort and resource investment to gather core information. For example, the strong link among HIV/AIDS, tuberculosis and malaria requires forecasters in any of these areas to gather information on all three to obtain a realistic picture of epidemiology and underlying needs.[4] Because information is not systematically shared across disease areas, resulting forecasts may not consider competing disease priorities or product introductions in their projections.

The most important information needs of forecasters can be grouped into five broad categories: international and macroeconomic data; population and health data; product information; specific national information; and behavioral data (see appendix F). Of 16 subcategories of data, 7 have critical gaps in quality, availability or both across a variety of stakeholders:

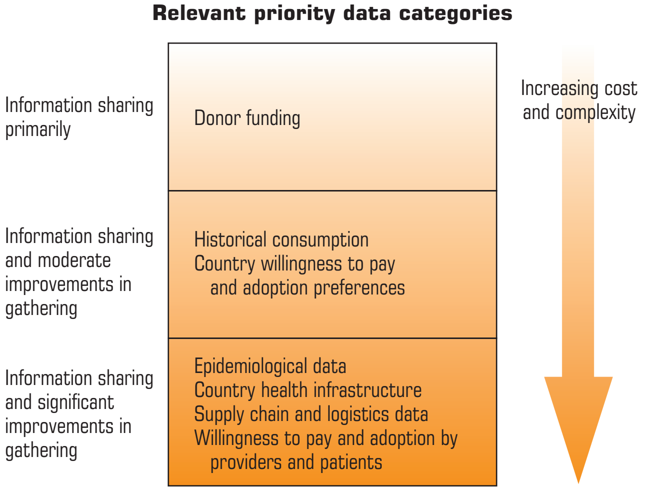
- Information about international donor funding and approved and projected funded demand.
- Historical consumption data.
- Information about willingness to pay and likelihood of adoption by policymakers at the country level.
- Epidemiological data.
- Country health infrastructure information.
- Country supply chain and logistics information.
- Information about willingness to pay and likelihood of adoption by providers and patients.

Data exist but are not shared

Data needs fall along a spectrum—from information that is currently available and needs to be better aggregated and shared to information that is not known and will require investment in further market research (figure 4.1).

Much of the information that does exist is gathered by suppliers and a few global players, including international agencies such as WHO and UNICEF; funders such as the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and GAVI; and large procurement agents. Though available, data are often not accessible or presented in a form useful for forecasting without extensive research. In addition, different data sources for the same information may show widely different estimates of basic variables (epidemiology, for example), and no single source seems to serve as the reference for specific data elements.

Figure 4.1
Approaching the information gap


Relevant priority data categories
Information sharing primarily
Donor funding
Information sharing and moderate improvements in gathering
Historical consumption
Country willingness to pay and adoption preferences
Information sharing and significant improvements in gathering
Epidemiological data
Country health infrastructure
Supply chain and logistics data
Willingness to pay and adoption by providers and patients
Increasing cost and complexity

While country-level data are more difficult to collect and aggregate, important data elements are collected by ministries of health, country disease programs, and wholesalers and distributors. International supply chain consultants such as John Snow Inc. and Management Sciences for Health also have access to a wide range of local data. A key complaint of country-level supply chain managers is that because data are often collected by disease rather than across the health system, each disease program houses its data in separate databases. This does not provide the comprehensive picture necessary to create and manage an efficient supply chain that uses limited resources optimally.

The tasks of gathering these disparate pieces of information and ensuring consistent and high-quality data are not trivial; they could have enormous benefit for ensuring access to life-saving drugs and supplies.

More and better market research is needed

Even if all existing data were shared, gaps in understanding of demand and supply would remain. Filling these gaps requires both continual data gathering on core parameters and investing in policy and primary market research. Three levels of market research are required to gather these data:

- Continual collection of data on basic supply and demand parameters such as consumption of products by disease area and therapeutic category; these types of data are usually collected by firms managing central data repositories.
- Policy preferences at the international, national and subregional levels; for example, what factors will determine whether Zambia adopts one first-line antiretroviral therapy regimen over another? How much will price play a role versus established relationships with suppliers and potential switching costs from older therapies? What factors will influence Ethiopia's adoption of WHO guidelines for the next generation of antimalaria drugs and how will this affect how quickly it switches to the current version of ACTs?
- Specific but generally ad hoc analyses of particular markets to provide a detailed understanding of local consumer and provider preferences. This type of research is generally conducted for new product introductions often by consumer research marketing firms or—increasingly in developing countries—by social marketing firms. Primary market research at this level requires significant time and effort; for example, visiting individual vendors in Indian villages to analyze prescriptions for tuberculosis drugs to understand local prescribing patterns and distribution channels and how they might affect demand for the next generation of tuberculosis therapy.

All these types of market research provide information that can be used by a variety of stakeholders across the value chain and across diseases. For example, research on uptake rates for new products can provide market analogues for forecasting other products in similar therapeutic classes, with similar geographies or with similar delivery modes or price points.

In developed countries the role of sharing data and continual data gathering on core supply and demand is usually handled by a few large firms. For the second and third levels of policy and primary research hundreds of firms have emerged to serve unique market research niches.

To better understand the capabilities that exist for all levels of data sharing and gathering and how they can serve developing countries' needs, the Working Group gathered information from an array of public and private firms that specialize in information sharing, market analyses and various types of market research.

Research by the Working Group led to the following findings and conclusions:

- Currently no single firm provides the full range of information sharing, market analysis, consulting and primary research services for many developing countries. A coordinated approach to gathering new data will require an existing or new body to develop partnerships with a wide range of firms and to manage the collection, analysis and dissemination of market research studies. Most companies have concentrated on developed country markets, but many are now focusing on emerging markets, particularly in Asia and Latin America, and private markets in middle-income countries in Africa. Specific market research capability, though, remains limited in low-income countries in Africa.
- In information sharing and the first level of market research, which involves continual collection of data on basic supply and demand parameters, IMS or a similar organization with an existing large data repository of basic information from hundreds of suppliers and wholesalers, provides a platform that could be expanded to gather and share data on developing world health products.
- A variety of businesses have expertise in market analysis and research across the spectrum of policy research to clinician- and patient-level data gathering. Some have worked in specific disease areas and developing countries. Several have contracted with public-private product development partnerships or international organizations to conduct one-off market research studies. If the market insights gained by these firms are to benefit the global health community more broadly, there needs to be a mechanism for sharing information systematically and for ensuring that data and analyses are not proprietary to the research firm. These studies should also be collected in a common repository to provide market analogues for other public-private product development partnerships, international agencies and suppliers to use.
- There is a need to build expertise in conducting primary market research in developing countries and low-income environments and to commission studies that improve understanding of how health products actually reach patients. This includes such issues as how distribution

channels function in private and public markets, what prices are paid by the patient, what the price elasticity is at the household level and what factors influence clinician prescribing patterns. If this information is to improve matching of supply and demand in the health market more broadly, information, analyses and methodologies need to be nonpropriety and widely disseminated. Recognizing this, some public-private product development partnerships, such as the TB Alliance, have recently made deliberate efforts to share their market research studies.

The need for a global health infomediary

Opacity of data from value chain constituents—including suppliers, funding agencies, national buyers and procurement agents—increases demand uncertainty and its associated risks. Two aspects of information sharing help reduce these risks. First, since each player has different information sets, combining information will improve forecasting accuracy (for example, the national buyer has better information about the status of procurement plans, the manufacturer knows more about supply constraints, and the procurement agent knows about country preferences for specific manufacturers). Second, even when some information from different players overlaps, it can produce a confirmation effect that increases forecast certainty and gives greater confidence to stakeholders in the forecasts produced.

The fragmentation of the market for global health products diffuses accountability for information sharing, and no single player has a clear incentive to share this information. This suggests the need for an infomediary for global health to effectively gather and analyze data needed for demand forecasts across a variety of diseases and products and to make this information widely available to all stakeholders.[5]

An infomediary would not address all the gaps in data that require policy and primary market research. It would instead serve as a repository to share data as they are gathered and to provide a mechanism for continual collection of core data elements.

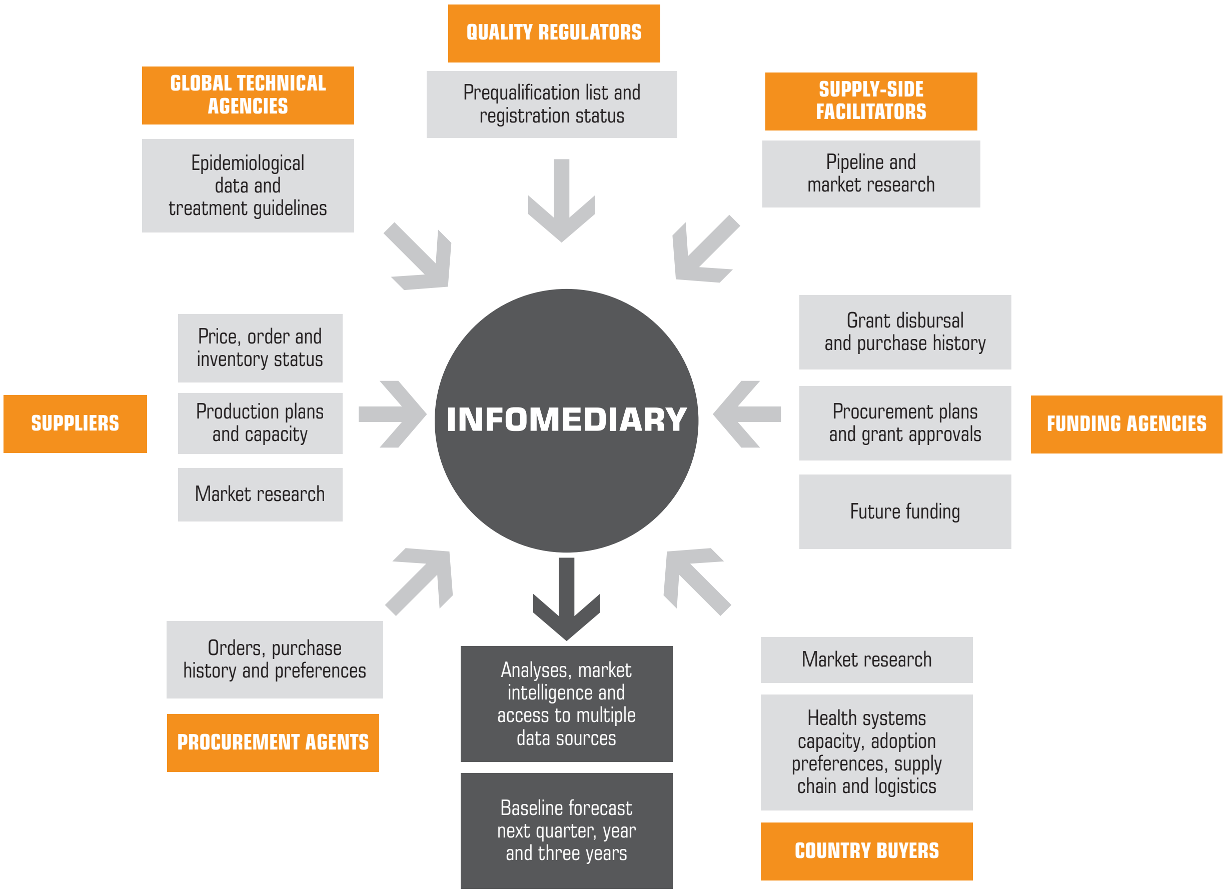
Specifically, key functions of the infomediary would be to:

- Serve as central repository of all relevant demand and supply data by collecting, synthesizing and disseminating information related to forecasting that individual organizations may not be willing or able to share independently (for example, due to antitrust concerns).
- Ensure data integrity and perform the labor-intensive tasks of cleaning and analyzing data received from multiple sources.
- Establish a mechanism for ongoing, continual gathering and updating of core forecasting information.
- Generate transparent baseline aggregate forecasts by product category based on the information sets provided that could serve as the common starting point for stakeholders to produce their own forecasts. Build aggregate and country-level models for generating demand forecasts that consider the unique developing country environment. The forecasts would be most valuable for products that are entering the market (or soon to enter). They could also be constructed, in the spirit of demand scenarios, for products that are quite far upstream in the development process but for which it would be useful to understand the main drivers of demand and capacity creation, at the country, regional and global levels.
- Incorporate information from specific market research studies that are conducted by the infomediary or other market research firms and stakeholders to provide a more complete data repository and refine assumptions for forecasts.
- Serve as a neutral and credible third party responsible only for information collection and generating baseline forecasts and not involved in demand generation, advocacy, target setting or other functions that could compromise the integrity and independence of activities. Maintain strong relationships with public and private supply chain partners and establish credibility with stakeholders.

While recognizing that those concerned with specific product categories and branded products will always need to engage in their own demand forecasting exercises to answer funder- or firm-specific questions, there are strong arguments for creating an infomediary with broad product and disease scope and multiple, centrally organized functions. These include:

- The efficiencies of obtaining and sharing the common data elements required across products.
- The strong benefit to country health systems of having information across a wide range of diseases and products to develop and manage efficient supply chain processes. While disease-specific repositories exist in many countries, they do not provide health systems or procurement

Figure 4.2
Schematic of a global health infomediary


QUALITY REGULATORS
Prequalification list and registration status
GLOBAL TECHNICAL AGENCIES
Epidemiological data and treatment guidelines
SUPPLY-SIDE FACILITATORS
Pipeline and market research
SUPPLIERS
Price, order and inventory status
Production plans and capacity
Market research
INFOMEDIARY
Grant disbursal and purchase history
Procurement plans and grant approvals
Future funding
FUNDING AGENCIES
Orders, purchase history and preferences
PROCUREMENT AGENTS
Analyses, market intelligence and access to multiple data sources
Baseline forecast next quarter, year and three years
Market research
Health systems capacity, adoption preferences, supply chain and logistics
COUNTRY BUYERS

Source: Yadav, Curtis, and Sekhri 2006.

managers with the tools they need to manage across the range of essential health products. In developed countries integrated repositories are essential for ensuring health system efficiency.

- The advantage of building and reinforcing relationships with a relatively small number of players (manufacturers, regulatory bodies, technical agencies and funders) who influence the market for many different types of products.
- The value of developing, refining and using similar forecasting methods appropriate across a range of global health products. This increases both forecasting and planning accuracy because dependencies across products and diseases can be better understood.

Implementation considerations for a global health infomediary

A global health infomediary must have three distinct but related components to have real value for stakeholders:

- *Developing a repository structure to gather and house data and provide analyses and forecasts by therapeutic category, geography and other parameters.* Considerations in constructing the repository structure include:[6]

  - *Database design and implementation.* What data model and approach best meet the different requirements?
  - *Hosting.* Will the data be viewed as commercially or otherwise sensitive? Will local or Web-based access be required? What response times are needed? What backup facilities are required?
  - *Access.* Will this be limited to specific users or organizations or will wide access be allowed? How will individual data be protected if access is broad?
  - *Reporting flexibility.* Will the repository feed other external systems? What explanatory materials might need to accompany any predefined reports? How flexible can or should the in-built forecasting models be?
  - *Query management.* How can users access the database on an ad hoc basis to meet their individual needs?
- *Populating the repository with available data and creating interfaces to update these data on an ongoing basis.* The task of gathering required data elements in many developing countries will be labor intensive. Initially the repository may contain a few readily available data elements (for example, funding data, consumption as reported by major suppliers, procurement agents and funders) and start with a few diseases. To be most useful to countries, this would expand to cover a broader range of information across multiple diseases and products This could also spawn the creation of national-level repositories that could house much more detailed data at the national level, linking with country-focused initiatives such as the Health Metrics Network. Key considerations include:[7]
  - *Data specification.* What data are needed? How will the data be used and what standards will be used to ensure consistency across time and place? What expectations are there that new data types will emerge?
  - *Data source management.* How will data be delivered, how often and in what format? What will be the responsibility of each stakeholder to ensure data consistency and provide data in a usable format for the repository?
  - *Validation of source data.* Who will be responsible for checking data for content, logic and completeness?
  - *Data input.* What can be automated, what is manual, what will have to be entered locally and what can be entered centrally? How will standards be maintained? Will this be done by the source organization or will data need to be transformed?
- *Gathering and incorporating new data and market research studies as they are conducted from a variety of sources (for example, public-private product development partnerships, suppliers and international agencies).* Considerations include:
  - *Essential market research and ad hoc studies.* What gaps in data must be filled immediately and what gaps can be filled over time as new products are launched or developed?
  - *Collaborating in designing market research studies across products.* Are there opportunities for commissioning joint market research. For example, would a study in India looking at the potential demand for new tuberculosis products also be able to capture information about the demand for specific HIV/AIDS therapies? Could policy research at the country level on what influences adoption of new malaria drugs also provide information on what influences adoption of new antiretroviral treatments?

Changing incentives

For the infomediary to be effective, the neutral or negative incentives of stakeholders to share information must be addressed by clearly defining benefits for each stakeholder. While the preceding discussion may make some of these obvious, it is worthwhile stating that for stakeholders to contribute data they must be assured that:

- Credible outputs, analyses and baseline forecasts are generated to help each stakeholder to better perform its core mission. For suppliers this could mean better and more complete information on demand and demand drivers so that they can appropriately scale up production capacity, resulting in less excess inventory and fewer shortages; for public-private product development partnerships, public-private partnerships and international agencies, this may mean channeling significant time and resources currently spent on data collection to focus on demand generation and advocacy. For funders, this could mean better matching funding flows to product needs resulting in fewer shortages and less waste of donor funds.

- A secure sharing arrangement exists so that information collaboration can take place without revealing any participant-specific data to others.
- Easy interfaces and other data collection and validation support are available to minimize the effort required by each player to provide their data to the infomediary and to access information relevant to them.

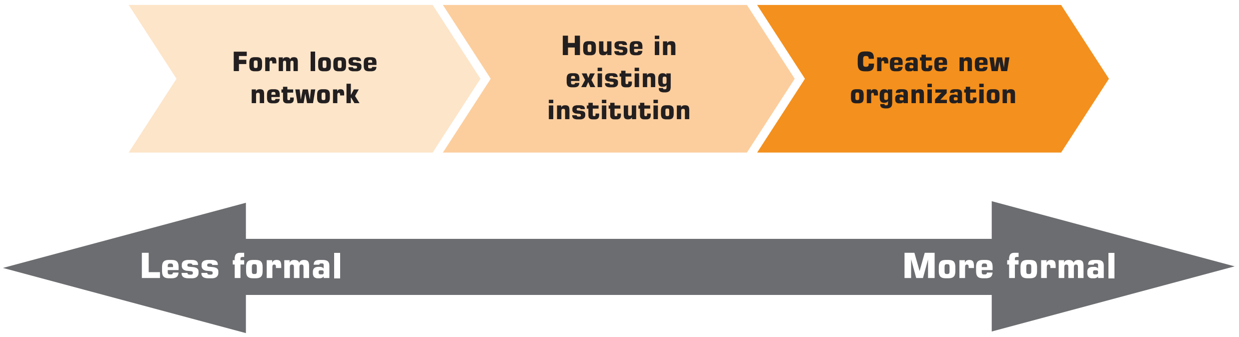
Table 4.1 describes the types of information that would be required from each stakeholder and the benefits that they would receive from participating in a global health infomediary.

Institutional arrangements and governance structures

To constitute the infomediary and ensure that its design and management meet the needs of stakeholders, an appropriate institutional and governance structure would need to be established. No single firm on the market now can perform the full range of infomediary activities for developing country health products without significant input from experts in the diseases and unique circumstances of low- and middle-income countries. For instance, the public-private product development partnerships that have chosen to contract with external firms to gather data for demand forecasting have found that a strong partnership is needed between the domain experts and the contracted organizations to guide data collection and analyses. The need for a formal institutional umbrella could change over time, once sufficient experiences and models exist in a wide range of developing countries.

Institutional arrangements for an infomediary range from a loosely organized committee that coordinates a network of stakeholders to an existing organization serving as host to the infomediary function to the creation of a new entity that manages

Figure 4.3
Spectrum of governance options for a global health infomediary



Selection criteria

- Technical and political independence.
- Legal and financial “fit” with business model.
- Technical expertise in supply chain management and demand forecasting.
- Efficiency and value for money.
- Strong accountability mechanisms.
- Implementation ability.

Table 4.1
Incentives and benefits for stakeholders

Stakeholder	Examples of data provided to infomediary	Examples of benefits received from infomediary
Global technical agencies	• Epidemiological data. • Treatment guidelines.	• Data on access on the ground—that is, effective demand to guide policies. • Consumption information to guide monitoring. • Baseline demand forecasts to be able to focus resources on core functions. • Trends in product usage to guide treatment guidelines and research.
Quality regulators	• Prequalification lists and status. • Approval status of products.	• Actual use of products approved to guide decisions about future approvals. • Systematic quality information from countries on results of batch checks to guide approval decisions.
Supply-side facilitators	• Information on pipeline of drugs and timing. • Policy and primary market research.	• Access to a wide range of market research and data on demand and supply to provide more accurate forecasts. • Ability to focus resources on product introduction activities rather than core data collection.
Funding agencies	• Disbursal information and high-level procurement plans, historical purchase data, future funding expectations and grant approvals.	• Actual consumption data to guide monitoring and evaluation of grants. • Demand forecasts for contracting with suppliers. • Country plans and preferences.
Buyers in country	• Adoption preferences. • Actual consumption and ordering history. • Health systems and supply chain capacity. • Product quality information. • Supply chain and logistics information from disease-specific repositories.	• Baseline demand forecasts to negotiate contracts with suppliers and plan supply chain capacity. • Future funding expectations. • Market research.
Procurement agents	• Historical orders. • Product preferences across buyers. • Consumption data.	• Comprehensive demand information across products and countries. • Trends in usage of products to guide contracting.
Suppliers	• Product sales. • Production capacity inventory status. • Production plans. • Price.	• Market intelligence. • Baseline forecasts to guide company forecasting for capacity planning, production and new product development.

Table 4.2
Preliminary institutional assessment and tradeoffs

Criteria	Form committee	House in existing organization	Create new independent entity
Technical and political independence	Depends on ability of members to represent common interests rather than their own institutional interests.	Depends on organization selected, but very difficult if organization plays multiple other roles.	Would be constituted with this purpose and established to achieve this objective.
Legal and financial "fit" with the business model (for example, ability to manage funds)	Legally difficult for committees to manage money and contract for services.	Depends on organization selected.	Would be constituted with this purpose and established to achieve this objective.
Technical expertise in supply chain management and demand forecasting	Depends on committee membership.	Depends on organization selected.	Would be constituted with this purpose and established to achieve this objective.
Efficiency and value for money with strong commercial skills	Least expensive to establish; commercial skills would depend on membership.	Would be less expensive to establish than creating a new entity; commercial skills would depend on organization selected.	Most expensive option to establish; staff with sound commercial expertise would be recruited.
Strong accountability mechanisms including an independent, legal board of directors	Difficult in practice for committees to have strong formal lines of accountability.	Depends on organization selected.	Would be constituted with this purpose and established to achieve this objective.
Implementation	Would be easiest to establish.	Would be moderately easy to establish.	Would take longest time and greatest effort to establish.

a wide range of information management, market research and stakeholder liaison functions (figure 4.3). In any of these arrangements the entity could choose to outsource certain functions or perform them in-house depending on market, capability and cost-benefit analyses.

A variety of institutional arrangements along this spectrum that could be feasible and each has tradeoffs that require consideration. The Working Group does not recommend a particular arrangement, but whatever institutional structure is selected must ensure:

- *Technical and political independence in managing the relationship between the infomediary and stakeholders.* Most important, the organization should by design be a neutral, trusted third party that focuses on forecasting demand, not on stimulating, advocating or filling demand. If the organization is also involved as another stakeholder in the supply chain, this can create a conflict of interest that can jeopardize the credibility of analyses and forecasts produced.

Box 4.1
How an infomediary helps take forecasting seriously

An infomediary could perform several activities to promote forecasting and to improve understanding of demand. In particular, they might:

- Share knowledge on forecasting by:
  - Serving as a technical resource, promoting the use of forecasting principles and sound forecasting practices.
  - Providing support to organizations doing demand forecasting by responding to questions, referrals to technical forecasters and attending related conferences.
  - Forming a network of entities engaged in forecasting for global health products; perhaps hosting a forum and holding regular online and in-person discussions for forecasters.
  - Engaging a broader audience in forecasting activities.
- Apply forecasting knowledge by:
  - Providing support and direction in the development of market research studies and forecasts.
  - Establishing framework contracts with market research firms that could be used as needed to collect data in developing country markets.
- Develop knowledge in forecasting for developing country health products by:
  - Building an expertise in forecasting for global health products thorough commissioning original, practically oriented research on relevant topics.
  - Keeping apprised of the latest concepts in the field and providing tools and analyses to apply these to global health products.
  - Providing assistance to organizations to test and implement demand forecasting concepts.
  - Taking advantage of expertise in information sharing, market research and supply chains in developed countries and adapting these tools to the developing countries.

- *Legal and financial "fit" with the business model, including the ability to establish contracts with private for-profit firms and a wide range of stakeholders and potentially participate in risk sharing if needed.*
- *Technical expertise in supply chain management and demand forecasting for developing country health products to guide data gathering, analyses and the creation of forecasting and market research models that are most relevant to stakeholders.* Technical expertise includes the ability to contract for the development of a multiparty and multilevel data aggregation and information management system and the ability to provide advanced technical and analytics capabilities in demand forecasting.
- *Efficiency and value for money in the operations of the infomediary, data gathering and market research.* Strong commercial skills, including those in financial management and contracting, will be necessary to develop and manage a self-sustaining business model.
- *Strong accountability to an independent board of directors composed of a wide range of stakeholders and investors.* The legally independent governance structure should be able to effectively balance the conflicting interests of stakeholders.
- *Implementation ability to allow the creation of the infomediary expeditiously and with adequate participation by key stakeholders.*

Table 4.2 identifies some of the tradeoffs of each option in relation to the criteria above.

In addition to these core functions, a variety of other forecasting related activities could be undertaken to take forecasting seriously and improve understanding of demand for health products in developing countries (box 4.1).

Funding and business model

The basic business model provides for a self-sustaining organization that would operate on a tiered subscription system for core infomediary outputs. The entity could be legally for-profit or not-for-profit as long as it is independent, financially viable and conscious of its mission to provide affordable information to developing countries.

Startup funding would be required to develop the basic repository and core data collection, including populating the repository with available data and creating interfaces to update data on an ongoing basis. This could come either through a single funder or a consortium of private or public sector funders.

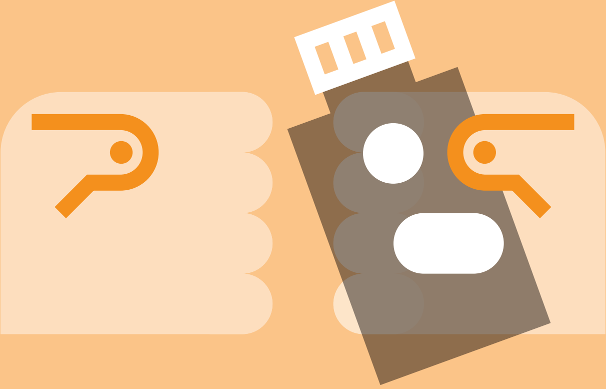
Ongoing distribution of analyses and forecasting information to a wide range of audiences would be provided at a fee to clients or at a fee to a consortium that would fund an ongoing set of information collection activities. To avoid free-riding while ensuring that data were available to those who need it, different levels of access could be established that allowed more detailed information for those with more contributions in money, time or other inputs. A sliding scale of fees also could be established based on ability to pay and in some cases donors or foundations might wish to subsidize access to low-income users.

Funding of targeted policy and primary market research studies to fill data gaps could continue to be done through individual institutions, or there may be opportunities to pool resources to conduct joint studies either through the infomediary or through separate firms. The Working Group does not propose a separate financial pool to fund market research studies, but this could be a possibility. In any case, a mechanism to input the data gathered from these studies into the common repository would be needed to ensure that all stakeholders benefit from the research.

Conclusion

The Working Group recommends that interested parties in the international funding, public health and supplier communities explore collaborating to create a global health infomediary. This would include analyzing core functions and institutional options and assessing the costs of each option. A promising approach to ensure the best possible arrangement that builds on the considerable expertise and institutional capacity for demand forecasting would be to develop a request for proposals that would welcome submissions from public agencies, not-for-profit private organizations and private firms.

As valuable as an infomediary would be, improvements in demand forecasting are unlikely to be fully realized without attention to the underlying asymmetries in the distribution of risk. Only with a more efficient risk allocation will all parties who can improve information, supply chain function and funding flows be motivated to do so. Recommendations related to risk sharing are presented in the next chapter.



5

Recommendation 3: share risks and align incentives for better forecasting

Chapter at a glance

- Aligning incentives among stakeholders to improve access requires sharing risks more efficiently.

- Selecting from a wider menu of contracting options provides a more immediate way of sharing risk, including:
  - Minimum purchase commitments.
  - Flexible-quantity contracts.
  - Buyback contracts.
  - Revenue sharing.
  - Real options.
  - Pooled procurement.

- Participating in risk-sharing contracts raises the stakes, making it more urgent to produce credible and accurate demand forecasts and participate in information-sharing mechanisms to mitigate some of the underlying risk.

Efficient contracts balance the costs of risk bearing against the resulting incentive gains that motivate all parties to perform at or above contractually specified levels.[1] Efficient risk sharing in the market reallocates unavoidable risks in a way that makes all participants better off.[2]

Aligning incentives among stakeholders

In a perfect world demand forecasts would be accurate, transparent and shared openly across a wide range of stakeholders to permit more efficient functioning of the entire value chain. However, as the misalignments for forecasting show, stakeholders need clearer incentives to produce accurate forecasts. And that means that they must share more directly in the risk of producing inaccurate forecasts.

Risk sharing can be done by changing the relationships of various stakeholders in the market or by structuring contracts between stakeholders in different ways. Methods to change the basic market structure include franchising, insurance, leasing and partnerships.[3] But while there may be opportunities to change the fundamental market structure for global health products to distribute risk differently among stakeholders, opportunities to better align incentives and share risks by restructuring contracts are more immediate. Effective contracting is also critical for ensuring that pooled purchasing mechanisms, which many funders are considering, achieve their objectives.

Binding contracts strengthen good forecasting. They make it in everyone's interest to take forecasting seriously. But binding contracts require good information, so the creation of a global health infomediary is a necessary first step for changing contracting practices.

Selecting from a wider menu of contracting options

A second step is to widen the set of contracting approaches used to procure essential medical technologies. Currently, most spending on health products is on supplies that manufacturers are expected to have on hand to respond to orders as they come in; long-term contracts with some type of risk sharing, or minimum guarantee off take, are rare. There are exceptions: for example, USAID and the Clinton Foundation HIV/AIDS Initiative, which have established contracts that commit purchasers to buying a minimum amount of a product, while also indicating an intention to purchase up to an agreed maximum.

Global health funders have made only limited use of the wide range of risk-sharing arrangements available.

Minimum purchase commitments

Minimum purchase commitments require that a buyer agree to purchase a specified quantity of a product, either in a single transaction or over time. By accepting some of the supplier's risk of production, the buyer has an incentive to accurately forecast demand. Typically, suppliers offer incentives to buyers to take on this risk through reduced prices for the minimum purchase commitment. Suppliers are not committed to producing above the specified amounts, so this arrangement works best for the purchaser when long-term demand is stable, substitutes are available that prevent stockout risk or there are opportunities to off-load excess inventory.

Flexible-quantity contracts

When demand uncertainty is high, buyers may prefer committing to a lower level of demand while retaining the flexibility to purchase more product to guard against stockouts. Flexible-quantity contracts allow the buyer to commit to a minimum amount at a certain price, while binding the supplier to make a specified additional quantity available at a premium price should demand be greater than expected. Suppliers may be interested in these contracts if the marginal cost of production is low, but the base setup costs are high if there are multiple suppliers or if there is uncertainty about which supplier a purchaser will select. The contract may also allow suppliers to collaborate to buy and sell excess inventory, which limits each supplier's individual risk. A variation is the rolling-horizon contract that has been proposed for ACTs for malaria (box 5.1).

Buyback contracts

Buyback contracts are useful in situations where demand is unstable but the risk of stockouts is asymmetrically distributed among stakeholders and has significant public health consequences. Such contracts are often used when the production cycle is long and it is difficult to scale up supply rapidly in cases of higher than expected demand or where the presence of supply can stimulate demand.[4]

Revenue sharing

Like buyback contracts, revenue sharing is useful in situations where demand is uncertain but the presence of the product

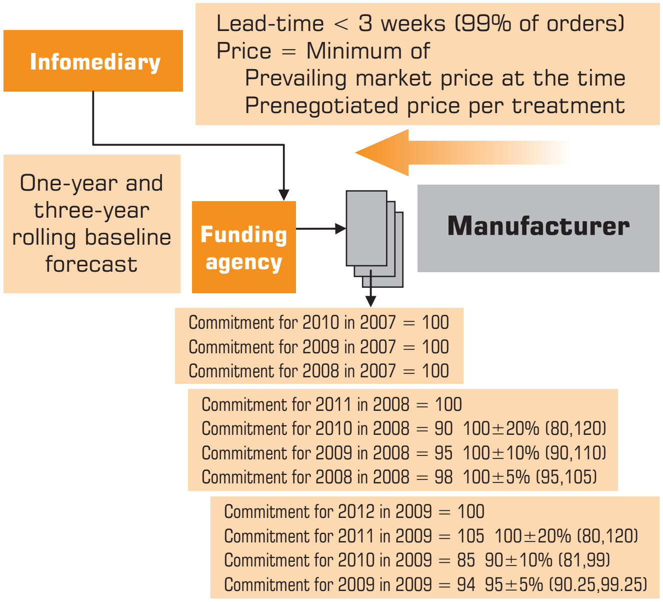
Box 5.1
Rolling-horizon forecast commitments

A rolling horizon forecast commitment has been proposed for ACTs for malaria because it transfers some of the long-term excess-inventory risk to funding agencies, while manufacturers retain most of the short-term risk. The mechanism provides funding agencies with a high level of long-term flexibility but less medium-term flexibility. These types of contracts have been used in electronics and telecommunication equipment supply chains, and a rigorous mathematical analysis of such contracts can be found in Quantitative Models for Supply Chain Management.[1]

In the rolling-horizon forecast contract the funding agency commits to purchase a certain quantity of the product in each of the following three years, with some flexibility on updating the commitment as new information becomes available. In return for the flexible purchase commitments the manufacturer guarantees the funding agency a maximum allowed lead time, upside purchase flexibility and low acquisition cost. Explicit contractual penalties are defined for the manufacturer if it is unable to meet its lead-time commitment or upside supply guarantee. Thus, the funding agency reduces its risk of supply shortage and price uncertainty by taking on some of the demand uncertainty risk. This is clearly a rational allocation of risks: manufacturers control price and supply and hence undertake those risks, and funding agencies have the most influence over levers to reduce demand uncertainty and hence undertake those risks. An appropriate flexibility parameter in the purchase commitment helps to strike a balance in the risk faced by the manufacturers and by the funding agencies.

A proposed rolling-horizon forecast commitment mechanism can be illustrated with a simple example. Imagine that in 2007 the funding agency provides the manufacturer with an advanced partially flexible commitment to purchase 100 units in 2010. In 2008 the funding agency has the flexibility to update its earlier commitment of 100 units by ±20% (between 80 and 120 units) should new forecast information indicate a change in demand. Now, say that the funding agency has new information to conclude that some of the orders slated to be placed in 2010 will now be placed in later years. It will revise its earlier commitment of 100 and choose a new commitment of 90 for 2010. In 2009 the funding agency, as it gains more precise information about quantity and timing of order placement, has the ability to further update its earlier estimate of 90 units for 2010 by ±10%, so the new commitment could be between 81 and 99. Assume it chooses to commit for only 85 units. At the start of 2010 the funding agency has one last chance to change its estimate by ±5% and therefore can

Example of risk sharing arrangements in rolling-horizon contract


Lead-time < 3 weeks (99% of orders)
Price = Minimum of
Prevailing market price at the time
Prenegotiated price per treatment
Infomediary
One-year and three-year rolling baseline forecast
Funding agency
Manufacturer
Commitment for 2010 in 2007 = 100
Commitment for 2009 in 2007 = 100
Commitment for 2008 in 2007 = 100
Commitment for 2011 in 2008 = 100
Commitment for 2010 in 2008 = 90 100±20% (80,120)
Commitment for 2009 in 2008 = 95 100±10% (90,110)
Commitment for 2008 in 2008 = 98 100±5% (95,105)
Commitment for 2012 in 2009 = 100
Commitment for 2011 in 2009 = 105 100±20% (80,120)
Commitment for 2010 in 2009 = 85 90±10% (81,99)
Commitment for 2009 in 2009 = 94 95±5% (90.25,99.25)

(continued on next page)

Box 5.1 (continued)
Rolling-horizon forecast commitments

now choose any quantity between 80 and 89, which then becomes its firm commitment to purchase. The manufacturer will guarantee the availability of 89 units with a three-week lead time. The figure illustrates this example.

The flexibility in the commitments at each stage and any contractual penalties for not meeting the guaranteed lead times need to be chosen carefully based on a thorough analysis of the forecast certainty, risk aversion ability and similar factors. The timing of the placement of orders within the year is a risk that the manufacturer undertakes as before.

In summary, bearing some of the long-term overage risk will incentivize the funding agencies to adopt stricter policies on timely procurement by recipient countries and to allocate sufficient amounts in early-stage grants to build an agile procurement organization within recipient countries.

Source: Yadav, Curtis, and Sekhri 2006. 1. Anupindi and Bassok 1999.

stimulates demand. This mechanism also encourages the sharing of demand and supply information between purchasers and suppliers. For example, the widespread and visible availability of bednets can stimulate their use. However, small local retailers may not have the cash flow to purchase a large number of bednets. In this case the supplier may make the bednets available to local retailers at a nominal price with the opportunity to share in the retailer's profits from bednet sales. Revenue sharing passes risk to the supplier but also aligns supplier and retailer incentives and encourages suppliers to produce sufficient levels of supply. When this system works well, suppliers get timely information about actual sales since they share in the profits generated by those sales and can adjust production capacity accordingly.

Real options

This contracting mechanism protects buyers against price uncertainty. An option gives the buyer the right (but not the obligation) to take some action at a future time for a predetermined price. Real options involve the actual sale and purchase of goods if and when the option is exercised. An option is defined by the option price (upfront price paid to acquire the option), exercise price (price at which the product can be purchased if the option is exercised) and an exercise date (typically a date range). A common form of real-options contract described in the supply chain management literature involves the buyer making a firm commitment to the manufacturer for future year purchases (years 1, 2, 3) for a certain amount of product and purchasing an option to buy additional units at predetermined prices in years 2 and 3. Based on observed demand in the first year, the buyer decides whether to exercise the option in the second and third years. Real-option contracts can achieve results similar to those in rolling-horizon flexibility contracts (see box 5.1).

Pooled-procurement mechanisms

The term pooled procurement has often been used as a catchall phrase for a spectrum of activities ranging from pooling information to pooling financing to pooling contracting to jointly purchasing drugs and commodities, which is how the term is defined in the classic supply chain literature (box 5.2).

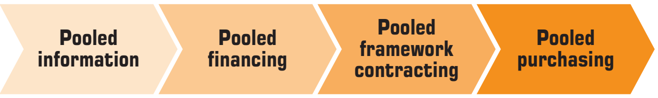
Conclusion

No single contracting option is optimal across all types of products and situations. Rather, a range of approaches should be considered that shift the allocation of risk. Currently, funders, procurement agents and national buyers in global health programs accept little or no risk, while suppliers gear their decisions about pricing and investments in capacity to a market in which they face significant unshared risk. While funders are the obvious stakeholders to bear greater risks in the supply chain, they should seek ways for other intermediaries to share in some of this risk as well. For

Box 5.2
Pooled procurement

Many funders are using or considering what they call “pooled procurement” mechanisms as a way to reduce price and, to some extent, better align incentives in the market. The term includes a spectrum of activities ranging from pooling information to pooling financing to pooling contracting to jointly purchasing drugs and commodities (see figure).

Types of pooling



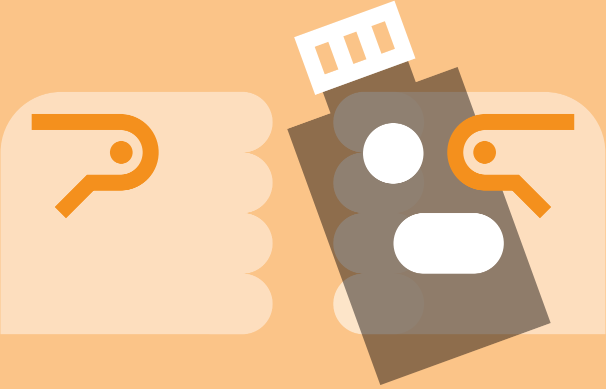
Moving along this continuum affects how much risk is reallocated and what outcome will be achieved. For example, mechanisms that pool information or financing can reduce overall risk in the market and create a more transparent environment. In some cases this will be sufficient to address the main distortions in the market. In other cases the remaining risk will need to be reallocated to ensure that the market functions efficiently. In these cases methods such as pooled framework contracting can be very effective for sharing risks between suppliers and buyers.

Pooled purchasing is most effective for creating new markets or reducing price. Because price reduction is a key reason for pooled purchasing, in traditional joint-purchasing arrangements buyers have limited choice of products. While these types of arrangements can reduce price and transaction costs, they are not a particularly effective way to reallocate market risk or ensure a competitive environment for new products.

Funders and others need to carefully consider their desired outcomes to determine how far they should progress along this continuum.

example, in the U.S. pharmaceutical supply chain procurement agents in the role of wholesalers bear some of the risk for poor forecasting. Buyers also bear some of these risks by participating in binding contracts. Similar risk-sharing arrangements should be considered for global health products. The benefits will accrue to everyone.

Stakeholders can also consider other strategies for risk sharing, such as more effective use of buffer stocks and developing regional supply hubs. While these are not explicitly addressed in this report, the general principle of creating a more efficient market by realigning the risks borne by each party is fundamental to ensuring long-term access to essential medical products.



6

An agenda for stakeholders

Chapter at a glance

- Full implementation of the mutually reinforcing near-term recommendations for improving demand forecasting is essential to support the broad objective of access to live-saving products.
- Success requires bold action on the part of donors, industry, national health programs and intermediaries.
- Reducing the structural uncertainties in global health requires a broader and longer term agenda of:
    - Strengthening country health systems and building supply chain capacity.
    - Increasing the market orientation of product development activities.
    - Enhancing the regulatory regimes and enforcement for global health products.
    - Improving the predictability of donor funding.

As more money becomes available for developing and purchasing products to diagnose, prevent and treat leading causes of death and disability in developing countries, the need to improve demand forecasting increases. Major pharmaceutical manufacturers cite inadequate demand forecasting as a major deterrent to greater engagement in developing country markets, and the market risks associated with forecasting are the source of inefficiencies—reflected in poor health and financial costs.

Chapters 3–5 present the Global Health Forecasting Working Group's major recommendations for addressing the challenge of demand forecasting in the near term: elevate demand forecasting as a vital function in the supply chain at all levels, create an infomediary to act as an impartial source of and clearinghouse for critical information about the supply of and demand for health technologies and broaden the range of contractual arrangements for procurement of global health products to include risk sharing between funders and suppliers.

These recommendations can be implemented independently or simultaneously—and they are mutually reinforcing. Armed with better information from a credible infomediary and better forecasting, funders and others can assume a larger portion of risk, allowing a greater return on their aid investment in the form of improved public health outcomes. Efficient contracting arrangements, in turn, provide a larger incentive for participants to improve data collection to produce reliable forecasts. More equitable risk sharing increases the importance of sharing information through an infomediary because better information mitigates shared risks. Fully implemented, these recommendations can save lives by dramatically improving aggregate demand forecasts for critical medical technologies.

Toward implementation

Achieving better demand forecasts for—and better access to—critical medical technologies in developing countries requires collaboration and investment from all key stakeholders in the value chain of these products and will benefit each of them in turn. The Working Group's three recommendations are feasible in the near term—with only modest financial resources. While the broader global health community is critical in advocating for the importance of taking forecasting seriously, coordinating information and sharing risk, success ultimately depends on the actions of donors, industry national health programs and those charged with generating demand forecasts.

Donors and funding agencies

Donors and funding agencies such as USAID, the U.K. Department for International Development and the Bill & Melinda Gates Foundation, as well as their beneficiaries such as GAVI and the Global Fund to Fight AIDS, Tuberculosis and Malaria, are fundamentally in the business of saving lives and thus place great value on effective use of their aid dollars. But only with better forecasting and efficient contracting will existing efforts to develop new products actually lead to a return on donors' aid investment in the form of improved public health outcomes.

In the realm of demand forecasting donors now face innovative opportunities both to go further and to translate their work across product streams by committing startup funding to a global health infomediary. These funds would go toward developing a repository structure to gather and house data; providing initial analyses and forecasts; populating the repository with available data and creating interfaces to update this data on an ongoing basis; and incorporating new data and market research studies into the repository as they are conducted. An immediate step toward this end would be a request for proposals that outlines the key functions of the infomediary, its business model and the qualifications of a host institution. Importantly, this should serve needs across products and diseases, contributing to broad systems.

Armed with better information from this infomediary, funders could then increase access to critical medical technologies—and reduce their hidden costs—by assuming a larger share of the financial risk currently borne by suppliers through the adoption of efficient contracting mechanisms.

Suppliers

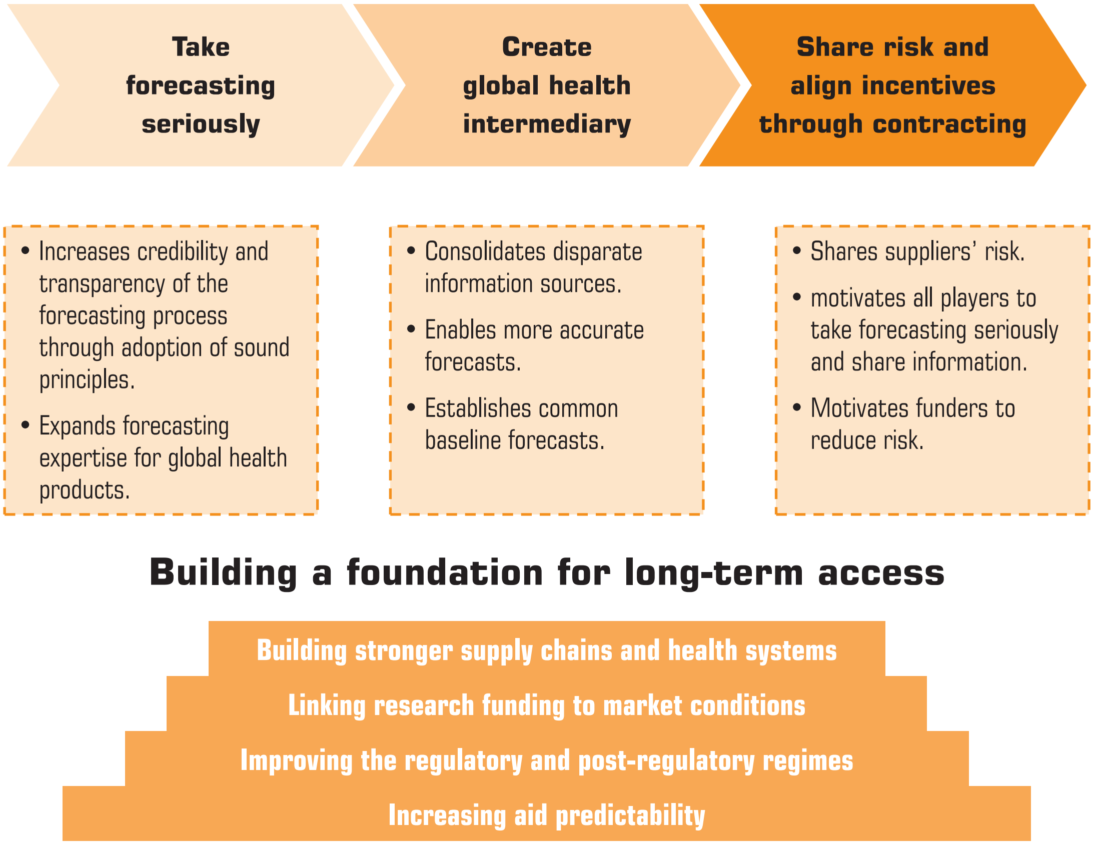
Suppliers of drugs, vaccines, diagnostics and other critical medical technologies value opportunities to serve as good global citizens by providing access to life-saving health interventions in developing countries while also exploring new markets and protecting their corporate interests. By collaborating with international donors and technical agencies, better demand forecasts could be produced to reduce and share risk in these markets, which in turn could help craft better business cases for investing in developing country products and making them available for those who need them most.

Supporting the funding, creation and widespread use of an infomediary that would generate better forecasts is both good for health and good for business. Specifically, individual suppliers could move toward better forecasts by providing both public and proprietary data to a global health infomediary; in turn, they could commit to purchase information and baseline forecasts to inform their internal decisionmaking processes. Suppliers could also contribute by sharing their technical forecasting expertise with other global health stakeholders through forums, online tutorials or other platforms.

National health programs

Developing country governments, and ministries of health in particular, are charged with the essential task of delivering essential health products to as many of their citizens as possible within the context of constrained health system capacity and limited financial resources. Getting district- and country-level demand forecasts right is critical to both the availability and affordability of these products because it eliminates shortages and wastage at the point of delivery and informs decisionmaking further upstream in the supply chain. To achieve this, national program managers can adopt principles of good demand forecasting, including increasing transparency of the demand forecasting process in countries and globally. Above all, the forecasting process must be independent, free from political interference and separate from advocacy and target setting.

Figure 6.1
Recommendations at a glance



Take forecasting seriously

- Increases credibility and transparency of the forecasting process through adoption of sound principles.
- Expands forecasting expertise for global health products.

Create global health intermediary

- Consolidates disparate information sources.
- Enables more accurate forecasts.
- Establishes common baseline forecasts.

Share risk and align incentives through contracting

- Shares suppliers' risk.
- motivates all players to take forecasting seriously and share information.
- Motivates funders to reduce risk.

Building a foundation for long-term access

Building stronger supply chains and health systems

Linking research funding to market conditions

Improving the regulatory and post-regulatory regimes

Increasing aid predictability

Global technical agencies, public-private partnerships and intermediaries

Many organizations have recently emerged with the purpose of generating demand forecasts as part of their broader mandate to improve access to essential medical products. To ensure that their forecasts reduce overall market uncertainty and better match supply and demand, they can adopt principles of good demand forecasting, including ensuring transparency and political independence of forecasting processes and clearly separating forecasting activities from advocacy and target setting.

Looking ahead: building a foundation for long-term access

Implementing the short-term recommendations of the Working Group would greatly enhance trust among funders, suppliers, intermediaries and users of health products. It would go far toward aligning incentives across participants in the global health value chain—essential for long-term improvements in access to quality products. Far from being small technical patches, these recommendations would help new funds and new products realize their potential of better health outcomes in developing countries.

Even with better forecasting capabilities, though, underlying uncertainty will remain in markets for developing country health products. It will require a broader and longer term agenda of strengthening in-country health systems and building supply chain capacity; increasing the market orientation of research funding; enhancing regulatory regimes and enforcement for global health products; and improving the predictability of donor funding. Elements of this broader agenda are discussed below.

Building stronger supply chains and health systems

The global community recognizes that new funding for health must not only fight major diseases but must also strengthen the functioning of developing country health systems. Considerable attention and funding are now being dedicated to supply chain strengthening and on-the-ground logistics and technical capacity. Ideally, these efforts should also include an information feedback system that allows manufacturers to respond more quickly to actual orders instead of relying so heavily on forecasts.

While all the interventions discussed above will greatly improve forecasting accuracy and credibility, forecasting can only go so far in predicting demand in dynamic and rapidly changing markets. An underlying uncertainty remains that affects the short-term matching of supply and demand. Many industries confront this uncertainty by reducing their reliance on forecasting for short-term production decisions. They have re-engineered their production and distribution processes to produce goods in response to actual demand rather than forecasts of demand.

With health technologies, however, uncertainty about future demand makes a significant difference to the probable supply response, since suppliers must make critical investment decisions years in advance because of the long technical and production lead times. This means that price and quantity are a function of supply and forecasted—not actual—demand.

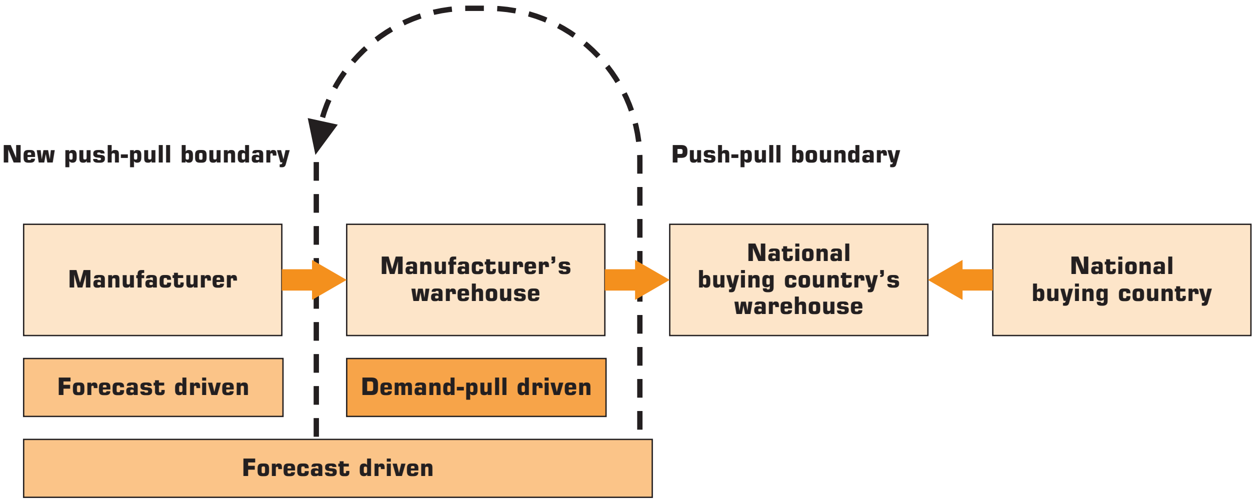
Once a technology reaches the market, a further difficulty arises in the discrepancy between supplier and national supply chains. Suppliers use mainly push-driven supply chains, which are based on anticipated demand, whereas countries often use pull-driven supply chains, which are triggered by orders or actual demand.

Most supply chains incorporate some combination of push and pull processes. The point of interface between push and pull—the push-pull boundary (or inventory-order interface)—varies by supply chain. When demand is uncertain, incorporating more pull processes into a supply chain, or moving the push-pull boundary upstream, can reduce supply and demand mismatches by decreasing the amount of short-term forecasting that is needed (figure 6.2). This can be done through demand-driven supply hubs, for example, that hold inventory and shorten delivery times. These are used in both in the U.K. and U.S. health systems, and the U.S. President's Emergency Plan for AIDS Relief is currently implementing demand-driven supply hubs for several AIDS treatment and prevention products for use in the countries they support.

Linking research funding to market conditions

It is now possible to stimulate considerable R&D activity for global health products. The number of new vaccines, therapeutics and diagnostics may still not be sufficient to tackle the health needs in developing countries, but they represent a qualitative step in that direction. However, the successes in developing a pipeline of potential products creates its own challenges, including but not limited to:

Figure 6.2
Push-pull boundary



Source: Kirsten Curtis, Massachusetts Institute of Technology–Zaragoza International Logistics Program, Zaragoza, Spain.

- How will the product purchases be financed, through domestic or international sources?
- Is the market robust enough to support several similar products simultaneously?
- What are the appropriate incentives to support countries' early introduction of life-saving products?

Given both the positive and negative experiences to date, attention should be given within the public-private product development partnerships to decisionmaking based on a realistic assessment of market conditions and the potential to stimulate demand and introduce and scale up key technologies simultaneously. This might include, for example, carefully assessing the impact on demand of different product profiles and allocating R&D funds accordingly, and undertaking the same sort of serious market analysis that guide commercial enterprises in making the tough "go–no go" decisions at key milestones. More important, the metrics of success for product development partnerships should be related to the true health impacts of the products and the market's long-term capacity to support manufacturers rather than to the number of candidates in the pipeline.

Improving the regulatory and post-regulatory regimes

The current system of regulatory and post-regulatory processes at the global level has emerged as a key bottleneck in the market for critical medical technologies. In many ways this problem is similar to the demand forecasting challenge and could benefit from technical analysis by multiple stakeholders.

Limited information about regulatory processes in low-income countries and post-regulatory processes at the global level as well as in developing countries is a major challenge for demand forecasting. On the regulatory side general information and expertise exist on how to approach internationally recognized regulatory authorities, including the U.S. Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products, and regulatory authorities in countries with large pharmaceutical industries, such as Brazil, China, India and South Africa. However, in low-income countries little information is available on the type of dossier necessary for approval of drugs and other medical products, and registration is often a very slow process.

Post-regulatory processes are even more challenging to understand and predict. Even after a product has been approved by a national regulatory agency, the process to get it introduced into national guidelines is often unclear. Although technical bodies have been constituted to develop treatment guidelines at the global level, no formal or written procedures exist for recommending a new product for treatment. Without such procedures implemented at the country level, a national disease control program is unlikely to change recommendations and introduce new technologies.

A set of solutions to these problems has been discussed, and WHO has been working to strengthen capacities and procedures at the national level (particularly for vaccines), but only limited progress has occurred so far. Among the ideas debated is the creation of regional or subregional regulatory bodies whose decisions would be adhered to by multiple states. Initiatives are also under way to harmonize registration processes among participating countries, to facilitate information sharing on national regulatory activities and to pool resources and expertise to improve approval and review process to match the increasing complexity of product applications. These initiatives could reduce transaction costs for pharmaceutical companies wishing to register products and could reduce administrative costs for countries using a regional service.

These issues are technically and institutionally complex but merit close attention in the near future. As in the case of demand forecasting, many of the core concerns about the regulatory and post-regulatory steps in the value chain affect multiple classes of products, and so a piecemeal solution—for one set of products or one purchaser—is likely to be less satisfactory than a comprehensive approach that serves a broad set of products.

Increasing aid predictability

Finally and perhaps most fundamentally for the long-term agenda, donors should increase the predictability of external funding for health. Funding volatility is perhaps the largest source of uncertainty in the market for the highest value global health products. Predictable aid funding is the exception rather than the rule. The annual budget cycle in developed countries such as Japan and the United States typically determines the volume and allocation of bilateral aid transfers, which fluctuate due to factors unrelated to health need or the ability of public health programs to effectively use resources. While the level of overall donor expenditures has been increasing in recent years, the availability of aid in individual countries has fluctuated significantly, often because of concerns about the political situation or corruption. Funds from multilateral development banks are generally longer term, typically over a five-year horizon. However, even for five-year projects, year-to-year availability of resources is often difficult to predict because of the lack of required counterpart funding, speed of procurement processes, high-level disputes between the sovereign and the bank and so forth.

Studies have found that donor aid is 20 times as volatile as government revenue as a share of GDP in poor countries—and 40 times as volatile as government revenue in constant U.S. dollars per capita.[1] Aid is least predictable in poor countries and fluctuates in a particularly unfortunate, "pro-cyclical" pattern—on average it rises when the economy is on the upswing and falls in times of economic downturn. This is precisely the opposite of what would protect the poor against economic shocks. The pattern is manifested because of the conditions that donors place on their funds, including maintaining International Monetary Fund–prescribed macroeconomic policies designed to keep inflation relatively low and trade relationships open. When donors and private investors lose confidence in a country because of allegations of corruption, countries simultaneously confront economic downturn and less external aid.

Moreover, aid promised does not always mean aid delivered. On average, less than 60% of aid committed actually makes it to programs—due primarily to lags in key activities required to access tranches of funds, such as staffing projects, procuring goods, mobilizing technical assistance and providing reports to donor agencies. This gap is exacerbated by the expense associated with government contractors and other intermediaries, which consumes a significant proportion of aid before it can reach developing countries.

Discouragingly, donor track records of living up to commitments have worsened in the past 5–10 years.[2] This unpredictability severely limits developing country governments' abilities to plan sensibly. Thus, those who count on development assistance do not know whether next year's (or next month's) deliveries of essential drugs will arrive or whether funding will be in place to build schools, health centers and rural roads—or even to finish the investments already started. Moreover, it means that governments find it difficult to efficiently plan program expansion and procure drugs, vaccines and other commodities.

Newer aid instruments in health do show significant promise, and are partially inspired by recognition of the need for

Box 6.1
Future policy research agenda

Several policy research topics emerged from Working Group discussions and constitute part of a longer term research agenda in support of market-related solutions to access to essential products. These include:

- Defining market characteristics of a range of different product types mapped against the degree of risks they face, and an audit of the accompanying incentives, which would help identify the key similarities and differences between products in a consistent manner.
- Understanding regulatory and post-regulatory regimes as a major source of unpredictability and a key constraint to access, characterized by high transaction costs, uncoordinated policy changes and a general lack of responsiveness to the broader market environment.
- Detailing how to strengthen supply chains and procurement systems by shifting the "push-pull boundary" upstream; an analysis would draw on examples from other industries.
- Developing insurance-like mechanisms as a possible method of pooling some of the market risks associated with demand uncertainty by guaranteeing orders.
- Developing approaches to manage the technology "traffic jam" as many new products enter the market, including confronting new questions about how the products will be purchased, whether the market is robust enough to support several similar products simultaneously and what are the appropriate incentives to get countries to quickly adopt these new technologies—work that would benefit from insights from game theory.
- Examining the impact of disease-based funding streams on global health market development.

greater predictability. The GAVI Fund, for example, provided five-year grants for vaccine and supplies purchase during its first phase, 2001–06, and in the second phase will provide commitments for periods of up to 10 years. UNITAID, funded largely through airline ticket levies, is intended to provide a steady flow of resources for the procurement of second-line antiretrovirals, pediatric AIDS formulations and new antimalarial drugs, albeit against an expanding set of needs for them. These efforts for more predictable development assistance are important and deserve the highest level of attention.

This long-term agenda is an ambitious one, but major steps have been taken or are being taken in each area. The Global Health Forecasting Working Group lends strong support to this work and emphasizes that progress in health systems, regulation, product development and health finance is essential to avoiding and reducing unnecessary risks. By eliminating structural sources of market uncertainty, these efforts will work to reinforce the important gains that can be made in the nearer term to improve forecasting and share risk toward the goal of broad access to critical medical technologies.

Abbreviations

ACT	artemisinin combination therapy (for malaria)
CGD	Center for Global Development
CHAI	Clinton Foundation HIV/AIDS Initiative
IAPSO	United Nations Inter-Agency Procurement Services Office
IPM	International Partnership for Microbicides
JSI	John Snow Inc.
MHRA	U.K. Medicines and Healthcare Products Regulatory Agency
MIT	Massachusetts Institute of Technology
MMV	Medicines for Malaria Venture
NHS	U.K. National Health Service
OECD	Organization for Economic Cooperation and Development
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PMI	U.S. President's Malaria Initiative
R&D	research and development
RBM	Roll Back Malaria
UNICEF	United Nations Children's Fund
UNITAID	International Drug Purchase Facility
USAID	United States Agency for International Development
WHO	World Health Organization

Glossary

Aggregate demand forecast. Estimate of the total effective demand for a given product during a specific time period, given assumptions about price (measured in product quantity).

Demand forecasting. Ongoing management process of planning and determining which products will be purchased, where, when and in what quantities (given assumptions about price).

Effective demand. The portion of the affected population expected to have access to the product given country policies and infrastructure, adjusted for individual and country willingness and ability to pay (represented by a curve as a function of product price).

Infomediary. A neutral third-party provider that acts as a custodian, agent and broker of customer information and serves as an intermediary between those who want the information and those who supply the information.

Long-term strategic demand forecast. Long-term hypothetical forecasts of effective demand (aggregate demand) for early-stage products in the development pipeline, assuming various product specifications; used to make an R&D investment case to suppliers and funders (sample product: AIDS vaccine).

Medium-term demand forecast. Demand forecast for a new product entering the market within a five-year time horizon, when the supplier has been identified and general product specifications are known or a multiyear sales forecast for an existing product; primarily used to guide manufacturer's capital investment decisions or a buyer's future funding needs (sample product: pneumococcal vaccine).

Need. Number of people affected by a disease based on epidemiological data and the proportion of those requiring treatment.

Price elasticity of demand. A measure of the degree to which the quantity demanded changes in response to an increase in a product's price.

Pull systems. Supply chains where flows are driven by actual demand (for example, orders or consumption).

Push systems. Supply chains where the flow of goods is driven by forecasts of demand.

Supply chain. A coordinated system of organizations, people, activities, information and resources involved in moving a product or service in physical or virtual manner from supplier to customer. The entities of a supply chain typically consist of manufacturers, service providers, distributors, sales channels (such as retail and e-commerce) and consumers (end customers). Supply chain activities transform raw materials and components into a finished product that is delivered to the end customer.

Supply chain demand forecasts. Used for routine, short-term forecasts of existing commodities to guide short-term production decisions and management of the supply chain after product has entered the market; also known as sales forecasts (sample product: DTP3 vaccine).

Value chain. Encompasses the supply chain as well as the research and development process.

Notes

Executive summary

1. Better forecasting capabilities will not address some of the underlying uncertainties in global health markets. To do so requires a broader and longer term agenda of strengthening in-country health systems and building supply chain capacity, increasing the market orientation of product development activities, enhancing regulatory regimes and enforcement for global health products and improving the predictability of donor funding.
2. The Center for Global Development has no institutional interest in taking on the role of the infomediary.

Chapter 1

1. Sekhri 2006.
2. The President's Malaria Initiative, www.fightingmalaria.gov.
3. UNICEF 2004.
4. GAVI Alliance 2006.
5. Rozenberg 2006.
6. Bulir and Hamann 2006.
7. The Global Fund to Fight AIDS, Tuberculosis and Malaria 2007.
8. The Global Fund to Fight AIDS, Tuberculosis and Malaria 2005.
9. International Drug Purchase Facility, www.unitaid.eu/EN-Mode-de-financement-innovant.html.
10. The Global Fund to Fight AIDS, Tuberculosis and Malaria, Board Information Session on Procurement Initiatives, 21 April 2005, Geneva.
11. Interview with Daniella Ballou-Aares, partner, Dalberg Global Development Advisors, 14 September 2005.
12. Aziz and others 2006.
13. Morbidity and Morality Weekly Report 2006.
14. McKinsey & Company 2006.
15. Based on the fact that the Global Fund has signed more than 400 grant agreements (www.theglobalfund.org).
16. Global Fund's Price Reporting Mechanism.
17. Kimani 2006.
18. McKinsey & Company 2006.
19. WHO 2006.
20. Newton and others 2001.
21. Moran 2006.

Chapter 2

1. However, the use of excess inventory has become more restricted even in developed markets as a result of the U.S. Sarbanes-Oxley legislation, which prevents drug companies from producing inventory above forecasts to counter "dumping" in the market.
2. Fisher 1997.
3. Yadav, Curtis, and Sekhri 2006
4. Expanding the study to map individual country public and private supply chains is recommended to provide a more complete picture of how ACTs reach patients and the specific risks and incentives faced by local stakeholders.
5. Yadav, Curtis, and Sekhri 2006
6. WHO 2005; Snow 2005.
7. WHO 2005.
8. WHO 2005.
9. Sanofi has recently licensed a new fixed-dose combination product, ASAQ, which was not on the market at the time that the risk and incentives audit was conducted. The presence of this competitor is likely to exacerbate several of the risks described below.
10. Public sector prices are as of September 2006.
11. CHAI 2006.
12. Yadav, Curtis, and Sekhri 2006.

Chapter 3

1. Mentzer and Moon 2004.
2. Armstrong 2001c.

3. Armstrong 2001c.
4. A.T. Kearney. 2003.

Chapter 4

1. Dalberg Global Development Advisors 2006
2. Some industries have gone beyond passive information sharing to recognizing that demand forecasting information is a key element of efficient supply chain coordination (Yadav, Curtis, and Sekhri 2006). A variety of companies including Wal-Mart and Best Buy, along with their suppliers such as Procter & Gamble and Kimberly-Clark, participate in the Collaborative Planning, Forecasting and Replenishment Initiative, which was launched to "create collaborative relationships between buyers and sellers through co-managed processes and shared information." Excellent benefits have been reported from this approach.
3. At times, a broader mandate can compete with the needs for forecasting. Because clinicians' needs often dominate decisions about what information to collect, inventory-related information that is of particular value for forecasting may not be collected and reported to higher levels in the supply chain.
4. Jamison and others 1991.
5. The Center for Global Development has no institutional interest in taking on the role of the infomediary.
6. Correspondence with IMS Health in response to the Working Group's request for information.
7. Correspondence with IMS Health in response to the Working Group's request for information.

Chapter 5

1. Tsay, Nahmias, and Agrawal 1999.
2. Eeckhoudt and Schlesinger 2005.
3. Tsay, Nahmias, and Agrawal 1999.
4. Yadav and Schmid 2005.

Chapter 6

1. Bulir and Hamann 2006.
2. Bulir and Hamann 2006.

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Appendix A

Profiles of Working Group members

Deborah Atherly is a health economist and policy officer for PATH's Immunization Solutions Strategic Program, primarily for the Rotavirus Vaccine Program. Rotavirus is a potential new vaccine for developing countries and for funding from the Global Alliance for Vaccines and Immunization, and Atherly is responsible for developing economic information on drugs, vaccines and devices as well as studying the cost-effectiveness of the rotavirus vaccine and creating financing strategies. She also manages a study on the economic impact of Hib vaccine introduction in Senegal. Atherly holds a master of public health degree from the University of Washington's School of Public Health and is a doctoral candidate in the University of Washington's Pharmaceutical Outcomes Research and Policy Program.

Jorge Carrion served as a regional supply chain consultant for the Immunization Unit of the Pan American Health Organization, where he was responsible for the consolidation and analysis of vaccine and syringe demand forecasting for Latin America. He has also worked with supply chains to ensure that demand and supply information is accurately and effectively communicated internally and externally with suppliers and countries. Carrion previously held various positions with Procter & Gamble México, including operations manager, supply chain manager and commercial manager for Latin America, and worked on supply chain management with Tibbet and Britten Group. Carrion holds a bachelor's degree in chemical engineering from the School of Sciences of the Universidad Nacional Autonoma de México, a diploma in business administration and logistics from the School of Business Administration in Mexico and a master's degree in international commerce and policy from George Mason University.

Rob Chisholm has worked in the pharmaceutical industry for 12 years, focusing on all aspects of forecasting and market research for early-stage development projects and large blockbuster products. He has worked for Western and Asian pharmaceutical companies, working on both emerging and developed pharmaceutical markets. Most recently he was head of global market research for Ranbaxy.

Renia Coghlan is the associate director for global access at the Medicines for Malaria Venture. She has 15 years of international health policy experience, with the public and private sectors, nongovernmental organizations and WHO. She brings expertise in access, delivery, market launch and policy for medicines and medical technologies. She holds degrees in international politics, business administration and public health.

Peter Evans is an expert in the area of procurement. Most recently he has provided strategic procurement advice for the establishment of the Asthma Drug Facility and the Global TB Drug Facility. During his 25 years of professional service in the UN system, he has been chief of procurement of WHO, chief of vaccine supply and quality at WHO, chief of medical procurement for UNICEF and chief of procurement for the United Nations Population Fund. Evans holds a bachelor's degree in chemistry and started his professional life in pharmaceutical and vaccine production. He later studied purchasing at the University of Toronto, becoming a professional purchaser. He coauthored *Managing Vaccine Supply,* the companion reference to *Managing Drug Supply,* and holds patents on several types of autodestruct syringes.

Gian Gandhi is a manager of policy research and analysis at the International AIDS Vaccine Initiative. He currently leads a research team focusing on demand forecasting and cost-effectiveness analyses for AIDS vaccines; his other research also includes investigation and development of R&D incentive mechanisms to stimulate further engagement of the private sector in the search for an AIDS vaccine. Gandhi previously spent six years in the pharmaceutical industry in a variety of managerial and research positions in health economics, epidemiology, health policy and market access teams covering these issues for HIV, vaccines, oncology, neurology and respiratory disease portfolios. He holds master of sciences degrees in health economics from the University of York.

John Hurvitz is a partner at the law firm of Covington & Burling, where he is co-chair of the Life Sciences Industry Group and chair of the Technology Transactions Group. He has extensive experience structuring and negotiating commercial, corporate and partnering transactions in the life sciences industry, including highly complex alliances to develop and commercialize products, mergers and acquisitions as well as product and business acquisitions and divestitures. In addition, he is an adjunct professor at Georgetown University Law Center, where he teaches a course on the regulation of drugs, biologics and medical devices. Hurvitz has been active in global health matters. He worked closely with the Center for Global Development in developing the architecture for its advance market commitment proposal, as reflected in *Making Markets for Vaccines: Ideas to Action* (CGD 2005), and subsequently worked with the World Bank and GAVI in connection with the recent funding of a $1.5 billion advance market commitment for a pneumococcal vaccine. He has also represented the International AIDS Vaccine Initiative, the Global HIV Vaccine Enterprise and GAVI on a range of issues. Hurvitz holds a bachelor's degree from Haverford College and a law degree from Yale University Law School.

Stephen Jarrett is the deputy director of UNICEF's Supply Division, where he is responsible for strategic supply issues and problem solving and oversees the global procurement and management of vaccines, pharmaceuticals and immunization materials acquired by UNICEF for more than 100 developing countries in all regions, valued at over $1 billion annually. He maintains contact with senior management in pharmaceutical and vaccine companies worldwide and oversees the procurement services offered by UNICEF to partner agencies in international development. Jarrett recently completed 35 years of service with UNICEF in various capacities, including field assignments in several countries in the Americas in the 1970s and as senior health officer in China in the 1980s, supporting the achievement of universal child immunization. Prior to his current position, he worked in UNICEF as a senior adviser on health systems strengthening, with a focus on drug supply systems in Sub-Saharan Africa and other low-income countries. Jarrett holds a bachelor of sciences degree in civil engineering from the University of Southampton and a master of public health degree from Columbia University. He has published numerous articles on issues concerned with immunization and health services strengthening.

Andrew Jones works on health policy issues at GAVI, focused on new vaccine introduction. He has been at GAVI since 2003 and initially worked on innovative financing instruments and was involved in GAVI's work to develop and launch the International Finance Facility for Immunization. He has worked on advanced market commitments with the World Bank, taking the initial work of CGD and others into a pilot for a pneumococcal vaccine. In addition, he coordinated the work of GAVI's supply strategy group and is the focal point for vaccine supply and procurement activities at the GAVI Secretariat. Previous to his work at GAVI, Jones worked for the Canadian International Development Agency on health systems and immunization issues as a health policy adviser. Jones also worked as an adviser to one of the senior government whips in the U.K. House of Commons. Jones' original background is in science research where he did graduate work on human genetics. Following that, he completed a joint master's degree with the London School of Economics and the London School of Hygiene and Tropical Medicine in health policy planning and financing.

Steve Kinzett is a public health specialist currently working as the technical adviser to the Reproductive Health Supplies Coalition based in Brussels. With experience in more than 25 countries in Africa, Asia and Latin America he has conducted forecasting and procurement planning for a range of public health commodities including contraceptives, condoms, drugs to treat sexually transmitted infections, HIV tests, antiretroviral drugs and safe motherhood commodities on behalf of the United Nations Population Fund, USAID, the U.K. Department for International Development and for country governments. Previously a lecturer in demography and population studies at the University of Wales in Cardiff, a senior technical adviser with the John Snow, Inc.'s DELIVER project (1997–2001) and the country director in Kenya for the DELIVER project (2001–06), he has contributed to many technical publications, particularly assessing contraceptive and logistics management needs for the United Nations Population Fund in several countries.

Ruth Levine (Chair) is a health economist with more than 15 years of experience working on health and family planning financing issues in East Africa, Latin America, the Middle East and South Asia. Before joining CGD, Levine designed, supervised and evaluated health sector loans at the World Bank and the Inter-American Development Bank. From 1997 to 1999 she served as the adviser on the social sectors in the Office of the Executive Vice President of the Inter-American Development Bank. Levine holds a doctoral degree from Johns Hopkins University, has published on health and family planning finance topics and is the coauthor of the books, *The Health of Women in Latin America and the Caribbean* (World Bank 2001) and *Millions Saved: Proven Successes in Global Health* (CGD 2004), which has been on the required reading list at more than 33 schools and universities in the United States and abroad, as well as the major reports *Making Markets for Vaccines: Ideas to Action* (CGD 2005) and *When Will We Ever Learn? Improving Lives through Impact Evaluation* (CGD 2006).

Andrea Longhi has 12 years of management consulting experience in the pharmaceuticals and healthcare sectors, and 3 years in the oil industry. He is currently director of commercial policy in the Commercial Directorate of the U.K. Department of Health, where he works on bringing choice, competition and markets to the National Health Service, including the procurement of $10 billion of clinical services from the private sector. Longhi previously spent three years at IBM Business Consulting Services helping pharmaceutical and medical device organizations with their customer relationship management programs. From 1995 to 2001 he was managing consultant at ZS Associates, responsible for the Italian business, helping large pharmaceutical manufacturers with their marketing and sales strategies and operational effectiveness. Prior to that he worked for Schlumberger Wireline and Testing on oil rigs in Italy and West Africa. Longhi holds a degree in mechanical engineering and a master's degree in business administration.

Elisabetta Molari leads the procurement, supply policy and management team at the Global Fund, where she works closely with senior management in setting strategic procurement priorities linked to global policy issues. Prior to joining the Global Fund, Molari held senior roles with UNICEF and with private sector organizations. She holds a master's degree in business administration from Duke University and a dottore in giurisprudenza law and economics from Libera Universita Internazionale degli Studi Sociali.

Morgan Musongole is a pharmacist with 28 years of experience working on health in the pharmaceutical sector in the United Kingdom. He is currently working in the Zambian Ministry of Health as the drug logistics specialist to manage supply chain management of newly introduced ACTs, ensuring efficient delivery of antimalaria drugs to the points of consumption, developing and adopting a routine efficient system for drug availability, developing an accurate quantification for national health facility and district requirements for antimalaria drugs, and forecasting and procuring antimalaria drugs to satisfy national requirements. Before joining the Ministry of Health, Musongole worked at several pharmaceutical companies in the United Kingdom and Zambia in various capacities, and he was the first Zambian to have formulated and produced artemether/lumifantrine tablets and an antiretroviral triple combination of Nevirapine, Stavudine and Lamivudine in Zambia (all of which are registered by the pharmaceutical regulatory authority in Zambia and Mozambique). Musongole holds a bachelor of science degree in pharmacy from Robert Gordons University, with a diploma in pharmacy technology and a certificate in business administration, logistics management and ACT procurement.

Angeline Nanni is the director of vaccine supply and finance at PneumoADIP. She previously worked for Baxter Healthcare Corporation as a senior manager in the Vaccines Commercial Division, where she was responsible for the strategic planning and market research for new pipeline products. Prior to working in industry, Nanni worked for seven years at Johns Hopkins University's Bloomberg School of Public Health in the Epidemiology and Mental Health Departments.

Donné Newbury is responsible for Bristol-Myers Squibb's Global HIV/AIDS Accelerating Access Initiative. In this role she leads the company's collaboration with other multinational pharmaceutical companies, international organizations and governmental agencies as part of their mission to extend and enhance the lives of people living with HIV/AIDS. She has developed strong global experience in virology franchise market development during the past 12 years with Bristol-Myers Squibb. Newbury holds a master of science degree in medicine in neurology and a master of medicine degree in psychiatry from the University of the Witwatersrand as well as an honors social science degree in applied psychology from Rhodes University. She is a cofounder of the Southern African HIV/AIDS Foundation and was awarded a Humanitarian Award for commitment to people living with HIV/AIDS. She has served on the board of numerous HIV/AIDS service organizations.

Hans Rietveld is director of global access and marketing for the Malaria Initiative at Novartis. In this capacity he was instrumental in redirecting the Coartem brand strategy, creating the basis for today's successful rollout at an unprecedented large scale in the public sector. He has held various positions in marketing and sales both within country operations and at company headquarters. Since 2004 he has served as an alternate board member representing the private sector for the Roll Back Malaria Partnership. Prior to working in the pharmaceutical industry, he was a management trainee with PFW Aroma Chemicals, then a subsidiary of Hercules Inc. He holds a bachelor's degree in economics and marketing.

Mark Rilling is chief of the commodities security and logistics division in the Office of Population and Reproductive Health, Bureau for Global Health, USAID. He oversees three agency programs to improve the availability of essential medicines, diagnostics and other health supplies in developing countries over the short and long term through improved forecasting and procurement, improved performance of national supply chains and improved global coordination. Prior to that, he worked in USAID's Office of Education to improve and expand basic education in developing countries, especially for girls. Before joining USAID, he worked in legislative affairs for a small grassroots educational organization successfully advocating for the creation of the United States Institute of Peace. He graduated from Wheaton College and Cambridge University with degrees in ancient languages and religious and theological studies.

Nina Schwalbe is the policy director at the Global Alliance for TB Drug Development, where she is responsible for engaging stakeholders from high-burden countries in clinical trials and drug development, increasing awareness among policymakers about the need for new drugs and creating an evidence base around policy-related questions. Prior to joining the Alliance in 2005, Schwalbe spent seven years at the Open Society Institute, where she established and directed the public health program for the institute's global network. In that position Schwalbe managed a public health program spanning 40 countries and encompassing a range of critical issues, such as workforce development, quality assurance, health policy and initiatives for vulnerable populations. In addition, she was directly responsible for the foundation's tuberculosis and HIV efforts and established the first harm reduction programs for HIV prevention in Russia. She has also managed reproductive health programs at AVSC International (now EngenderHealth) and the Population Council in New York, the former Soviet Union and Southeast Asia. Schwalbe holds a master of public health degree from Columbia University, a certificate in Soviet studies from the Harriman Institute and a bachelor of arts in Russian and Soviet studies from Harvard University.

Neelam Sekhri is the chief executive officer of The Healthcare Redesign Group Inc., bringing more than 25 years of experience in health financing, health systems and health services management. She has worked with purchasers and payers, managed the delivery of integrated healthcare services and advised government ministries, insurers, providers and international organizations. Sekhri served as health financing and policy adviser at WHO until January 2007, where she was responsible for providing technical and policy guidance on health financing strategies with a particular focus on private and social insurance and methods to complement public financing with private funding instruments. Prior to founding The Healthcare Redesign Group Inc., Sekhri spent 14 years with Kaiser Permanente, where she held executive positions in hospital and medical group management, organizational development and finance. She currently serves on various boards, including the Commercial Advisory Board of the British National Health Service and the Organisation for Economic Co-operation and Development Working Group for Private Insurance. Her recent publications include, "Private Insurance: Implications for Developing Countries," "Regulating Private Insurance to Serve the Public Interest," "Getting More for Their Money: A Comparison of the NHS and Kaiser Permanente," "Cross-Border Health Insurance: An Overview of Mexico and the United States," "Managed Care: the U.S. Experience" and "Global Health Care Markets."

Anil Soni is executive vice president for access programs at the Clinton Foundation HIV/AIDS Initiative, where he leads global activities to negotiate pricing agreements with suppliers of HIV/AIDS medicines and diagnostics and to help more than 60 countries access associated products and prices. From 2004 to 2005 Soni was the executive director of Friends of the Global Fight, a non-profit organization that advocates in the United State for increased public leadership and private engagement to support the Global Fund to Fight AIDS, Tuberculosis and Malaria. Previously, Soni served as the adviser to the executive director of the Global Fund in Geneva, where he provided senior policy counsel to guide the organization's development and operations in its first two years. Soni was also a consultant at McKinsey and Company, where he served such clients as the Bill & Melinda Gates Foundation and the Botswana Ministry of Health. He also worked for Northwestern Memorial Hospital, in the White House Office of National AIDS Policy and with nongovernmental organizations in Ghana and the Middle East. Soni is a graduate of Harvard University.

Jeffrey Sturchio is vice president for external affairs in the Human Health, Europe, Middle East and Africa Division at Merck & Co., Inc. He is responsible for the development, coordination and implementation of a range of health policy and communications initiatives for the region. Sturchio holds a bachelor's degree in history from Princeton University and a doctoral degree in the history and sociology of science from the University of Pennsylvania. He has been a postdoctoral fellow and senior fellow at the Smithsonian Institution's National Museum of American History.

Krista Thompson is the vice president and general manager for global health at BD, a medical technology company providing devices, such as autodisable syringes, and diagnostics relevant to HIV/AIDS, tuberculosis and malaria in developing countries. She is responsible for both increasing access to the company's current technologies and coordinating investments in new technologies appropriate for these environments. Thompson has a bachelor of science degree in medical technology from Indiana University and a master's degree in business administration from New York University.

Christine Tonkin is the director of the United Nations Inter-Agency Procurement Services Office (IAPSO). She worked extensively in government procurement for several years prior to joining IAPSO, most recently as the director of Queensland purchasing. Tonkin's expertise is in procurement management and associated organizational development and change, with particular interests in procurement-related cost reduction, effective use of electronic commerce, formation of effective supplier relationships, and the development and retention of procurement and contract management skills. She has a master's degree in business administration with a concentration in accounting from Queensland University of Technology and a graduate diploma of Procurement Management from Griffith University.

Saul Walker is the executive director for global public policy at the International Partnership for Microbicides (IPM), where he is responsible for leading IPM's contribution to the international policy agenda on microbicides and the development and introduction of new health technologies to meet the needs of developing countries. Before joining IPM, Walker managed the implementation of the U.K. Policy and Plans on Access to Medicines in developing countries at the U.K. Department for International Development. There he coordinated policy responses across government departments on such issues as public health, partnership with the pharmaceutical industry and strategies to support research and development of health commodities for developing countries. From 2001 to 2004 Walker was policy adviser at the International AIDS Vaccine Initiative, where he focused on strategies to ensure rapid access to and widespread and appropriate use of future HIV vaccines and led policy engagement with the European Commission and European Parliament. From 1997 to 2001 he was senior policy adviser to the National AIDS Trust (U.K.), where he focused on international HIV policy, the participation of people living with HIV in policy development and the needs of African communities affected by HIV living in the United Kingdom. He is currently a trustee director of NAM Publications, a community-based HIV information provider based in the United Kingdom. Walker has a bachelor's degree from King's College Cambridge and a master's degree in philosophy and social theory from the University of Warwick.

Edward Wilson is a public health logistics and information technology specialist with 25 years of experience working in Africa and Asia. He currently manages the $2.75 billion USAID|DELIVER PROJECT, an indefinite quantity contract funded by USAID and implemented by John Snow Inc. (JSI) with the objective of increasing the availability of essential health supplies in countries supported by USAID. Prior to that Wilson served as director of the DELIVER Project (the precursor to the USAID|DELIVER PROJECT), as team leader for JSI's Software

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Appendix B

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During the course of this project, many individuals offered comments, critiques and suggestions. These individuals are listed below, but bear no responsibility for the content or recommendations of this report. Institutional affiliations are provided for identification purposes only. We apologize for any omissions.

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Appendix C

Uncertainty and risk: using economic concepts to identify the role of forecasting

The pharmaceutical enterprise is generally considered to be a "risky" one, with the main sources of risk associated with distinct steps in the supply chain. From the suppliers' perspective, risk is seen as part of the stages of researching and developing, manufacturing and selling products, including but not limited to:

- The transition from investments in the basic scientific discovery process to viable molecules that merit clinical studies.
- The survival of products being tested through the phases of clinical studies, so that they are candidates for licensure, through a regulatory pathway that may have unpredictable elements.
- The inclusion of a product on a list of recommended products or on a particular financier's or institution's formulary.
- The ability of manufacturers to secure adequate supplies of raw ingredients or to create biological products in a predictable fashion at a marginal cost that permits the manufacturer to clear an expected level of returns, given a particular product price.
- The effective demand expressed by consumers or their agents, given a particular price, which manufacturers must predict with sufficient lead time to meet the demand.
- Post-marketing issues of adverse events, which may cause public relations or liability problems.
- The emergence of competing products, either those that directly compete (for example, in the same class) or those that reduce the incidence of the health condition for which the product is indicated. Among other effects, the presence of competing products may lead to the exclusion of products from recommended lists or formularies.

From the perspective of consumers and financiers, available supply and price may be unpredictable.

While those in the pharmaceutical business face these risks to some degree in all product lines and markets, there are many ways in which products for developing country markets are seen as particularly risky. A few of the key reasons are listed below:

- *R&D stage.* Firms may know less about how to manage clinical trials in developing countries and may face greater logistical, political and other obstacles. Because of historically low levels of investment in products for developing countries, much of the basic science may be in a less advanced stage.
- *Licensure and regulatory stage.* Manufacturers may be required to comply with national regulatory processes with which they are unfamiliar, and may not know either the criteria for or timing of the WHO recommendation and prequalification processes.
- *Manufacturing stage.* Basic historical consumption data that is routinely available in developed country markets may be scarce, and donor financing and price sensitivity may not be predictable. There can be political and public relations pressures for manufacturers to offer products at low margins, and competing products may emerge rapidly, particularly if and when intellectual property regimes are challenged.

Although the issues described above are often referred to as risks, some are what economists would refer to as risks because the decisionmakers know the probabilities of distinct outcomes, and others are more precisely referred to as uncertainties because they represent situations in which this randomness cannot be expressed in terms of mathematical probabilities. In real life—and certainly in the pharmaceutical sector—a spectrum of unknown situations are represented, ranging from those in which the likelihood of all the possible outcomes at one end (that is, risk) is known to those

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This appendix summarizes "An Introduction to Risk and Uncertainty" by Owen Barder and Ruth Levine (available at www.cgdev.org/forecasting).

in which no knowledge of the likelihood of possible outcomes at the other (that is, uncertainty) exists. The difference between risk and uncertainty is often subjective: it relates to the information that is available to an individual.

Taken together, the set of risks and uncertainties in the pharmaceutical sector gives the appearance of a wildly unpredictable situation, in which it is impossible for manufacturers to know how much to produce for what price to maintain a viable business and equally impossible for consumers (or those who finance their pharmaceutical purchases) to know how much dealing with particular health problems will cost. However, when the risks are disentangled a bit, regularities emerge—and the dynamics of the market help, over the long run, to establish demand-supply equilibriums. Moreover, specific actions can be taken to smooth the unpredictable features manifested in the short run, partially protecting suppliers and consumers (and funders) from shortfalls in revenue or products.

In the pharmaceutical sector, as in all other business domains, decisions are taken with the full knowledge that outcomes are unknown; sometimes the bets will pay off with positive returns, and sometimes they will result in losses. When decisions are made in risky situations, the expected returns from each choice serve as a guide to action. The expected return is calculated by considering the return in each possible state of the world and then constructing a weighted average, where the weights are the estimated probability of each state. Expected values are measured in the same units as the variable itself; by contrast, risk is a way of characterizing the range of possible outcomes, and no single variable completely describes risk. Risk is sometimes summarized by the variance of the returns. Risk might also be characterized by the probability of making a net loss, an estimate of the maximum possible loss or the variance and skewness of the return. Expected returns and risk measure different types of things, and there is no simple way to combine the two into a single indicator.

Other things being equal, people always prefer higher expected returns to lower expected returns. But other things are rarely equal: in practice, individuals examine both expected returns and the amount of risk that they involve and choose a suitable combination of risk and returns. The willingness to trade lower returns for lower risk is a signal that an individual is risk averse. Most people (and thus most firms) are risk averse to some degree at some levels of risk and return. In other words, they have to be paid—in the form of higher expected returns—to take risks. Risks can be diversified so that individuals or firms can choose from a more advantageous set of risk-return combinations without affecting the total risk to the community as a whole—the actual probabilities are all unchanged; the larger and more diverse the group, the greater the risks it can bear.

Mainstream microeconomic theory revolves around understanding how supply and demand relate to prices. The downward slope of the demand curve indicates that a greater quantity will be demanded when the price is lower (figure C1). Conversely, the upward slope of the supply curve indicates that as the price rises, producers are willing to produce more goods. The point where these curves intersect is the equilibrium. At price *P* producers will be willing to supply *Q* units; at that price buyers will demand the same quantity. In this example there is one equilibrium price.

The demand curve therefore shows how willingness to buy varies according to price. When prices change, moving along the demand curve shows what quantity people will want to buy at that price. But demand is determined by other factors as well as price, such as the level of income, consumer preferences, the price of substitute goods and the price of complementary goods. If there is a change in any of these determinants of demand, the demand curve will shift on the graph (figure C2).

If *D1*—the first red line on the graph—shows the demand for a product, when the quantity demanded at each price rises due to a change in consumer preferences, the whole demand curve shifts to the right, to *D2*. If the supply curve does not change,

Figure C1

Supply-demand relationship at equilibrium

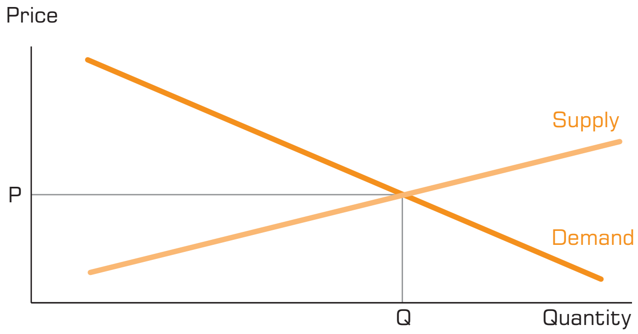
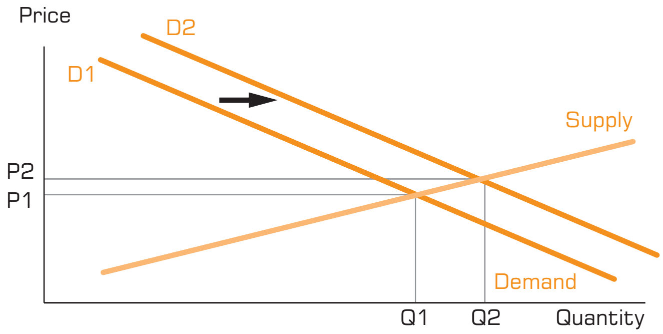


Figure C2

Supply-demand relationship with shift in demand



then the equilibrium prices rises (from *P1* to *P2*), and the quantity produced increases (from *Q1* to *Q2*).

The supply curve shows the quantity that producers are willing to sell at each price; as quantities rise, firms need to be paid higher prices to produce. Just as a shift in the demand curve moves the equilibrium along the supply curve, so a shift in the supply curve moves the equilibrium along the demand curve. A rise in the cost of labor would move the supply curve upward, and so the equilibrium would move to the left along the demand curve. The equilibrium price would rise and the quantity bought would fall.

In practice, supply may not be able to change rapidly in response to a shift in market conditions. For example, it may take time to build new manufacturing facilities, train workers or assemble products. These periods of discontinuity—when demand expands more quickly than supply—are often highly disruptive. Again, for a variety of reasons, this may be more likely in developing country markets than in more established developed country market environments.

In this situation the supply curve may be steep—possibly vertical—in the short run (figure C3). The quantity of goods that can be produced and sold is effectively fixed in the short run. When demand increases, the price may rise but there is no immediate change in the quantity that is produced and sold. In these circumstances an increase in demand (from *D1* to *D2* on the diagram) leads to a movement up the short-run supply curve at first, from *A* to *B*. If the increase in demand is expected to be sustained, in the long run suppliers can adapt to higher demand, and the equilibrium shifts from *B* to *C*. Prices rise at first, and then fall back as supply increases.

Note that the long-run supply response depends largely on expectations of what will happen in the future. Uncertainty about future demand therefore makes a significant difference to the probable supply response.

Many of the determinants of the supply and demand functions are not known with certainty. On the demand side there is uncertainty about incomes or budgets of purchasers, tastes and the prices of complementary and substitute goods. On the supply

Figure C3

Short-run and long-run supply

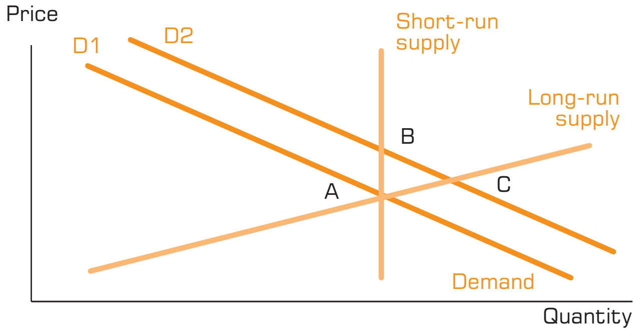
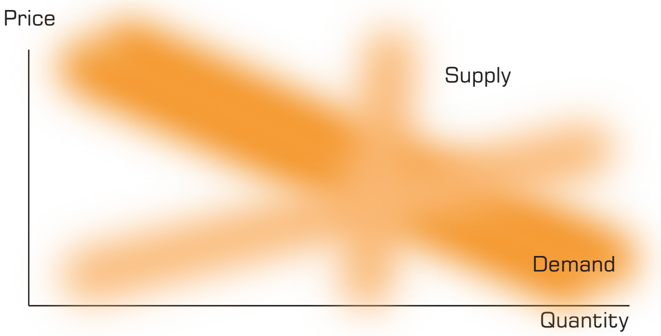


Figure C4

Supply and demand with uncertainty



side there is uncertainty about costs of inputs such as labor and about the technology that will be available to translate those inputs into the required output. Those causes of uncertainty are examined later.

Uncertainty and risk about the position of the demand curve lead to uncertainty about where equilibrium will lie on the supply curve. Conversely, uncertainty and risk about the determinants of supply leads to uncertainty about where the equilibrium will lie on the demand curve (figure C4). Together, these uncertainties can lead to a potentially large set of possible outcomes. This means that both prices and quantities demanded and supplied are highly uncertain and could vary considerably depending on the actual position of the supply and demand curves.

If all economic agents were risk neutral or could fully diversify their risks, they would only take account of the expected returns from each option without caring about the risk. But if firms or customers are risk averse, they will be willing to forgo some expected returns to secure lower levels of risk. In other words, the existence of undiversified risk imposes a cost on risk-averse economic agents.

There are several classes of risk that might affect the location of the supply curve in markets for global pharmaceutical products and diagnostics:[1]

- *R&D risks.* A long-term supply risk is whether a product is successfully developed at all or if it fails during clinical trials.
- *Batch failures.* A short-term supply risk is that a firm produces batches of products that fail tests for effectiveness, uniformity or safety due to a failure in a process, component or system or because of personnel error.
- *Supply chain failures.* Health products may depend on intermediate products from other suppliers, and uncertainty in the supply of these other products will affect the supply of the final product.
- *Credit risk.* The possibility that a borrower, supplier or customer might fail to honor its contractual obligations. In the pharmaceutical market this may be quite pronounced

Table C1
Incentives and benefits for stakeholders

Risk	Reduce uncertainty	Diversify risk	Allocate remaining risk to
Batch	Improved production systems	Self-insurance by producers	Producers
Supply chain	Contractual arrangements	Producers seek alternative suppliers	Producers
Regulatory	Stable and predictable regulation Supranational regulators		Regulators
Budget	Predictable aid Medium-term budgeting Improved sharing of information for demand forecasting	Demand pooling	Donors Developing country governments
Bargaining	Long-term contracts Purchase commitments	Reduce monopsony	International organizations
Competition	(Benefits of competitive pressure outweigh costs)	Investors or producers may diversify portfolio Industry risk pooling	Producers
Obsolescence	Open publishing of scientific data	Producers may diversify product portfolio	Producers
Policy and preference	Sustained investment in advocacy and education Improved mobilization and sharing of information for demand forecasting	Take-or-pay contracts	Developing country governments

if the contractual obligations are weakly enforced—again, a feature of developing country markets

- *Regulatory risk.* For many suppliers a key risk is that the regulatory regime will change or that it will be applied in unexpected and possibly capricious ways. This includes the WHO recommendation and prequalification process and national regulatory procedures for licensure or registration.

The main demand-side risks relate to funding, public sector demand and the bargaining power of public sector purchasers:

- *Budget and purchasing power risks.* Volatility in donor budgets for global public health lead to volatile and unpredictable demand. Furthermore, if developing countries pay for some or all of the costs, volatility of domestically financed health budgets may also impact the position of the demand curve.
- *Bargaining risk.* Public sector purchasers are often the main or only purchaser of medicines or diagnostics for their jurisdiction, and they may collaborate across countries to secure lower prices through greater bargaining strength. If suppliers have to invest in production without a binding precommitment from purchasers, the buyers subsequently have an incentive to negotiate prices down once the investment is sunk.
- *Competition risks.* Some products benefit from a temporary period of exclusivity through intellectual property protection, and others face little competition because of the complexity of production or regulatory barriers. But where there are alternative products that can produce health benefits, the price and availability of these products can made a significant difference to demand for a company's product.
- *Obsolescence risks.* A long-term demand risk for some products is that they are made obsolete—for example, because a better alternative is developed or because another approach is adopted for the condition.
- *Policy and preference risks.* Adoption of medical technologies is frequently dependent on a range of uncertain determinants, such as availability of data about the burden of disease, public attitudes to the disease, understanding of the range of interventions, and stigma and understanding about the particular product.
- *Complementary input risks.* Complementary inputs are required for product usage, including skilled personnel to diagnose conditions and to administer treatments, physical infrastructure such as clinics and roads, supply chain and logistics capacity, controls on corruption and theft, and the capacity to plan, budget and manage the introduction and use of new medical interventions. Under severe resource constraints in a health system, as an increasing number of products are introduced, the potential to deliver each of them may be compromised.

Genuine risks and uncertainty characterize the past, present and future and must be taken into account in any decisions that affect supply and demand.

In principle, three types of approaches can reduce the cost of uncertainty:

- Reducing uncertainty and risks by making more information available to decisionmakers.
- Diversifying risk to reduce its costs or hedge in financial markets.
- Allocating remaining risks to the stakeholder that can bear them at least cost.

From the point of view of the costs and risks borne by the community, it is better first to reduce uncertainty wherever it is cost-effective to do so. Remaining risk should be diversified by pooling or hedging. Remaining risks should then be allocated to the stakeholder best able to minimize and bear them. Table C1 sets out on a very broad canvas the main risks and the most promising avenues for reducing them or managing their impact.

Note

1. This risk categorization was adapted for the final Working Group report.

Appendix D

Supply chains for developing country health products

Supply chains in healthcare are more complex than those in most industries. Unlike many other global commodity chains, they must cope with fluctuating demand from changes in patients' needs (including tolerance, resistance and unexpected outbreaks), short product lifespans, frequent product innovations with uncertain uptake patterns and demand, and susceptibility to disruptions from economic, political, trade regime and regulatory changes in developing countries, which are often suppliers of raw materials and intermediary products.[1] Manufacturers and purchasers must finely balance efficiency with availability because shortages cost lives and come with significant political and economic consequences.

While these challenges exist in both developed and developing countries, historically higher levels of health spending and the existence of third-party payers in developed country markets have allowed manufacturers and buyers to use responsive, higher capacity supply chains and excess inventory to buffer against market uncertainties. In recent years the use of excess inventory has become more restricted—even in developed markets—as a result of the U.S. Sarbanes-Oxley legislation, which prevents drug companies from producing inventory above forecasts to counter "dumping" in the market.[2]

Developed country markets are also characterized by relatively good information and market research, in part because more money has been invested for information gathering. Developed country markets also have purchasers and suppliers with established relationships and balanced market power.[3] For example, the U.S. pharmaceutical market (the largest in the world, accounting for 44% of all sales in 2003) has three wholesalers that cover 90% of the wholesale market.[4] Wholesalers are the major private sector customers of manufacturers, spending $212 billion in 2004.[5]

Developing country markets are nascent and much more complex. Data are limited and unreliable, few tools exist to gather good market research, and both money and human resources are in shorter supply. At the same time disaggregated and small purchasers, and multiple layers of international and national decisionmakers, make the process more uncertain and more expensive for manufacturers and buyers. In addition, health goods are delivered by multiple supply chains including public, nonprofit or nongovernmental organizations and the formal private and informal sectors. For many products, such as those used to treat malaria, public sector supply chains are not the most dominant ones.

The discussion here contrasts two public sector supply chains: one in a developed country market, the United Kingdom, and one in a typical low-income country, purchasing with donor financing (figure D1). The sad consequence of these differences is that a child in Zambia, for example, must wait at least 3.5 years longer than a child in the United Kingdom to get access to a life-saving treatment in the public sector, even when money is available.

What causes these differences at each step of the supply chain?

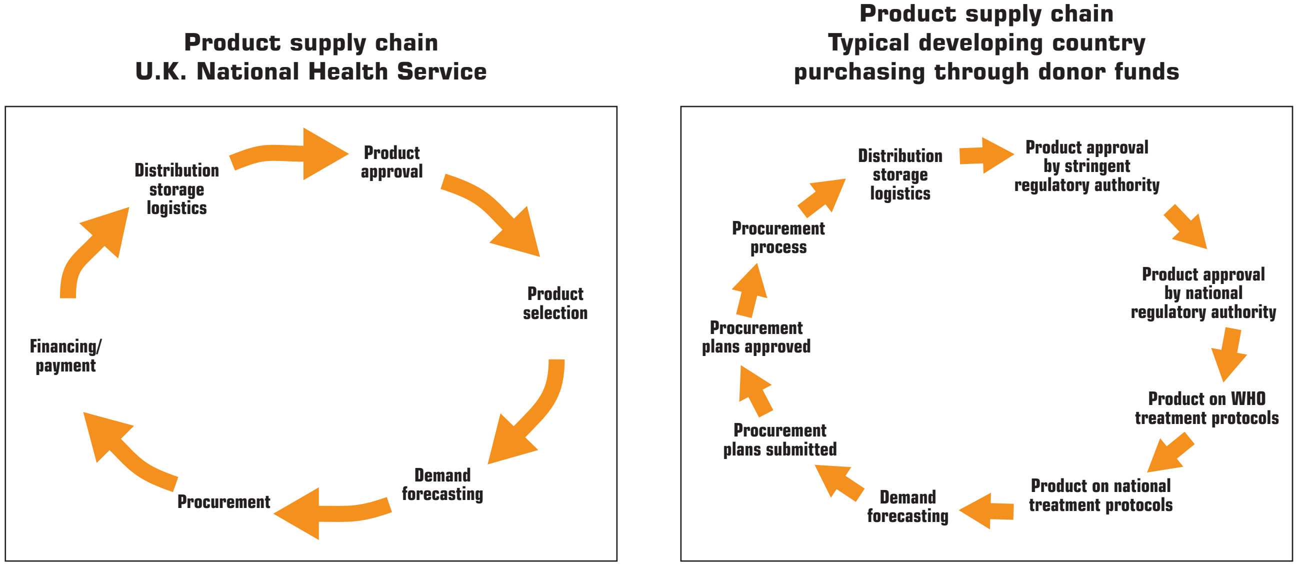
Product approval

The large and lucrative U.K. National Health Service (NHS) market (£8.1 billion in 2005 and growing at 10.8% a year)[6] makes it attractive for manufacturers to have their products registered for use in the United Kingdom. If the drug has been manufactured outside of the United Kingdom by a regulatory authority approved by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S),[7] sharing of standards and dossiers between regulatory agencies makes the approval process straightforward through the U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA).

By contrast

If the developing country has a small market, the manufacturer may not have registered its drugs for approval by the national regulatory authority in the country. Unlike PIC/S-approved authorities, requirements for dossiers are not consistent or shared

Figure D1
Product supply chains in the United Kingdom and for developing countries



Product supply chain
U.K. National Health Service

Product supply chain
Typical developing country
purchasing through donor funds

Product approval
Product selection
Demand forecasting
Procurement
Financing/ payment
Distribution storage logistics
Distribution storage logistics
Product approval by stringent regulatory authority
Product approval by national regulatory authority
Product on WHO treatment protocols
Product on national treatment protocols
Demand forecasting
Procurement plans submitted
Procurement plans approved
Procurement process

among all countries. This makes the approval process for suppliers much longer, more complex and more expensive. Even if the drug has been approved for national use, most donors require approval from a PIC/S-registered regulatory body or WHO.[8] WHO is a new player in the product approval process and has recently begun to prequalify drugs for developing country markets (although the national regulatory authority of vaccine producers have been in the prequalification business much longer). Their prequalification processes are under development and the relationships with PIC/S-approved authorities are beginning to be established.

Once a supplier has requested country approval, the in-country registration process can take an additional 6–12 months (although, again, this varies with vaccines, where an accelerated process means that concurrent activities can be considered).[9] This can mean that even if multiple suppliers exist globally, many countries have access to only a single supplier. Some manufacturers cite these regulatory barriers as the single greatest hurdle to wider access to drugs in low-income countries.

Product selection

In the NHS, after the manufacturer obtains approval of its drug from the MHRA, doctors are free to prescribe it without further authorization from an NHS body or purchasing agency. There is no "white list" of approved drugs that can be ordered.[10] This is changing though with the development of treatment guidelines by the National Institute of Clinical Excellence and by regional technology assessment agencies; while these guidelines are not mandatory, they are increasingly being monitored by oversight bodies and considered in resource allocation decisions.

By contrast

Donors generally approve purchase of drugs that follow internationally recognized treatment guidelines (usually developed by WHO). These guidelines are created through processes that bring together international experts in "informal consultations" on an ad hoc basis.[11] Experts examine clinical evidence on the usefulness of the drug based on trials in developing countries, which are often not funded by manufacturers, prolonging the time needed to prove the drug's effectiveness on the ground. At the country level national treatment protocols must be revised before the drug can be purchased with public funds, a process that can take 6–12 months. Separately, most developing countries have essential drugs lists based on the WHO list and require that drugs procured by public funds be on these lists.[12] The WHO essential drugs list is updated every two years in a process distinct from that used to create treatment guidelines. Changes in treatment protocols and prequalification can have a profound effect on the demand for branded versus generic drugs, prescribing patterns and overall drug costs.

Demand forecasting

In the NHS national demand forecasting is done through a specialized technical body called the Purchasing and Supply Agency, which works with suppliers to forecast demand and establishes long-term framework contracts through which NHS Hospital Trusts procure drugs and supplies.

By contrast

National and local demand forecasting systems in developing countries are often weak or nonexistent. Although donors typically require procurement plans specifying which drugs a country will order and their purchasing timeframe, the quality of these plans varies. The dearth of good epidemiological data and consumption information, lack of trained personnel and political pressures to achieve targets add high levels of uncertainty to these plans. In recent months, due to supply shortages and recognition of the importance of demand forecasting, various departments in WHO have started to create aggregate needs and demand estimates for particular drugs; for example, the Roll Back Malaria Partnership with WHO has begun demand forecasting for new malaria products and the WHO AIDS Medicines and Devices Service is starting work on forecasts for first-line antiretroviral drugs. In addition, the Clinton HIV/AIDS Initiative already creates demand forecasts for antiretroviral drugs to negotiate price agreements with generic suppliers and will begin to play a similar role for ACT drugs.

Procurement agents such as UNICEF, IAPSO, Crown Agents and Mission Pharma will also create demand forecasts for their customers. However, their planning horizons are often very short, and procurement agents may not be able to provide 12-month rolling forecasts to manufacturers. In addition, the bidding process between agents and countries may result in double counting of demand; for example, when multiple agents place orders based on unconfirmed bids. Government tendering processes can complicate these problems.

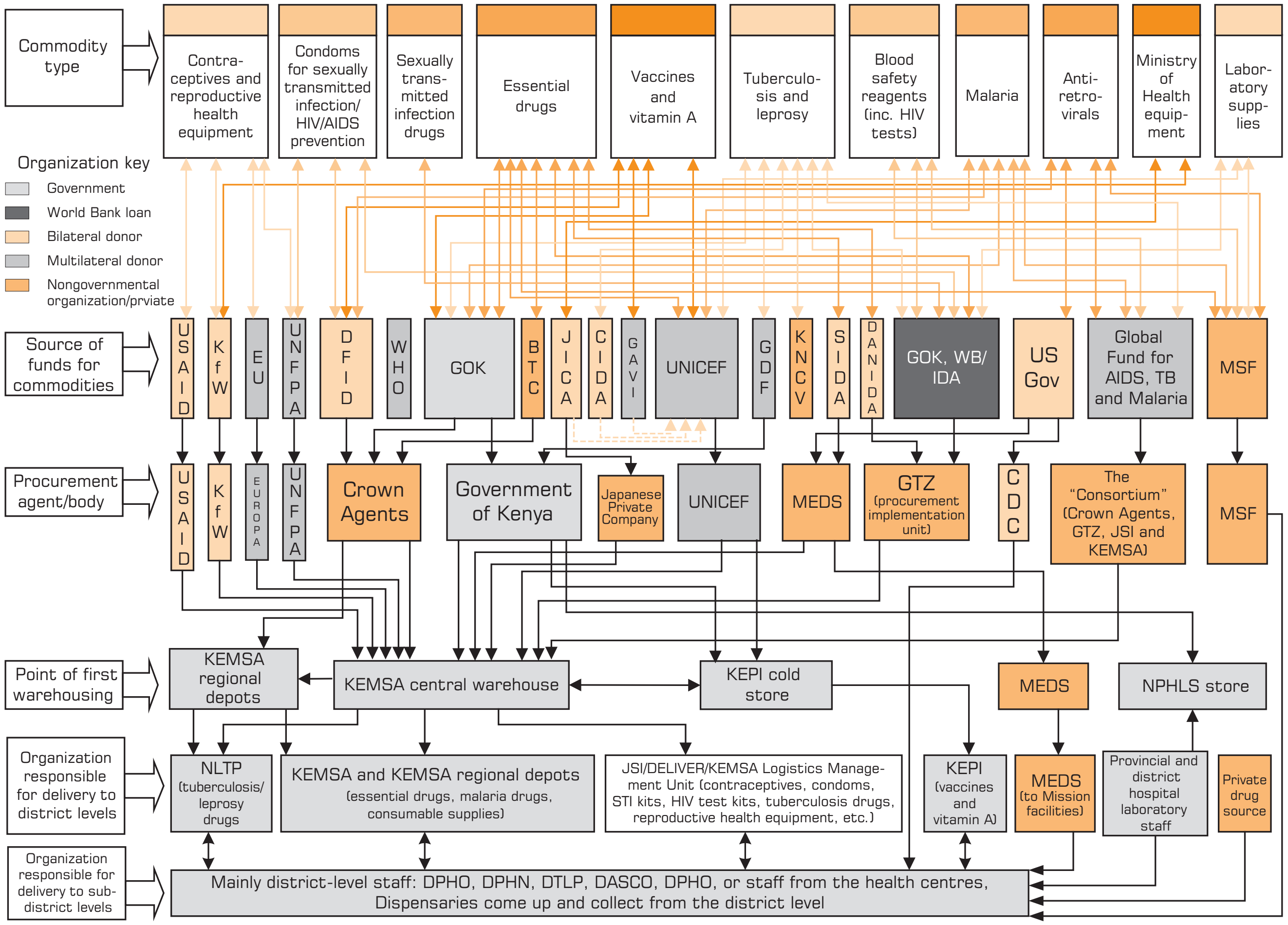
Procurement

For drugs prescribed in NHS hospitals, the Purchasing and Supply Agency negotiates contracts and prices with suppliers; NHS hospitals order independently, based on these rolling long-term (typically four-year) agreements. The agency uses sophisticated electronic analytical tools to obtain the optimal price to encourage competitiveness and ensure drug availability.

By contrast

Most procurement in developing countries is conducted through rigid, paper-based competitive tender processes. Long-term

Figure D2
Commodity logistics system in Kenya


Commodity type
Contra-ceptives and reproductive health equipment
Condoms for sexually transmitted infection/ HIV/AIDS prevention
Sexually trans-mitted infection drugs
Essential drugs
Vaccines and vitamin A
Tuberculo-sis and leprosy
Blood safety reagents (inc. HIV tests)
Malaria
Anti-retro-virals
Ministry of Health equip-ment
Labor-atory supp-lies
Organization key
Government
World Bank loan
Bilateral donor
Multilateral donor
Nongovernmental organization/prviate
Source of funds for commodities
USAID
KfW
EU
UNFPA
DFID
WHO
GOK
BTC
JICA
CIDA
GAVI
UNICEF
GDF
KNCV
SIDA
DANIDA
GOK, WB/ IDA
US Gov
Global Fund for AIDS, TB and Malaria
MSF
Procurement agent/body
USAID
KfW
EUROPA
UNFPA
Crown Agents
Government of Kenya
Japanese Private Company
UNICEF
MEDS
GTZ (procurement implementation unit)
CDC
The "Consortium" (Crown Agents, GTZ, JSI and KEMSA)
MSF
Point of first warehousing
KEMSA regional depots
KEMSA central warehouse
KEPI cold store
MEDS
NPHLS store
Organization responsible for delivery to district levels
NLTP (tuberculosis/ leprosy drugs
KEMSA and KEMSA regional depots (essential drugs, malaria drugs, consumable supplies)
JSI/DELIVER/KEMSA Logistics Management Unit (contraceptives, condoms, STI kits, HIV test kits, tuberculosis drugs, reproductive health equipment, etc.)
KEPI (vaccines and vitamin A)
MEDS (to Mission facilities)
Provincial and district hospital laboratory staff
Private drug source
Organization responsible for delivery to sub-district levels
Mainly district-level staff: DPHO, DPHN, DTLP, DASCO, DPHO, or staff from the health centres,
Dispensaries come up and collect from the district level

agreements sometimes exist, but typically with terms that yield neither significant pricing benefit to buyers nor increased certainty for suppliers. The bidding process itself can take six to nine months, and negotiators are often civil servants with limited training in contracting. Products can be available more quickly if international procurement agents are used, but agents usually negotiate only one-year agreements with suppliers and charge countries high fees (often 3%–16% of product value).[13]

Financing and payment

In the NHS once the hospital orders the drug, payments can generally be handled electronically. Financing is based on pre-established budgets. A new case rate payment system is being introduced for hospitals that may impact the prescribing patterns of physicians, but is unlikely to affect the electronic payment process for drugs.

By contrast

While some donors—such as GAVI and USAID—undertake pooled procurement, arrangements where products are purchased directly by countries are more common (for example, the World Bank and most Global Fund grants). To release funds from a donor to a country for purchasing products requires multiple checks. Once funds are released, bureaucratic processes in the country, involving several ministries and layers of approval, can further delay financing approval, and consequently the ordering of necessary drugs and supplies. Even once drugs are received, uncertainties around taxes, duties and customs can create delays. Insufficient budget planning for these additional costs can mean that products are held up in customs for months awaiting release of funds. Many procurement agents and companies also require partial prepayment on orders, which may be difficult with current donor processes.

Distribution, storage and logistics

In the NHS contracts specify that manufacturers must deliver drugs to hospitals directly or via a specialist distributor. For products other than pharmaceuticals, the NHS has established an arm's length logistics agency that specializes in these functions. The contract for managing this agency was recently awarded to DHL.

By contrast

Difficulties in transportation, storage capability and logistics expertise make this a very cumbersome process in many developing countries, as illustrated in figure D2, which depicts the complex commodity logistics system in Kenya. The figure is included less as an illustration of the specifics than as an example of the general observation of the complexity of logistics systems in developing countries and how those complexities are exacerbated by multiple donor-funding streams. Much has been written on in-country logistics issues, and several donors are investing in strengthening distribution capacity.[14, 15] John Snow Inc. and Management Sciences for Health, among others, are also very active in helping countries improve logistics once products reach the country. The costs of distribution, storage and logistics can be very high, and these recurrent expenses are often not funded by donors. One study in Ghana, for example, estimates that the direct costs of the logistics system for drugs ordered through the Ministry of Health is 13% of its total budget; an astonishing 73% of this is for storage and warehousing.[16]

Notes

1. SmartOps 2005.
2. Sarbanes-Oxley Act of 2002, PL 107-204, 116 Stat 745.
3. Fisher 1997.
4. The Health Strategies Consultancy 2005.
5. The Health Strategies Consultancy 2005.
6. U.K. Department of Health 2004.
7. Clinton HIV/AIDS Initiative [www.clintonfoundation.org]. PIC/S refers to 1 of 36 stringent regulatory authorities that participate in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme or the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
8. In some cases there are not enough PICS/WHO-qualified drugs to meet demand. Donors such as the Global Fund

and the Global Drug Facility have developed cascading product selection guidelines that allow for the purchase of nonqualified drugs if they meet certain requirements. See the Global Fund to Fight AIDS, Tuberculosis and Malaria [www.theglobalfund.org] and the Global Drug Facility [www.stoptb.org/gdf/drugsupply/procurement_notice.asp].

9. Boston Consulting Group 2005.
10. Harland, Knight, and Sutton 2001.
11. WHO 2001.
12. WHO 2004.
13. See the Global Alliance for Vaccines and Immunization [www.vaccinealliance.org], UNICEF [www.unicef.org] and the Global Drug Facility [www.stoptb.org/gdf].
14. Family Planning Logistics Management Project 2002.
15. U.K. Department of Health 2004.
16. Huff-Rousselle and Raja 2002.

Appendix E

Forecasting principles

Customer-focused principles

1. Identify the principal customers and decisionmakers of the forecast and clearly understand their needs

Description and purpose

Identifying the key customers and understanding how they will use the forecast is the first step in the forecasting process. If the purpose of the demand forecast is to estimate the appropriate supply of products, suppliers will be important customers, and so it is necessary to understand their needs and the environment in which they are making production and investment decisions. If the purpose of the forecast is for procurement or distribution, key customers will be health program managers, procurement agents, supply chain managers and funders. It is important to understand their needs, time horizons and the stage at which they will be making certain decisions.

Application

Meet with key decisionmakers to jointly define the forecasting problem and understand what purposes the forecast will serve. Determine the timeframe for which the forecast is intended; for example, is it a short-term forecast for supply chain or ordering decisions, a long-term product development forecast or a forecast to inform midrange investment decisions? Obtain agreement on the level of engagement that customers or decisionmakers would like in the process.

In some cases different customers will require forecasts for very different purposes with varying time horizons and levels of accuracy. This requires separate forecasts and forecasting processes. Each of these forecasts should be independently specified with customers and their needs clearly defined.

Good practice suggests that discussions take place in face to face meetings with the users of the forecast to probe their needs in detail. These should be explicitly confirmed in writing before the forecasting process begins.

2. Understand and clearly communicate the purpose of the forecast and the decisions that it will affect

Description and purpose

Forecasts are necessary only if they can affect decisionmaking. If decisions won't change as a result of the forecast, there is no economic justification for forecasting. Understanding the specific decisions that will be affected by the forecast and the timing of these decisions is critical if the forecast is to have any real impact.

Application

Meet with decisionmakers to agree on which decisions will be affected, how the forecast will inform these decisions and the specific circumstances under which they will change their decision based on the forecast. Understand their detailed needs, including interrelationships with other decisions, level of aggregation required, timeframes, important geographies on which to focus and analogous forecasts that should be considered.

One approach is to present forecasts under different possible conditions to produce distinct options for decisionmakers. For example, if the facility is built at a capacity of Q, the price would have to be P, and we forecast that demand at that price is significantly lower than Q, which means a buildup of inventory, so we shouldn't make the investment; however, if the facility is built to a larger capacity and efficiencies permit us to charge a

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This appendix summarizes "Principles for Forecasting Demand for Global Health Products" by Neelam Sekhri, Rob Chisholm, Andrea Longhi, Peter Evans, Mark Rilling, Edward Wilson and Yvette Madrid (available at www.cgdev.org/forecasting) lower unit price, and we forecast that demand at the lower price matches the higher capacity, we should consider making the capital investment.

Document all decision parameters in writing.

3. Create a forecasting process that is independent of planning and target setting

Description and purpose

Forecasts are not plans and they are not targets. A forecast is how the future is likely to look, whereas plans and targets are how we would want it to look. Credibility and trust in the forecast and the forecasting process are compromised if it is based on plans, goals and targets. However, plans will serve as inputs to forecasts and will also be influenced by them. While there is a mutually reinforcing feedback loop between planning, marketing and distribution and forecasting, they should be considered distinct processes.

Application

This can be a difficult principle to implement in practice because of the necessary interdependence between planning, marketing, goal setting and demand forecasting. As a rule of thumb, forecasts should drive planning to a greater extent than the other way around.

Within an organization separating the demand forecasting process from planning processes and having different people perform these functions are good structural ways to ensure greater independence. At the same time, ongoing and explicit feedback and data loops between these functions must be built into the structure.

One method for addressing management's desire to accommodate plans, sales goals and targets into forecasts is to generate separate forecasts for alternative plans or targets and present these in concert with plans. For example, "If we achieve 80% of the target, demand for this ACT drug is likely to be 160,000; if we achieve 90% it is likely to be 200,000. The likelihood that we will achieve 80% of the target is 70%, whereas achieving 90% of the target has only a 50% chance." This allows decisionmakers to understand and balance their risks in the context of other priorities. It will also allow procurers to decide how much risk they are willing to take in their orders.

All adjustments to forecasts should be based on evidence of justified opinion and always supported by documented rationale.

4. Protect the forecasting process from political interference and ensure its transparency

Description and purpose

Political issues surrounding forecasts are often difficult to disentangle from the need for demand forecasts in the first place. Some may argue that because markets for global health products function within and are influenced by global, regional and national politics, public sector programs, and lobbying, politics is inherent to the process of forecasting for these products and should not be disassociated.

Clearly the political and policy environment influences the demand for health products either directly or indirectly, and therefore their impacts must be considered. While these factors should be explicitly taken into account as process drivers or assumptions in developing the forecast, political considerations should not be used to change the results of the forecast. Adjustments should not be made to forecasts simply because the results of the forecast do not meet political objectives (for example, what a minister says the demand should be or what the sales department wants demand to be).

If the purpose of the forecast is to give customers as objective a sense as possible of future demand, its credibility is compromised by serving political objectives, providing a tool for advocacy or trying to generate additional resources.

Application

To deal with political considerations, it is helpful to map the political issues surrounding the forecasting process and to develop a strategy to manage them. Explicitly documenting political pressure to influence inputs or final forecasts and identifying the likely impacts of these inputs are also useful to protect the integrity and transparency of the process.

Changes and inputs should be rationally justified, supported by evidence (quantitative or qualitative), agreed upon and documented.

Process- and context-focused principles

5. Embed the forecast into the broader environment taking into account market conditions, public policy, competitive forces, regulatory changes and health program guidelines

Description and purpose

Forecasts should be an expression of market knowledge that convey a clear understanding of the wider market context to the audience. The quality of the forecast is more dependent on the extent to which forecasting is carried out as part of a broader analytical process than complex models and methodologies. When a forecast is developed with insightful market understanding this will be apparent and the results communicated and understood by a wide audience.

Application

While it is a distinct process, forecasting should not be carried out in isolation from other functions. A cross-functional matrix team approach should be adopted to optimize efficiency. The individual responsible for developing or updating a forecast should work in collaboration with those responsible for other analytical activities, including those active in market and policy development.

In the case of a public-private product development partnership, for example, which has several products under development that may compete with each other, creating forecasts for a single product launch should include managing the entire product portfolio strategically by modeling the impact of different demand scenarios of these products together, including potential timing of introduction, price points and other product characteristics.

6. Create a dynamic forecasting process that continually incorporates and reflects changes in the market, public policy and program capabilities

Description and purpose

Demand forecasting is an iterative process that is influenced by external drivers and changes in the capabilities and requirements of health programs. Forecasts are an important input into the decisionmaking process and should change as the environment changes. Identifying key market, policy and capacity drivers and as they change ensuring that the forecasting process incorporates these changes on a continual, agreed upon schedule is an important component of forecasting. For this to happen efficiently the critical drivers and assumptions should be highlighted and monitored closely.

Application

The use of rolling forecasts (for example, updating forecasts for the next 18 months) is standard practice. The most important demand drivers should be identified, monitored and reported to reflect changing market conditions and new information. Strategic forecasts are frequently updated annually or more often depending on need. Operational forecasts can be updated monthly, quarterly or more frequently as needed (box E1).

A governance process for forecasts should be defined. It is also important to incorporate an ongoing evaluation process to measure the accuracy of forecasts against actual results. This analysis should identify key causes of errors so that the process and variables used in producing the forecast can be continually refined. A commonly used practice, particularly closer to product launch when risk is high, is to seek external validation and have an outside agency (for example, a market research firm or econometric group) repeat the forecast to ensure consistent results.

For health programs forecasting processes will be tightly and iteratively linked to distribution strategies; as the forecast changes the distribution strategies should change to reflect this and vice versa. If these processes are out of sync, shortages and expirations at point of patient care are likely to occur, even when there is an adequate supply of product.

Methodology- and data-focused principles

7. Choose the methodologies most appropriate to the data and market environment and obtain decisionmakers' agreement on the methodologies to be used

Description and purpose

Different forecasting methods are appropriate under different circumstances. If the environment has sufficient cross-sectional and time-series quantitative data and the environment is stable, a variety of quantitative analytical tools can be used. If large changes are anticipated, historical data will need to be augmented with causal models and expert analyses. In many cases quantitative data are limited, and large changes are expected in funding or policy and so it is necessary to collect and analyze qualitative or "judgmental" data using a variety of methods such as Delphi, prediction markets, role playing, structured analogies and game theory. Applying these methodologies requires considerable knowledge and skill; these are best used by those with training in gathering and understanding these types of data and forecasting methodologies.

In many cases, several methodologies will be appropriate for the forecasting problem and can be combined to improve forecasting accuracy.

Box E1
Coordination of demand forecasting at the country level

In Zambia there has been a concerted effort to improve coordination of forecasting at all levels. Implementing partners of the HIV/AIDS programs jointly agreed to create a national forecast for antiretroviral therapy drugs. This forecast provided the basis for discussions with various funding sources to ensure sufficient funding to cover forecast needs. The partners also reported information on their issues to facilities, on their stock on hand and on their planned shipments. This provided a picture of the national stock situation. All partners are using procurement management software, PipeLine, to facilitate the timely sharing of key information, including months of supply by product. By sharing information the partners can enhance their coordination and take concrete actions to ensure product availability. For example, one partner had 50 months of Efavirenz, 50mg, almost guaranteeing expiration and waste, while another partner was stocked out. The partners were able to transfer stock, which allowed the stocked-out partner to meet the demand for Efavirenz, 50mg, and to cancel future shipments until the stock within the country was used, thereby lessening the chance of expiration.

Source: USAID/DELIVER 2006.

Gaining acceptance of forecasts requires that decisionmakers understand the methodologies selected and their limitations and strengths.

Application

List the important selection criteria before selecting the methods for forecasting with input from unbiased experts. In new product markets creating market analogues that look at other products with similar characteristics to understand uptake speed and switching rate from existing products is a commonly used technique. Analogues can be based on products launched in similar therapeutic classes, with similar orders of entry and by companies with similar promotion budgets. Analogues can also be used to identify submarkets and regions or countries that may behave similarly (box E2).

Describe how the forecast will be made to decisionmakers in understandable terms and obtain agreement on the methods and approach that will be acceptable to them.

8. Keep the methodology simple and appropriate to the situation; don't introduce too much complexity, but include sufficient detail to address the investment risk and level of accuracy required

Description and purpose

"It is better to be broadly right than precisely wrong." The level of accuracy needed in forecasts increases as the time horizon shortens. The level of confidence in the forecast is proportionate to the investment decisions and associated risks; for example, ordering forecasts will require a much higher level of accuracy and certainty than strategic long-term forecasts (figure E1).

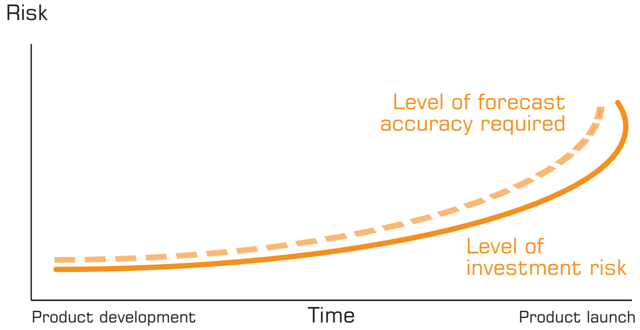
When producing strategic forecasts, understanding the level of uncertainty is critical. These types of forecasts are best guesses of how the future will look in 10–20 years; giving a false sense of accuracy can be misleading and counterproductive, actually decreasing customers' confidence in the forecast.

Box E2

The use of banding in immunization forecasts

In projecting immunization demand, the WHO Expanded Program on Immunization grouped countries into bands by size and wealth, focusing on the rate of adoption of a global program within each band. It was initially assumed that larger and wealthier countries would adopt more quickly and smaller and poorer countries would adopt more slowly. These initial groups were modified as the program progressed so that banding became more accurate with time and was based on a variety of characteristics beyond simply size and income level. When using the banding strategy to determine rate of adoption, it was useful to consider China, India and South America separately. These countries and regions are influenced by global programs but usually act based on local data and may choose a variation of the global program. The Expanded Program on Immunization has created several models all showing that even with a good infrastructure in place and few funding problems a 70% takeup requires about eight years. However immunization is a preventive strategy rather than a curative strategy. People may be more motivated when they are sick or threatened immediately; for example, meningitis vaccination can achieve levels of 50% coverage up from 0% within a matter of weeks during an epidemic.

Figure E1
Forecasting accuracy and investment risk



Box E3
Demand forecasting in health programs

A demand forecast typically starts with an assessment of the program situation and an appraisal of the current conditions and performance. This includes consideration of products, distribution channels and an assessment of a health program's political and technical elements that are necessary prerequisites for changes in use of products and supplies. The assessment should also provide a realistic assessment of the characteristics of products—their stability, shelf life, turnover rate, side effects, controversies around use, ease of manufacture, simplicity in resupply and the like. Data on implementation plans, targets, objectives and goals can then be fed into the equation to assess likely changes from historical trends. In addition to providing the key inputs into the forecast, these factors will inform the frequency and horizon of the demand forecasting process.

Application

Make sure the forecast is appropriate to the level of investment risk being undertaken and the decisions that will be made based on the forecast. For example, a strategic forecast might involve interviewing 50 stakeholders; while a short-term purchasing forecast might involve interviewing hundreds of stakeholders to get precise information on timing of orders, demand and price considerations (box E3).

Clearly identify the confidence level of the forecast and provide explicit confidence intervals if possible. If qualitative judgments are being used, making it difficult to provide statistical intervals, simple low, medium and high estimates may be necessary. However, even in these cases it is important to try to estimate the likelihood of achieving each of these estimates (for example, "There is a 50% chance that we will hit the medium forecast but a 90% chance that we will hit the low estimate"). In the early stages of a product lifecycle, for example, forecasters may decide to use the lower deciles in the confidence range of forecasts—rather than the midrange forecast—as the baseline, because making conservative assumptions in these cases will give greater credibility to forecasts. However, very conservative estimates all along the supply chain can lead to shortages, which can have serious public health consequences. Manufacturing investment forecasts, for example, may need to use the higher estimates.

It is important to be explicit about the level of uncertainty in the forecast so that users understand how much they can realistically discount it. Higher levels of uncertainty will require increased levels of flexibility across entire supply chains including procurement, distribution, manufacturing and sales processes.

In situations of high uncertainty or very small or large numbers, the forecasting problem might be decomposed into its component parts and each part may be forecast separately with the results combined at the end. One way to do this is geographically; for example, in the early uptake of a new product, it is better to build bottom-up forecasts on a country-by-country basis and then aggregate them to determine the global forecast rather than looking at aggregate trends.

Regular monitoring and evaluation are also very important: the more uncertain the forecast, the more often it should be checked against actual demand and revised accordingly.

9. Make forecast assumptions clear and explicit

Description and purpose

To ensure acceptance of forecasts, it is important that decisionmakers understand the basis for the forecasts as well as the key drivers and risks to which the forecast is particularly sensitive. Forecasts should provide an accurate representation of the current situation and should continually change as these conditions change.

Application

Explicitly identify key drivers of the forecasts by using theory and domain expertise to define causal links and risks (box E4). In specifying key drivers, limit irrelevant variables and don't select variables simply based on statistical techniques such as stepwise regression or data mining, which can yield spurious relationships between variables that do not have face validity.

Funding flows and the timing of these flows will often be key drivers in forecasts for global health products. Capacity constraints, human resources, available instruments and plans and policies of various agencies are also relevant. The forecasting process should recognize which drivers are most critical at a particular point in the lifecycle of the product and the program and should continually update and refine the drivers and their inputs. For example, early in a health program, the amount and timing of funds may have a more critical impact on the forecast, while later in the program, availability of human capacity may be the most significant driver.

Test with key contributors and users of the forecasts that all relevant players have the same understanding of the key assumptions and their implication for the forecasting process and output. Particularly in global forecasts, language and culture can create serious misunderstandings in assumptions and their impact.

Ensure that each new forecast has clear and documented statements on the changes in assumptions compared with previous forecasts and explicitly quantify the impact of these changes. Date stamp all forecasts.

Box E4
International AIDS Vaccine Initiative: determining drivers

The International AIDS Vaccine Initiative started its forecasting project by identifying the key determinants or drivers of demand. Some of these drivers are largely independent of disease area and can be used by any health program.

- Need: potential recipient populations.
- Product profile: vaccine characteristics specification.
- Political will and access: regulatory hurdles, health system capacity and effectiveness.
- Attitude: vaccine acceptability.
- Funding: government and donor budgetary constraints.
- Targeting: vaccination strategy.

10. Understand data and their limitations; use creativity and intelligence in gathering and introducing data into forecasts; incorporate qualitative inputs rigorously and systematically

Description and purpose

The data do not always speak for themselves, or if they do, it is sometimes hard to know what they are saying. Understanding which data to collect and how to use these data underpin good forecasts. Using theory and research to decide which key data elements to collect is the first stage. For example, short-term demand forecasts that will influence sales are often based on market size, ability to purchase and underlying need. These may be the most critical variables on which to focus first; measures such as income, availability and price can be added to refine forecasts.

It is also important to understand the sources of data and the particular biases of each source. Identify these biases before analyzing the data, particularly in healthcare, where those who collect data may intend to impact policy and funding based on their information. Data collected for advocacy purposes to emphasize the importance of a disease and secure more funding for its treatment may be subject to biases that will need to be clearly addressed when applying these numbers to demand forecasts.

Application

If it is difficult to find unbiased sources for core data, it is best to find multiple and diverse sources with differing biases. For example, in looking at epidemiological data, it is useful to obtain data from a variety of sources with different estimates. While it can be difficult to deal with conflicting data, forecasts will be more accurate if data from a range of sources are combined, giving a better estimate of the actual prevalence and incidence of the disease (box E5). Although this may seem counterintuitive, averaging and combining can be powerful statistical tools if they are appropriately applied. If forecasts are to be used for decisions requiring high levels of investment, primary market research will be required.

Explicitly reference the sources of data, their context and limitations. Check data for face validity by having impartial experts independently review the data and outputs to see if they are relevant and appropriate.

Box E5

Continual updating of data and assumptions

In Zambia, in the absence of data, consultation with experienced providers for the provision of first-line antiretroviral therapy informed the estimated uptake of antiretroviral therapy and the breakdown of patients by first-line regimen. Because assumptions were based on providers' experience, the forecast for first-line antiretroviral drugs was relatively accurate. However, because the program was relatively new, the providers' experience with second-line treatment was limited. Thus, the assumptions were less informed by experience and relied more on expectations, thus leading to an overestimate in forecasting consumption for second-line antiretroviral drugs. Procurement planning was based on those assumptions— weak as they were—because of the lack of any kind of data. Fortunately, as a result of careful monitoring of consumption, a second-line drug shipment due in six months was postponed, preventing a number of expensive, second-line antiretroviral drugs from expiring in the warehouse. Frequent reviews and adjustments to a quantification, which are based on actual consumption, allow programs to respond to rapidly changing environments. (USAID|DELIVER 2006).

Note

1. For a comprehensive description of forecasting methods, see Armstrong 2001.

Appendix F

Information sharing and gathering as a public good

Good information plays a critical role in the development of accurate demand forecasts, not only in global health, but in any industry where projections of future product demand determine expectations for future investments in manufacturing capacity, sales and marketing efforts, or other such commercial investments. Access to more reliable and comprehensive data has the potential to significantly improve forecasting accuracy and to provide all stakeholders in a supply chain with a common understanding of market potential. Furthermore, the improved forecasts that result from better information reduce the likelihood of product shortages, delivery delays and overproduction—all of which engender significant costs (financial and otherwise) to suppliers and end users. In global health inaccurate demand forecasts cost lives.

Despite the critical nature of good information to demand forecasting, those currently engaged in forecasting for health products in developing country markets frequently find that the data they need are either not available or not credible. Such information limitations are clear drivers of forecast inaccuracy. The global health community is increasingly recognizing the need for concerted action to address the challenges inherent in gathering and disseminating the information required to credibly forecast demand in developing country markets.

Identifying information requirements and priorities across players and forecast types

The information that suppliers, public-private product development partnerships and buyers utilize for demand forecasts falls into four categories: international data, national data, disease and product data, and target population and behavioral data. Within these categories there are 17 specific information elements that together capture the information used most frequently by forecast developers (table F1).

The consistency of the “information wishlist” provided by forecast developers, even across organizations, products and disease areas, is a significant finding in itself. Furthermore, all players identified significant and highly consistent gaps in the availability and reliability of the majority of information currently available for use in forecasting.

While most respondents reported using most or all of these 17 information elements, 8 were highlighted as being of particular importance to forecast development. These are:

- Epidemiological data.
- Treatment guidelines and policies.
- International donor funding data.
- Historical consumption data.
- National health system and accounts data.
- Supply chain and logistics data.
- Demographic data.
- Product profile data.

Even more telling is that gaps identified in information quality and availability exist across the majority of information elements, but are in fact most severe in high-priority information categories. As highlighted in table F2, particularly severe gaps in information availability and quality exist within data on epidemiology, international donor funding, historical consumption, national health system and accounts, supply chain and logistics, and country willingness to pay.

Identifying sources, users and specific gaps for priority information elements

Why do those forecasting demand face such severe challenges with regard to information on epidemiology, international donor

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This appendix summarizes “Information Sharing & Gathering as a Public Good” by Daniella Ballou-Aares and Priya Mehta from Dalberg Global Development Advisors (available at www.cgdev.org/forecasting).

Table F1
Information used most frequently by forecast developers

	Information element	Description
International data		
1	International treatment guidelines and policies	Information on global regulatory processes and treatment guidelines, including: • WHO preapproval process. • WHO treatment guidelines. • WHO essential drugs list. • Other global processes and guidelines.
2	International donor funding and program data	Information on donor-generated resources, including: • Historical international donor funding by product by country and program. • International donor funding targets and projected funding by product by country and program. • Anticipated timing of funding availability. • Other funding constraints.
National data		
3	National macroeconomic and sociopolitical data	Information on country wealth, growth and sociopolitical factors, including: • GDP growth rates. • GDP per capita. • Sociopolitical indicators (for example, political stability, government effectiveness, regulatory quality, rule of law, control of corruption and accountability).
4	National health service coverage data	Indicators of historical and present healthcare coverage of target population, including: • Rate of immunization. • Rate of detection and diagnosis. • Percent receiving treatment. • Contraceptive prevalence.
5	National health system and accounts data	Indicators of the strength and capacity of the healthcare system (both personnel and facilities), including: • Public expenditures on health (including historical and projected national government spending on healthcare, programs or specific products). • Private expenditures on health (out of pocket expenditures and prepaid plans). • Physician, nurse, midwife, dentist, pharmacist and health worker density. • Hospital, hospital bed, pharmacy, laboratory and clinic density. • Number of medical and nursing schools. • Indicators on responsiveness of health system.

Table F1 (continued)
Information used most frequently by forecast developers

	Information element	Description
6	National and nongovernmental organization program targets	Information on the size, scope and impact of country programs, including: • Patient targets of in-country programs. • Service statistics of in-country programs. • Plans for expansion and scale-up across in-country programs.
7	Government willingness to pay and likelihood of adoption	Indicators of government willingness to invest in and adopt a product, including: • Market research on country willingness to make investment in product compared with other potential investments. • Proxies for likelihood to adopt, including: • History of clinical trials. • Adoption of other new technologies. • Historical data on lags to adopt (for example, post-licensure lag).
8	National and nongovernmental organization guidelines and policies	Information on national regulatory policies and treatment guidelines, including: • National regulatory processes. • National treatment guidelines (for example, national health policy, national drug policy). • National trade and export-import regulations (for example, minimum shelf life requirements). • Program treatment selection processes and guidelines. • Program implementation protocols and monitoring of compliance.
9	Supply chain and logistics data	Information on the forecasting process, supply status and delivery times for particular product types, including: • Mappings of forecasting process. • Time and location of product receipt. • Historical and current product inventory levels and location. • Lead times. • Mappings of procurement and distribution systems.
Disease and product data		
10	Product profile data	Information on key product characteristics for existing or future products (as relevant and available), including: • Product formulation and specifications (for example, efficacy, duration, dosing schedule, shelf life, storage and handling requirements). • Likely target population (for example, child, adolescent, adult or other). • Regulatory status. • Product price. • Delivery and operations costs.

Table F1 (continued)
Information used most frequently by forecast developers

	Information element	Description
11	Historical consumption data	Historical market sales data, including: • Historical product sales (for existing products), segmented by product and by country. • Historical product sales for analog products (as a proxy for products that have not been launched), segmented by product and by country.
12	Market trend analysis	Market analysis on product trends, including: • Market growth. • Market share. • Anticipated introduction of competitor and substitute products. • Analysis of public and private markets.
13	Country-level procurement plans	Country- and program-level plans for product procurement, including: • Specific procurement plans describing anticipated quantity and timing of product procurement. • Historical and outstanding tenders issued by buyers for purchase of specific products.
Population and behavioral data		
14	Demographic data	Demographic data by country, including population characteristics such as: • Age. • Sex. • Race and ethnicity. • Income and socioeconomic status. • Fertility rates. • Birth rates. • Life expectancies. • Height and weight. • Mortality rates.
15	Epidemiological data	Disease-specific epidemiological data by country and target population, including estimates and projections of: • Incidence. • Prevalence. • Mortality. • Morbidity.

Table F1 (continued)

Information used most frequently by forecast developers

	Information element	Description
16	Consumer behavioral data	Information to understand consumer product preferences, cultural norms, acceptable locations and providers, including: • Household surveys. • Attitudinal surveys. • Social anthropological studies. • Compliance with existing vaccines and drugs. • Market research on consumer willingness to pay. • Level of education.
17	Physician behavioral data	Information to understand physician product preferences, including: • Physician willingness to prescribe and physician prescribing data. • Physician knowledge level.

funding, historical consumption, national health system and accounts, supply chain and logistics, and country willingness to pay? Several factors about the way information is currently shared are important drivers:

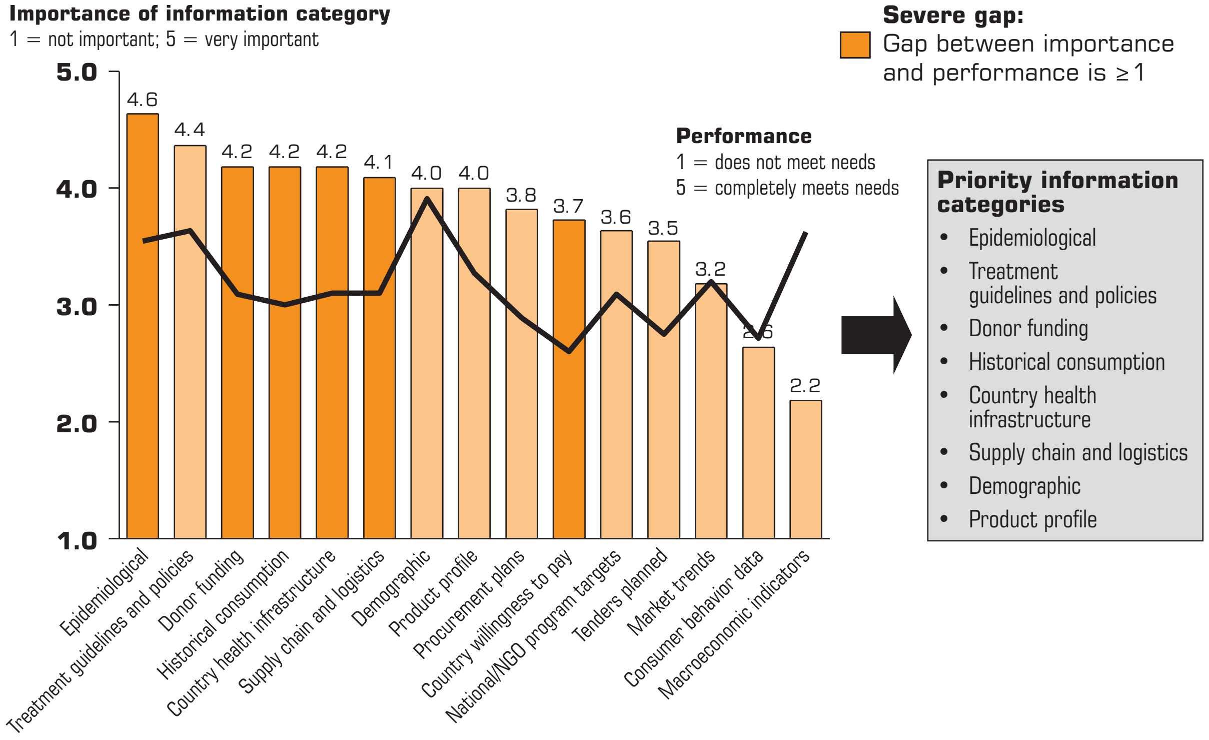
- Information is often shared only in ad hoc manner.
- There is a tendency to treat information as proprietary by default.
- There is very little of the data standardization required to share data systematically and across multiple stakeholders.

As this summary of the sources and users of each priority information element illustrates, closing high-priority gaps will require more effective and systematic consolidation and dissemination of existing information. To this end, it is reassuring to note that there are several specific information sources that cut across multiple information categories, which could help focus information gathering efforts. However, addressing the priority information gaps will require not only better information sharing but also additional and explicit investments in gathering "new" information—information that is not currently collected in any formalized or ongoing manner.

Information sharing in developing countries

As the previous section shows, there exists a set of readily identifiable information consistently demanded by forecast developers; information that if accurately recorded, effectively compiled and clearly presented to forecast developers would eliminate many avoidable information-related forecasting uncertainties. Yet though the "information wishlist" is clear, current efforts to gather and share such information have been unable satisfy the demands of those engaged in forecasting. Core forecast developers emphasize that certain primary data are not currently captured and therefore nonexistent for current purposes. Furthermore, many indicate that existing data are too often inaccessible, incomplete

Figure F1
Overall importance and performance of information categories



or inaccurate. Data from one source are invariably inconsistent with those of another source, to the point that forecast developers have minimal confidence in their own ability to distinguish which data are reliable. The following section describes the current approaches to sharing information in developing country markets and contrasts them with the models used to share similar information in the developed world context. Comparing developed and developing country "markets" for information lends insight into the viability of new information-sharing solutions in the developing country context.

In recent years resources devoted to addressing developing country health challenges have rapidly and drastically increased. Yet despite this growth in available resources and the intensity of public attention to these markets, difficulties persist in gathering accurate information about the resources, products and regulatory environments in developing country markets. Such limitations are becoming increasing frustrating. Priority must be given to addressing information gaps, as they hinder not only the ability to create the accurate demand forecasts, but also the ability to make the many crucial product and supply chain investments that depend on accurate demand forecasts.

Table F2

Information sources, users and gaps

Information element	Sources	Users	Gaps	Implications for information-sharing solutions
Historical consumption	• International buyers. • National buyers. • Suppliers. • Public-private product development partnerships. • Funders.	• Suppliers. • Public-private product development partnerships. • International buyers. • National buyers.	• Multiple sources of historical data exist per disease, but much of the existing information is not effectively or systematically shared. • Data that are shared are generally not consolidated by product and must be compiled across sources. • Even for individual sources, data are largely unavailable or incomplete.	• Historical consumption data are used by and sourced from both buyers and suppliers. • Suppliers would be the easiest source from which to compile information, as they are more consolidated and maintain fairly standardized records of sales.

International donor funding	• Funders.
	• National buyers.
		• Suppliers
		• Public-private product development partnerships.
		• International buyers.
		• National buyers.
			• Key users have little access to product-specific funding forecasts.
			• A consolidated view of funding across multiple funders is often not available by disease.
			• Lack of transparency into country procurement processes, financing and funds flow.
			• Significant uncertainty in the reliability and timing of funding.
				• Efforts by funders are required to:
				  • Provide consistent reporting across diseases and donors.
				  • Provide relevant country- and product-level information.
				  • Increase timeframe of funding commitment information.

Epidemiological	• National government surveillance data. • International agencies. • Other (for example, clinical research)	• Suppliers. • Public-private product development partnerships. • International buyers. • National buyers.	• Disease data for developing countries is inconsistent across sources (for example recent attempt to compile HIV, tuberculosis and malaria statistics across 10–12 countries revealed inconsistencies between UN, WHO and country data). • Need for better projections of disease evolution and patient flow over time. • Data are often unavailable or incomplete.	• National buyer investments are required in improved surveillance systems. • International sources should address discrepancies in disease data.

Table F2 (continued)

Information sources, users and gaps

Information element	Sources	Users	Gaps	Implications for information-sharing solutions
National health system and accounts	• National government. • Program implementers, distributors. • International agencies. • Other.	• Suppliers. • Public-private product development partnerships. • International buyers. • National buyers.	• Of 192 WHO member countries, only 39 have sufficient health infrastructure information. • 92 have only census data, old survey data or no data at all. • Need for more frequent country health infrastructure assessments and projections.	• Existing data within international agencies, national governments and programs could be better compiled and organized. • Significant long-term investment needed to support additional, more frequent country health infrastructure assessments.
Supply chain and logistics	• National buyers. • International buyers. • Other (for example, customized research).	• Suppliers. • Public-private product development partnerships. • International buyers. • National buyers.	• Supply chain and logistics data such as inventory quantity and location are often unavailable, as systems are not in place to manage supply chain. • Manually maintained records at the facility level make compilation and analysis difficult. • Lack of accurate data at lower levels in the supply chain.	• Buyer data could be shared in a more systematic manner. • Investment also required in buyer systems to improve data reliability.
Country willingness to pay and likelihood of adoption	• National buyers. • International buyers. • Funders.	• Suppliers. • Public-private product development partnerships. • International buyers.	• Entirely conducted through proprietary, customized research projects that are not shared. • Few expert providers of research and analysis exist in developing country health markets.	• Customized research will continue to play an important role. • Potential opportunity to share core information across players.

In response to these uncertainties, initiatives have begun to emerge to collect and disseminate information relevant to forecasting. These initiatives are distinct from previous initiatives in that the collection and dissemination of this information is the initiative's central function or at least central to its mandate. And at the same time, existing initiatives have expanded the scope of the data that they provide, in order to better meet the expanding needs of stakeholders. Yet despite these improvements,

Figure F2
Information sharing in developed markets

	Key players	Market characteristics	Example organizations
Information sharing	Private firms focused on collecting and disseminating health product data across diseases	• Few players for consumption data (1–3 per market), where standardized data a priority. • Many private firms providing product and market info. • Data sold for a fee.	• IMS • NDC
	National public health entities providing free, widely available data	• Public entities set standard. • Data are free. • Private firms offer synthesized data for a fee.	• CDC • NHS
Customized information gathering and analysis	Private firms focused on research and analysis of key market data, including product trends and purchaser behavior. May be focused on specific industry, disease or geography.	• Many players in each market. • Mix of generalist market research organizations and specialized organizations focused on health products market. • Analysis sold for a fee.	• TNS • Datamonitor • Cambridge Pharma • BioSeeker Group • Wide range of consulting firms

information gaps remain. One challenge is that while these initiatives themselves may focus on forecasting demand, they typically remain within existing organizations that have much broader mandates, for which demand forecasting is a low priority.

Information-sharing models from developed countries

As noted by Raman and Narayanan (2004), inaccurate demand forecasts are a frequent challenge for numerous product supply chains across the globe. Misaligned supply chain incentives are the key cause of poor demand forecasts, and Raman and Narayanan point out that a key root cause of such misaligned incentives is "hidden information." Thus, information-sharing initiatives and organizations are a common approach to improving the ability of supply chain stakeholders to forecast demand and more effectively manage the supply chain. It is therefore not surprising that there exist a multiplicity of organizations providing market and consumption information for pharmaceutical products and that such information resources exist in a wide variety of other developed country product and service markets.

Can a comparable market for information exist in developing countries? Given the significant increase in resources and growth in markets for these products, the answer must be yes. But how will this be achieved? Some of the lessons from developed countries are particularly instructive.

First, in both developing and developed countries public organizations provide key demographic and epidemiological data. However, in developed countries these data are perceived as more robust and credible, and they benefit from significantly greater resources invested in collection, validation and dissemination. Improving the quality of data from public health entities and national censuses providing these data for developing countries would improve the ability of forecast developers to predict demand in those markets. It should be noted that the timeline and investment for improving such information is significant, and that as discussed below, there are other opportunities for more rapid improvements through the use of new information-sharing models for product and market data.

Several observations about developed country models for information sharing and gathering provide particular insights about opportunities to rapidly improve the availability of information for developing country markets.

The most significant difference between developing and developed country markets for health product information is the presence in developed countries of a diverse set of independent organizations dedicated to collecting a wide range of data relevant to forecasters as their primary *raison d'être:*

- Primary market data collected by a few key, credible sources not currently operating extensively in developing countries (such as IMS Health).
- Customized market information gathering and analysis is provided by a multitude of private organizations.

These organizations are focused exclusively on information collection and analysis and need to build reputations with their customers for the quality of their information to succeed.

- Quality and credibility of information is the result of established global networks of sources and trusted methodologies.
- Risk to the firm's reputation and future revenue helps maintain information quality.

Finally, these organizations collect data from diverse sources and serve as a neutral and objective information collector where direct sharing of information across stakeholders might be impossible or cumbersome.

- Market data are typically collected through payment of external sources and available only for purchase.
- Customized market information is collected through primary and secondary research and available primarily for purchase.

A similar model should be explored for developing countries in the form of a global health infomediary.

Appendix G

Supplier needs

Manufacturers rely on information from other supply chain stakeholders to complete their forecasts at each stage. Specifically, they need demand forecasts, funding forecasts or alternative scenarios (that is, upside, realistic and downsides), activity timelines and agreed procedures. For vaccines in particular, they require a three-year forecast, ideally revolving on one-year period, with a firm contract for the first year for 90% of the order, then decreasing for the following years 60% and 40%. Most important, the global needs should be transparent to all players.

This information should be updated on an annual basis, with special updates as appropriate (for example, on announcement of new funding initiatives). For existing products, supply chain forecasts should be provided at least quarterly if not monthly. Vaccines are a special case, where it is necessary to have the information updated annually for global volumes (and the last revolving year three), quarterly for year two and monthly for year one. While suppliers would ideally like to see the data in addition to the actual forecasts, if just the forecasts are provided that it is essential to have transparent assumptions.

At the same time suppliers have information at each stage that could be shared to help other players better estimate demand. For example, in the case of antimalaria drugs, it would be useful to share ACT drug needs between prequalified laboratories in conformity with enlarged criteria (price, quality, pharmacovigilance and the like). This would allow for medium-term forecasts, would stabilize the artemisinin market, would help minimize the risks to manufacturer and would allow countries to learn how to manage ACT drugs. For vaccines it could be helpful to share information about batch failures or any other industrial incident possibly affecting the supply chain, with respect of confidentiality to other competitors, and it is possible to give the price three years in advance.

Funding transparency, support for faster track approvals, firm contracts and regular updates (as mentioned above) could all help reduce uncertainty and risk for suppliers. Suppliers would also like to see greater transparency in the award process, with the knowledge that various suppliers may be treated differently to permit procurement agencies to achieve the objective of secure supply.

Finally, suppliers had several suggestions on how to educate international organizations, funders and procurement agencies on the particular needs of the producers in terms of demand forecast information. Suppliers noted the importance of having individuals with experience from concerned product areas involved when planning any project. It is also key to understand the differences between drug and vaccine supply chains, with vaccine supply chains characterized by extremely long production lead times (and industry capacity building); a limited number of suppliers, making alternative availability scarce in case of short supply; and a higher frequency of batch failure.

The tables on the following pages summarize the key supplier needs from the global health community in order to more effectively engage in developing country markets.

This appendix summarizes the outputs of a subgroup convened by the International Federation of Pharmaceutical Manufacturers and Associations to inform the Global Health Forecasting Working Group of suppliers' specific forecasting needs from the broader global health community.

Table G1
Key supplier needs from the global health community

What do suppliers need?	From whom?	When and how often?	Why?
Pre-product development			
• Unmet need and epidemiology (currently, and potential drivers of growth). • Geographical spread of diseases. • Rates of diagnosis and treatment protocols. • Array of beliefs and perspectives on these issues at different points (clinicians, policymakers, patients; for example, “influence cascades”). • Country-specific price and registry policies. • Public market demand and trends (especially WHO, UNICEF and PAHO): their strategies and future plans. • Market research. • Price elasticity and nonprice determinants of demand (through market research). • Need to take into account the different segments of demand within developing countries. • Needs to be product-specific, in particular for innovative products. • Nonpolitical information on long-term donor forecasts and plans. • Donors to state long-term commitments.	• WHO is the primary source for epidemiology (also GAVI for vaccines). • Hypothetical joint market research organization could have some benefits in no-profit no-loss situations, but could have competitive risks to return on investment (also differs according to primary and secondary and quantitative and qualitative dimensions).	As early as possible in the process (scenarios for 5–10 years ahead).	• Market attractiveness drives decision to invest. • Key drivers of demand, and the degree of certainty or uncertainty of each are fundamental for capacity planning. • Need better interpretation from WHO of need and demand compared to political targets (data not influenced by political agendas). • Funders need to bear some contractual risk even at this early stage.
Product development (phases I and II)			
• Impact of tolerability, safety, dosing and the like on the market. • Implications for price sensitivity. • Expected price ranges and scenarios compared with competitors prices, based on cost components.	• Funders (for example, GAVI for vaccines)—some informal discussions already taking place, but not at a high level or great extent. • Discussions with other partners that would guide strategy.		At this point industry does not know details on what their prices will be, so it can only engage in informal discussions with donors. (Unless commitments are to hold same prices as existing product for new products, but this is a particular case).

Table G1 (continued)
Key supplier needs from the global health community

What do suppliers need?	From whom?	When and how often?	Why?
Large-scale clinical trials (phase III)			
• Reassessment of price indication and expectation. • Need forecasting envelope—both expected forecast and upper bound, which will drive maximum capacity decisions. • Better understanding of subpopulations and target market subsets (women, children). • Large-scale safety issues and impact on demand (contingency scenarios). • Funding forecasts and donor willingness to pay and affordability limits.	• WHO can help identify and assess patient segments. • WHO guidance on characteristics of products they recommend ("signals" for industry).		Funding forecasts will be an indication of the long-term sustainability of resources, and therefore a key input for the industry to assess its level of risk. Affordability indicators by funders are a proxy for market research data in developing countries (public market).
Product launch and post-launch (phase IV)			
• Binding contracts, distinct from "intentions." • Contracts to include reference prices for producers (in particular when product faces competition). • Information on procurement systems of funding beneficiaries (that is, governments). • Information on funding cycles.	Funders.	1–3 years in advance.	Contracts need to provide enough lead time (take into account the product's shelflife, and producer's contracting with raw materials producers). On antimalarial drugs, for example, companies need to commit with raw material volumes in an annual basis. Availability of resources is not the only question, producers face bureaucracy and corruption when working with procurement beneficiaries directly—governments.

Table G1 (continued)
Key supplier needs from the global health community

What do suppliers need?	From whom?	When and how often?	Why?
Ongoing product usage			
• Binding contracts, distinct from "intentions." • Contracts to include reference prices for producers (in particular when product faces competition).	Funders	1–3 years in advance.	Contracts need to provide enough lead time (take into account the product's shelflife, and producer's contracting with raw materials producers). On antimalarial drugs, for example, companies need to commit with raw material volumes in an annual basis. Availability of resources is not the only question, producers face bureaucracy and corruption when working with procurement beneficiaries directly—governments. In the case of antimalarial drugs, there are some unclear points in the list of accepted products to be procured based on the Global Fund resources (WHO prequalification list? Global Fund compliance list?).
• Information on procurement systems of funding beneficiaries (that is, governments). • Information on funding cycles. • For antimalarial drugs, need a coherent list of medicines that can be bought with international funds (M2S2 list based on prequalified files or on the way to being prequalified versus Global Fund "compliance list," unreliable regarding some products and laboratories).	WHO, Global Fund		

For an electronic version of this book, visit the Center for Global Development at **www.cgdev.org/forecasting.**

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Advance praise for **A Risky Business: Saving money and improving global health through better demand forecasts**

“The ability to improve the forecasting of demand for medicines that are needed urgently is a critical key to building a strong and responsive health system. This Working Group has shown that we could make tremendous progress by taking specific steps, with our international partners. Now that the main analyses are complete, it is imperative that we move toward implementing the recommendations so that we will see sustained health benefits from new resources and new technologies.”

Dr. Hetherwick Ntaba
former Minister of Health, Malawi

“While there are many ‘bottlenecks’ that help explain the limited use of existing drugs in resource poor settings, none are bigger than those related to improving the capacity to develop credible forecasts. This complex area has received little attention and is poorly understood by most. If implemented, the recommendations made in the new report of the Global Health Forecasting Working Group of the Center for Global Development will go a long way to improve access to existing medicines and will lower the barriers to the development and delivery of new therapies.”

Dr. Gail Cassell
Vice President for Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company

“This report addresses the critical challenge of all donor agencies engaged in global health—how to improve our ability to forecast demand for essential medicines and diagnostics, with an aim of creating greater access to them in the poorest countries. We at USAID welcome this new and insightful analysis as a means to further healthy and fruitful dialogue about how to work together more effectively with all stakeholders and partners.”

Dr. Kent Hill
Assistant Administrator, Bureau for Global Health, U.S. Agency for International Development

“Scientific progress is critical to developing new technologies, but so, too, is the policy framework that facilitates science. Accurate, robust and dynamic demand forecasting is a key element of this framework that can help drive policy making, funding and research and development.”

Mitchell Warren
Executive Director, AIDS Vaccine Advocacy Coalition

“The recommended road map toward improving the demand forecasts essential to an efficient supply chain details the roles of all stakeholders in a true spirit of partnership that is urgently needed to maximize aid effectiveness and enhance the impact of the Global Fund to Fight AIDS, Tuberculosis and Malaria and others. The stakes are much too high for the world to ignore. The time to act is now.”

Dr. Thelma Tupasi
President, Tropical Disease Foundation

“Practical as a good recipe book, with the intensity and determination of a rallying cry and the thoroughness of a wining battle plan, this book’s suggestions seem so doable that many readers will be tempted to join the fight.”

Dr. Santiago Kraiselburd
Executive Director, Zaragoza Logistics Center

“This report, which takes a fresh look at the problem of demand forecasting, shows clearly how actions at the international level could genuinely facilitate improvements at the country level. I look forward to seeing the recommendations taken forward.”

Dr. Simon Mphuka
Executive Director, Churches Health Association of Zambia

“This book beautifully clears the path for credible forecasts, a means for sharing them and thus a reduction in risk for those of us who are struggling to bring the new technologies to the developing world.”

Dr. Una Ryan
President and Chief Executive Officer, AVANT Immunotherapeutics, Inc.

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