
DFID

HEALTH

RESOURCE

CENTRE

GHP Study Paper 8:

THE PRODUCT DEVELOPMENT PATHWAY

This paper forms part of the 2004 DFID Study: *Global Health Partnerships: Assessing the Impact.*

Chris Gingerich

DFID Health Resource Centre
27 Old Street
London EC1V 9HL
Tel: +44 (0) 207 251 9555
Fax: +44 (0) 207 251 9552

The DFID Health Resource Centre (HRC) provides technical assistance and information to the British Government's Department for International Development (DFID) and its partners in support of pro-poor health policies, financing and services. The HRC is based at IHSD's UK offices and managed by an international consortium of five organisations: Ifakara Health Research and Development Centre, Tanzania (IHRDC); Institute for Health Sector Development, UK (IHSD Limited); ICDDR,B - Centre for Health and Population Research, Bangladesh; Sharan, India; Swiss Centre for International Health (SCIH) of the Swiss Tropical Institute, Switzerland.

This report was produced by the Health Resource Centre on behalf of the Department for International Development, and does not necessarily represent the views or the policy of DFID.

Title: The Product Development Pathway

Author: Chris Gingerich

DFID Health Resource Centre
27 Old Street
London EC1V 9HL
Tel: +44 (0) 20 7251 9555
Fax: +44 (0) 20 7251 9552

Table of Contents

1.	A Road Map for Research	1
2.	Design Principles	2
3.	Design Details	3
4.	Discussion	4
5.	HIV	6
6.	TB	7
7.	Malaria	8
8.	Definitions – Row 1.....	9
9.	Definitions – Row 2.....	9
10.	Definitions – Row 3.....	10
11.	Definitions – Row 4.....	10
12.	Definitions – Row 5.....	11

1. A ROAD MAP FOR RESEARCH

New, cheap and 'simple to use' health products are needed if poor countries are to combat HIV, TB, Malaria and other diseases. DFID and other donors are making substantial investments in health research, but research to develop new health products is an expensive and complex process. It involves many different players, multiple sources of funding and a range of investment strategies. This makes it difficult for DFID to identify how it can use relatively small resources to best effect. During the early stages of the wider GHP study commissioned by DFID in 2004, a need was identified to produce a visual representation of the processes that must occur to move a health product from original concept to tangible products being used in a developing country setting. The requirement was a user-friendly tool to aid both advocacy and analysis. The following Product Development Pathway has been developed by Chris Gingerich, using HIV, TB and Malaria as the disease examples. The diagram identifies the different processes required to generate new products, and the barriers and linkages between the various processes. It also identifies "who is doing what" at each stage of the research process.

Discussions on the potential use of the Product Development Pathway Tool in advocacy and analysis are still ongoing, with interest from partners including The Gates Foundation; MRC; Wellcome and Rockefeller. The discussions will have possible implications for DFID's research funding strategy and evaluation of Public Private Partnerships. Issues being debated include:

1. Does the pathway differ between drugs and vaccines, and between diseases?
2. How can the tool be used to address health systems and pro-poor issues? Do issues of poverty need to be more strongly embedded within the tool, or is it more a question of how the tool is used and interpreted?
3. How can the tool be used for advocacy?
4. Where are the gaps/shortfalls/overkill – in terms of research spend/activity, particularly in the field of vaccine research?
5. How can we use the tool to evaluate our investments in product development, such as, for example, our investments in Malaria drug research?

2. DESIGN PRINCIPLES

- **Ease of Use** – The diagram attempts to maintain a bias towards “ease of use” and simplicity. Every attempt was made to make use of intuitive and uncluttered design elements, and to limit the overall number of graphical constructs. The diagram is (ideally) intended to be wholly self-contained, however definitions of the cells are presented below.
- **Comprehensiveness** – The diagram attempts to be comprehensive in its coverage of the major “sub-paths” that together comprise the overall product pathway.
- **Detail** – The diagram attempts to provide sufficient detail to understand the major linkages in the pathways and to provide insight into issues such as funding, coordination and potential pitfalls – yet does not provide so much detail as to become overly complex.
- **Flexibility** – The fact that the diagram is constructed out of a number of individual “cells” provides for great overall flexibility:
 - Cells can be added, removed, or merged for specific health products and/or disease areas, and to achieve the desired level of detail.
 - Cells can be re-ordered and repositioned (relative to one-another) to represent observed differences between products and diseases, and to represent the difference between the prescriptive ideal and what is observed in reality.

3. DESIGN DETAILS

- **Cells** – Each cell identifies a specific “step” in a sub-path. Cells can represent one or more processes or a specific outcome.
- **Cell Color** – Colors are used to distinguish major process groupings from one another.
- **Cell Borders** – Colored cell borders represent potential barriers (red) or notably critical (green) processes or outcomes.
- **Arrows** – Arrows represent key linkages or dependencies, in which the initial process is critical for successful progress in the dependent process.
- **Shaded and Un-Shaded Circles** – The circles represent the number of GHPs (shaded) and PPPs (un-shaded) that have activities, programs or funding relevant to the cell. For this diagram, each full circle represents 2 of the specified organization type.
- **Cell Position** – This diagram emphasizes the sequencing of events. Time flows from left to right, cells are positioned along the diagram in observed sequence. *Note however that cell width and space along the x axis is not proportional – i.e. the diagram representing sequencing only.*

4. DISCUSSION

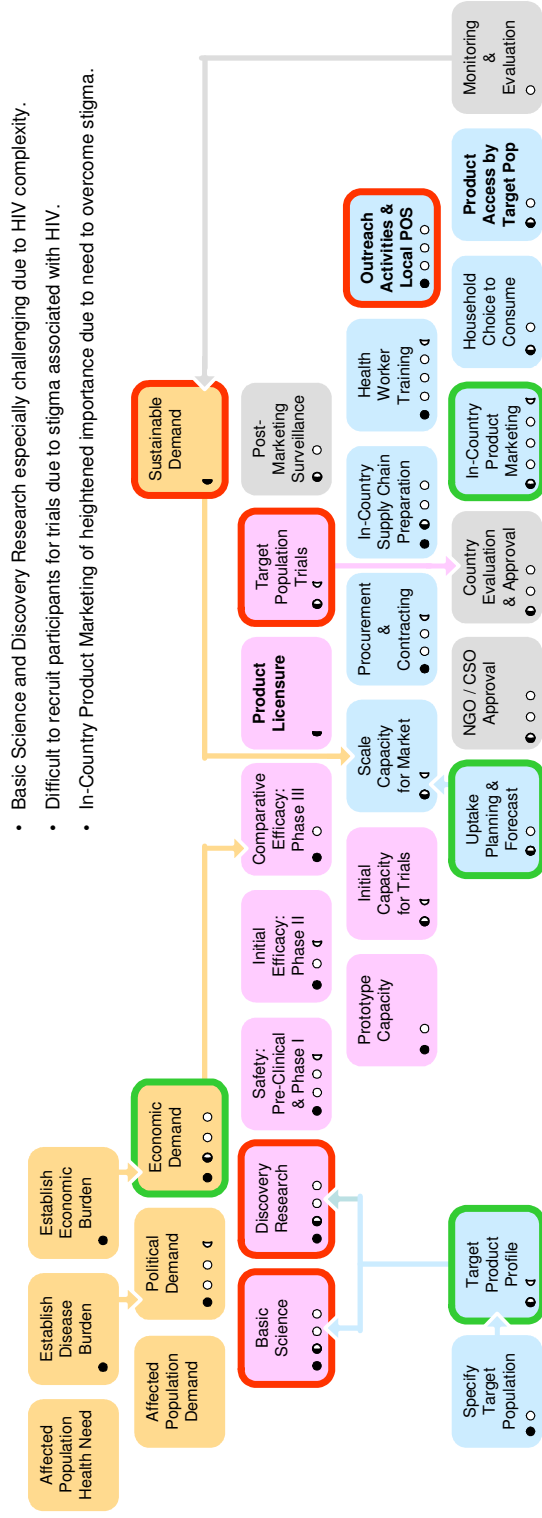
The impetus for creating the diagram was a need to represent in an easily digestible fashion – with a minimum of text or prose – the processes that must occur to move a health product from original concept all the way through to being used in a developing country setting, and to map the GHPs and PPPs that are working along this pathway.

- The development of the diagram has been an exercise in trade-offs and compromise for the primary reason that the requirement for an “easily digestible” diagram limited the ability to represent a high level of detail and a large number of concepts on the slide.
 - To show individual linkages between specific GHPs / PPPs and specific boxes would clutter the diagram – thus it was decided that much of the desired impact could be communicated by showing the *number* of GHPs / PPPs involved in each cell, without specifying the *exact organization(s)* involved.
 - In some sense, each cell is a potential barrier, and each cell is linked to one or more other cells along the pathway. An attempt was made to highlight only the most important barriers and linkages in order to maintain simplicity.
 - Since each diagram is for a single disease – but encompasses a wide range of health product types – a certain amount of product-specific detail had to be removed in order to produce a diagram that was general enough to be relevant across a wide range of health products. (Note that the Product Development sub-path is still somewhat specific to pharmaceuticals.)
- The mapping exercise could be improved upon, if a more detailed investigation were feasible
 - Aside from a limited number of conversations with key experts (Roy Widdus, Hannah Kettler), information on the activities and program of the GHPs and PPPs was taken obtained from organization web sites and the previous report by Kent Buse. Additional extended interviews with experts, and direct conversations with the organizations would prove useful in improving the accuracy of the mapping.
 - There was much room for interpretation. Many organizations are not currently involved in specific activities, although their mission statement implies that they will be in the future – in these cases, organizations were assumed to be included in the mapping. Likewise, many organizations (e.g. CVP, GAVI/VF) do not currently work in HIV, TB or Malaria, however it is reasonable to expect that they will become heavily involved once vaccines become imminent. In these latter cases, such organizations were excluded from the mapping.

The results of the mapping exercise show some strong trends, but may be misleading:

- Surprisingly, there appears to a comparable amount of activity in the Product Supply, Marketing & Access and Product Development areas. However, this may be misleading for the following reasons:
 - The difference in the scope and/or magnitude of the organizations' involvement in any of the cells can be extreme (for example, some organizations may focus their efforts on limited project in a single district, while others have broad programs across multiple countries). This phenomena tended to favor organizations appearing in Product Supply, Marketing & Access group.
 - The amount of funding required to maintain programs in Product Development may be greater – especially in later stages – than the amount required for supporting other types of activities along the pathway. The phenomena results in fewer organization being shown as mapping to Product Development even though the Product Development area may represent a larger share of total funding.
- Looking across the three different disease areas, it is readily apparent that there are a greater number of organizations involved in HIV than in either TB or Malaria.
- Recommended next steps include:
 - Developing a dynamic or animated version of the diagram that would enable the presenter to alternately display and hide specific elements of the diagram, thus allowing for the inclusion of a much greater level of detail and an increased number of visual concepts to represented, while maintaining the overall simplicity of the diagram.
 - Perform a more focused and extensive review of GHPs and PPPs for the mapping (mentioned above).
 - Seek out new applications for the diagram (e.g. mapping funding levels or project planning)
 - Develop product-specific applications of the diagram, thus allowing for more detail, and reduced “generalization”.

5. HIV



- Basic Science and Discovery Research especially challenging due to HIV complexity.
- Difficult to recruit participants for trials due to stigma associated with HIV.
- In-Country Product Marketing of heightened importance due to need to overcome stigma.

Process Groups

- Product Demand
- Product Development
- Product Supply, Marketing & Access
- Product Monitoring, Evaluation & Approval

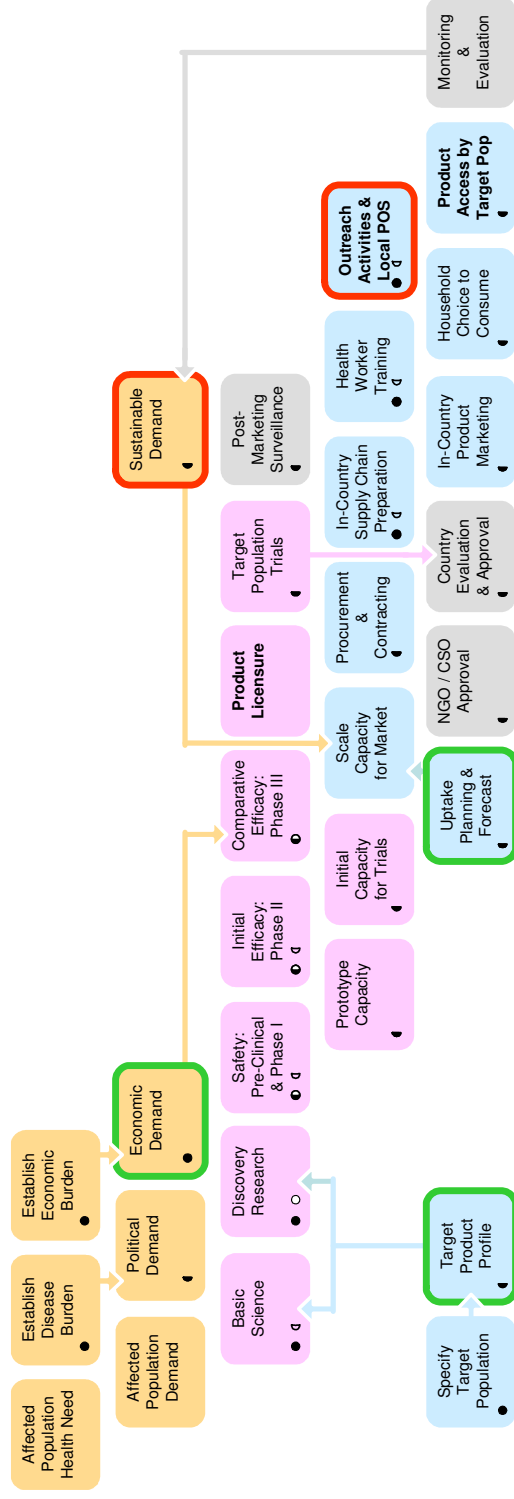
Barriers & Linkages

- Potential Barrier / Difficult Process
- Important Process (Often Overlooked)
- Key Dependency

GHP / PPP Mapping

- = 2 GHPs
- = 2 PPPs
- ◐ = 1 GHP & 1 PPP
- ◑ = 1 GHP
- ◒ = 1 PPP

6. TB



Process Groups

- Product Demand
- Product Development
- Product Supply, Marketing & Access
- Product Monitoring, Evaluation & Approval

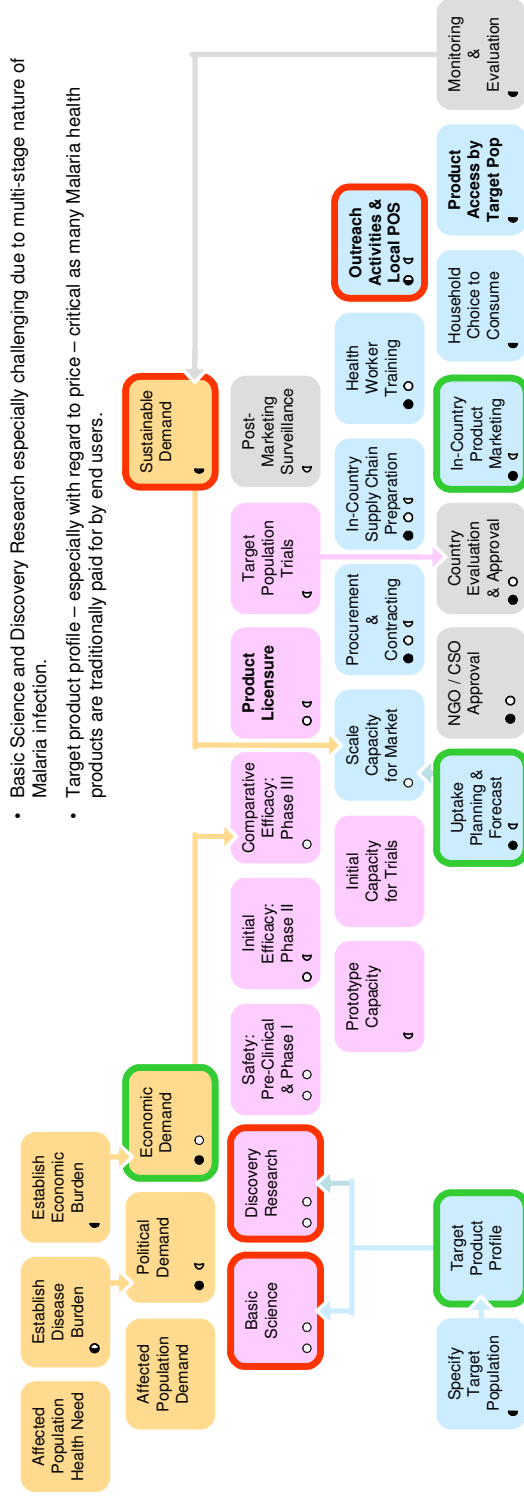
Barriers & Linkages

- Potential Barrier / Difficult Process
- Important Process (Often Overlooked)
- Key Dependency

GHP / PPP Mapping

- = 2 GHPs
- = 2 PPPs
- = 1 GHP & 1 PPP
- = 1 GHP
- d

7. MALARIA



- Basic Science and Discovery Research especially challenging due to multi-stage nature of Malaria infection.
- Target product profile – especially with regard to price – critical as many Malaria health products are traditionally paid for by end users.

Process Groups

- Product Demand
- Product Development
- Product Supply, Marketing & Access
- Product Monitoring, Evaluation & Approval

Barriers & Linkages

- Potential Barrier / Difficult Process
- Important Process (Often Overlooked)
- Key Dependency

GHP / PPP Mapping

- = 2 GHPs
- = 2 PPPs
- ◐ = 1 GHP & 1 PPP
- ◑ = 1 GHP
- ◒ = 1 PPP

8. DEFINITIONS – ROW 1

Cell Title	Description
Affected Population Health Need	Recognition of adverse health among a specific population, due to the disease in question.
Establish Disease Burden	Quantification of the impact of a given disease on the health status of a specific population (as quantified by chosen statistical measures; for example, the Disability Adjusted Life Year (DALY)).
Economic Burden	Quantification of the economic burden of a disease from epidemiologic disease burden data -- includes direct costs such as treatment and hospitalization, as well as opportunity costs from lost productivity.

9. DEFINITIONS – ROW 2

Cell Title	Description
Affected Population Demand	Expressed (economic) demand among the specific population for the health product type (e.g. diagnostic, prevention, treatment) in question. (Note that the level of demand need not be of the magnitude required to obtain specific products).
Political Demand	Establishment of expressed political demand from developing country governments for new and improved health products for treating the disease(s) in question
Economic Demand	Mobilization economic demand by affected populations, governments and donors, resulting in a credible market for the health product.
Sustainable Demand	Stabilization of reliable and predictable long-term funding for the health product in question.

10. DEFINITIONS – ROW 3

Cell Title	Description
Basic Science	Basic research into the pathogen(s) in question demonstrating a new level of understanding of the pathogen(s), which offer insight into new diagnostic and treatment possibilities.
Discovery Research	Applying scientific findings to assess the promise of new diagnostic and treatment strategies in a laboratory setting.
Safety: Pre-Clinical & Phase I	Performance of clinical trials on a few persons with a candidate product in order to determine its safety. Positive results allow for Phase II testing.
Initial Efficacy: Phase II	Performance of clinical trials on more persons than in phase I, evaluating the efficacy of a treatment for the disease in question and monitoring possible side effects. Positive results allow for Phase III testing.
Comparative Efficacy: Phase III	Performance of large scale clinical trials, which provide conclusive data on efficacy, safety, and side-effect profiles. Positive results allow the product in question to be assessed for approval by a given regulatory agency (FDA, EMEA, or other).
Product Licensure	Formal approval of the health product by appropriate national regulatory agencies. Product now eligible for mass production and marketing.
Target Population Trials	Additional field trials amongst specific target populations in developing countries, to demonstrate the safety and efficacy of a product within the target population.
Post-Marketing Surveillance	Ongoing monitoring for adverse events once the health product is in use amongst the target population.

11. DEFINITIONS – ROW 4

Cell Title	Description
Prototype Capacity	Production of a sufficient quantity of the health product for use in pre-clinical testing, and phase I & II clinical trials.
Initial Capacity for Trials	Production of a sufficient quantity of the health product for use in phase III clinical trials.
Scale Capacity for Market	Increase in capacity to move from quantities needed for phase III & IV trials, to a capacity to meet anticipated market quantity demand.
Procurement & Contracting	The process of negotiating short and long-term purchase contract with manufacturers or other suppliers, and taking delivery of the goods.
In-Country Supply Chain Preparation	Ensuring that the systems and processes needed to distribute the health product from the receiving port(s) to point-of-service are suitable to deliver the desired quantity of product to the target populations in a safe and timely fashion.
Health Worker Training	Training existing and new local health workers to distribute / administer the product to the target population.
Outreach Activities & Local POS	The final stage in delivering the health product to a point where it is accessible by the target population, including making the product available at local points of service and/or taking the product directly to the target population (as in vaccination campaigns).

12. DEFINITIONS – ROW 5

Cell Title	Description
Specify Target Population	Recognition of the specific demographic groups expected to utilize the health product. Documentation of specific needs, circumstances and/or other concerns that are pertinent to the target population.
Target Product Profile	Description of desired health product characteristics such as packaging, dosage, efficacy, safety, storage requirements, shelf-life, and price.
Uptake Planning & Forecast	Strategic plan for the introduction of a new health product, including near and medium term quantity forecasts; ideally co-developed by developing country health ministries, donors and all relevant NGOs, GHPs and PPPs.
NGO / CSO approval	Formal product approval by NGOs (e.g., WHO) and major GHPs/PPPs (e.g., GFATM).
In-Country Product Marketing	Development and implementation of a marketing plan to encourage uptake of the product among the target population.
Household Choice to Consume	The decision by targeted individuals (or their caretakers, in the case of children) to seek out and/or accept the health product.
Product Access by Target Population	The process of product access or utilization by members of the target population.
Monitoring and Evaluation	Data collection on key process and performance measures, and reporting of findings back to appropriate organization for ongoing refinement of products, processes, procedures and funding.

