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Committing to vaccine R&D: a global science policy priority

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Abstract

The amount of vaccine R&D performed, especially that geared towards health issues affecting the developing world, is relatively modest. Despite immunisation representing the most effective tool for achieving disease eradication, and the general consensus being optimistic about the development of a vaccine capable of fighting AIDS, Malaria and Tuberculosis, neither private nor public entities are investing sufficiently in the field. Reasons can be associated both with a lack of market incentives as well as with the low priority that these diseases are given on Western political agendas. However, seen through a "Global Public Good" lens, it appears to be in the interest of high-income countries, and their governments in particular, to invest public resources – financial and infrastructural – in vaccine R&D for global pandemics. The paper suggests managing international cooperation through the creation of a global fund. It discusses a number of proposals put forward in the existing literature and offers a range of policy options.

Keywords: Science and health research policy; Communicable diseases; Global governance; Global public goods

1. Introduction: current trends in vaccine R&D activities

Diseases such as AIDS, Malaria and Tuberculosis (TB) are responsible for the death of over 5 million people a year world-wide (WHO, 2000), with over 70% of these deaths occurring in Africa alone (European Commission, 2000). It is also estimated that AIDS, Malaria and TB infect 5 million (UNAIDS and WHO, 2002), 300–500 million (Harvard Malaria Initiative, 2000) and 17 million (WHO and UNICEF, 2002) individuals each year, respectively. The economic and social repercussions that entire countries and continents experience as a result of these pandemics are tremendous: the UN (2001) estimates that AIDS alone will cause South Africa's GDP to fall by 17% by 2010—this without taking into account the falling productivity of workers, declining savings and investment, rising business costs and decreasing life expectancy. Similar patterns are also envisaged for Malaria and TB (WHO and UNICEF, 2002).

To date, medical science has developed a number of drugs for the treatment of these diseases: there is an AIDS "cocktail" drug capable of reducing con-

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siderably the magnitude of the disease's manifestation; Malaria can somewhat be prevented, although full immunity cannot be guaranteed; and the Bacillus Calmette-Guerin (BCG) vaccine for TB has proven effective, but in young children only (Kaufmann, 2000). What has not been developed yet is a vaccine capable of eradicating these diseases, despite leading health organisations (WHO and UNICEF, 2002) having argued in favour of preventive immunisation as being both economically and socially preferable to treatment—the most remarkable example being the eradication of smallpox in 1977 as a result of WHO's smallpox eradication programme (Fenner et al., 1988).

Unfortunately, despite the proven success of immunisation, the resources devoted to vaccine R&D are still scarce, compared with those geared towards treatment. The case of AIDS is illustrative: annual vaccine research expenditure still represents just over 10% – about US $400 million – of the annual global HIV/AIDS anti-retroviral R&D spending – US $3 billion (Esparza, 2000; EU, 1999; IAVI, 2002). The figures for Malaria and TB are even more disconcerting. Just over US $55 million is the total worldwide spending on a Malaria vaccine (Malaria Vaccine Initiative, 2003), whilst for the development of a new TB vaccine, the WHO (WHO and UNICEF, 2002, p. 61) estimates that over the past decade spending has totalled no more than US $150 million. It is the purpose of this paper, on the one hand, to encourage the political support necessary to guarantee a robust and long-term financial commitment to preventative immunisation, and on the other to provide a rational justification for doing so. As the paper will argue, fighting infectious diseases is not a purely technical issue. On the contrary, it is a debate in which economists and policy scientists can contribute considerably.

The paper is organised as follows: Section 2 examines the scientific uncertainty surrounding vaccine R&D activity, and Section 3 discusses the importance of incentives in shaping the direction of R&D investment. Section 4 is devoted to the North-South divide in knowledge capabilities and financial resources, whilst Section 5 provides an estimate of the ideal resources necessary to fund vaccine R&D. Section 6 provides a rational as to how, and why, these resources should be distributed across countries. The implementation and the implications of the proposal are discussed in Section 7.

2. Are these vaccines within reach?

Given the importance of preventative immunisation, it is worth asking ourselves the reasons why research in this field is so minimal. Could it be that the current state of scientific knowledge is impeding the discovery of an effective vaccine against these diseases? Or could the lack of investment in the field reflect a rational evaluation of the expectations of hitting the target? Scientific investigation is by nature surrounded by uncertainty, and even more so when searching for major scientific breakthroughs. On the whole, three scenarios can be identified in relation to the investment of targeted scientific research:

(1) *One searches for something but never finds it*: despite the wholehearted commitment, research does not yield the desired results. The research carried out may stimulate learning and build investigative capacities, and in some cases it may even lead to the identification of blind alley-ways, though the problem still remains unsolved. The case of an anti-tumour vaccine falls within this category.
(2) *One searches for something and finds something else*: the investments destined to scientific research do not lead to the objective set, but the results obtained are still relevant to different research areas despite their failure. Kroto's discovery of the C_{60} molecule is a perfect example of serendipity.
(3) *One finds what is being looked for*: the massive concentration of human and economic resources on specific projects allows one to obtain the results one is aiming for. The Manhattan project and the conquest of the moon represent striking examples of scientific results obtained as a consequence of strong financial and political commitment.

The economics of scientific research suggests that there is no clear linear relationship between input and output, since any scientific investigation is dominated by incertitude[1], including that of vaccine R&D. However, it is the opinion of experts in the field that the

[1] This concept of *incertitude* was developed by Andrew Stirling and subsequently used by the UK Economic and Social Research Council (ESRC) (1999). Stirling divided *incertitude* into four main areas related to the occurrence of an event: risk, ambiguity, uncertainty, and ignorance. These areas have been constructed on the basis of the knowledge we hold of the likelihood of an event occurring and the possible outcomes. Risk: outcomes are well defined/some ba-

major impediment to basic vaccine science appears not to be so much related to a knowledge gap, as to a lack of serious financial commitment (Médecins Sans Frontières, 2001; International AIDS Vaccine Initiative, 2001; WHO and UNICEF, 2002; Webster and Hill, 2003).

3. The system of R&D incentives

If a knowledge gap cannot explain the lack of investment, could a lack of incentives be blamed instead? Two aspects need to be considered: the first one relates to R&D expenditure of both profit-seeking and public & non-profit agents; whilst the second one relates to the distribution of the disease burden across countries.

Back in 1962 Kenneth Arrow suggested that scientific knowledge is costly to produce but that its diffusion could occur at zero or very low costs. This assumption has proven wrong for the majority of scientific and technological fields, as indicated by a vast literature on technology transfer (e.g., Pavitt, 1987). The same literature has pointed out that there are substantial differences across technologies. In a comparative perspective, vaccines, and more generally drugs, are one of the fields in which substantial costs reside in the initial research, whilst duplication can occur at much lower costs. To this however, a third and equally significant stage should be added: the diffusion and administration of vaccines, which – if not supported by an adequate infrastructure - can be problematic and costly.

Distributing and administering vaccines involves a variety of organisational problems and can prove extremely costly, even when the knowledge upon which they have been developed is made freely available (see Woodle, 2000; Kaul et al., 2003). However, past experiences illustrate how, in some cases, financial resources have been found once a successful vaccine has been made freely available: the development of the measles vaccine, for example, has enabled 60% of 1-year-old children to be fully immunized in low income countries, and 89% in high income countries (UNDP, 2003, Table 6, column 5). In contrast, the early stages of drug development find it much harder to inspire financial commitment—confirming the negative effects of uncertainty on research investment. In other cases, the gap between the development of a successful vaccine and its diffusion has been extremely long, even in the absence of proprietary regimes, as illustrated by the case of smallpox. The smallpox vaccine had been discovered in the second half of the 18th century, yet the WHO smallpox eradication programme was carried out only between 1967 and 1980, when financial resources (about US $300 million) were eventually found (see Fenner et al., 1988, p. 542 and p. 258). In other words, vaccine science illustrates the difference between freely available knowledge, and knowledge that can be effectively used. As shown by a vast literature (see, for example, Callon, 1994; Cockburn and Henderson, 1998), absorptive capacity is needed in order to apply knowledge to production. In this field, freely available knowledge is a necessity, but not a sufficient condition to allow the effective implementation of policies for its diffusion. Despite the technical hurdles associated with vaccine programmes, current R&D efforts are inadequate in addressing the control of communicable diseases. A possible explanation can be found in profit-seeking investors' reluctance to chance their capital to fund R&D activities over which they have little guarantee of appropriating the returns from their discovery. The dispute over the diffusion of the HIV/AIDS cocktail drugs, between the US's so called Big Pharma and the South African government in 2001, is a perfect example of the serious implications that knowledge, and the ease with which it can be diffused, has on private investment (May, 2002). For these reasons, Arrow (1962) had warned about the dangers of leaving to market forces alone the responsibility for providing the financial incentives necessary to stimulate scientific R&D, since this would generate a knowledge-investment sub-optimal to that socially desirable. In an attempt to overcome this market failure, Arrow referred to two possible solutions, both requiring active involvement by the State:

(1) Resorting to institutional mechanisms, such as Intellectual Property Rights (IPRs), that guaranteed agents the right to benefit from the results of their inventions and which represent the institutional mechanisms by which private agents would be pro-

sis for probabilities of the event occurring. Ambiguity: outcomes are ill defined/some basis for probabilities of the event occurring. Uncertainty: outcomes are well defined/no basis for probabilities of the event occurring. Ignorance: outcomes are ill defined/no basis of probabilities of the event occurring.

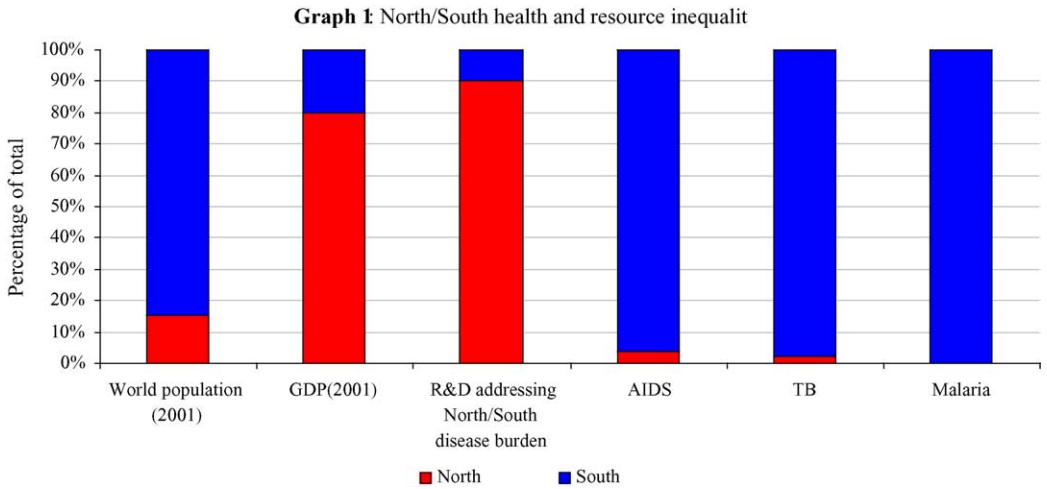

Fig. 1. North/South health and resource inequalities. Sources: for *Malaria*, UNDP (2002), Table 7, column 8, p. 173. For *AIDS*, UNAIDS and WHO (2002), p. 6. For *TB*, UNDP (2002), Table 7, column 9, p. 173. For *GDP*, World Bank (2003), Table 3, column 1, p. 239. For *World Population*, World Bank (2003), Table 1, column 1, p. 235. For *R&D addressing North/South disease burden*, MSF (2001), p. X. *North*: high income countries. *South*: all others. (See UNDP, 2002).

vided with the incentives necessary to invest time and resources in scientific research.

(2) Alternatively, resorting to direct public intervention as a primary financier of scientific research – either by entrusting public infrastructures, or by outsourcing research activities to private contractors.

Within modern capitalist economies, both these forms co-exist: IPRs provide protection for private investors;[2] the public sector performs research through a variety of publicly owned infrastructures, such as academic research laboratories, as well as outsourcing research projects to private operators – as exemplified by the space and military R&D programmes contracted to the business sector.

Governments have often provided the funding necessary for research in critical areas where IPRs have failed to act as a sufficient incentive for business investment. Examples are provided in the areas of defence, space, public transport, cancer and, more recently, the SARS health scare. There has never been a pure market economy to constrain government-spending when faced with socially or politically sensitive issues. Regrettably though, the overall share of publicly funded R&D has experienced a substantial reduction in the past decade. In OECD countries for instance, government financed R&D represents just 30% of the total R&D funding (OECD, 2003, Table 14).

4. The North-South divide

The lack of incentives alone therefore does not explain the constrained investment towards targeted R&D for vaccine development. Geo-economic factors must also be involved. Fig. 1 illustrates the distribution of diseases across the North (high-income countries) and the South (low-income countries), clearly showing that the bulk of infections are almost entirely confined to the South. Malaria, for instance, is today a disease exclusive to the South, since in the North it has been eradicated by improving overall environmental conditions[3]; similarly TB has an incidence of infection 13 times higher in the South than in the North[4]; AIDS also is far more prominent in low-income countries than in high-income countries, with the result that, in the North,

[2] It should be noted that Arrow (1962) also associated with IPRs a reduction in output compared to unconstrained market competition.

[3] The only high-income country with reported malaria cases is Korea (UNDP, 2003, Table 7, column 8, p. 258).

[4] There are 18 new cases per 100,000 inhabitants in high income countries, but as many as 233 in low income countries (World Bank, 2003, Table 2.19, column 3, p. 110).

AIDS represents a much more serious health threat than Malaria or TB. Not surprisingly, AIDS benefits from much greater global research and financial commitment than Malaria or TB – the annual AIDS vaccine research budget is in fact seven times greater compared to Malaria vaccine research, with US $400 million (IAVI, 2002) and US $55 million respectively (MVI, 2003). The fact that the North concentrates 80% of the world's GDP and 90% of the world's R&D budget (see Fig. 1) confers it not only the resources and the competences necessary to address these diseases, but also the power to set the global medical research agenda. In contrast, the South lacks the resources, the competencies and the political power to do so. This mismatch between global R&D efforts and global health needs has come to be known as the 10/90 gap: 10% of the world's total R&D expenditure addresses 90% of the total disease burden (Global Forum for Health Research, 2004). In a nutshell, countries affected by diseases lack the resources and expertise to combat them, whilst countries holding the resources and the expertise to fight them, lack a direct health threat to do so.

Many occasions, the South has benefited from the diffusion of knowledge originally developed for the North, as in the case of the smallpox vaccine. In other occasions, firms in the North have developed technological innovations to the benefit of the South (such as hybrid seeds), although such innovations had been developed on the expectation of a market demand in the South. There is no doubt that the "social" demand for such vaccines is higher than its "market" demand. However, there is no guarantee that the South, in spite of the high share of the disease burden, will also be able to provide a "market" demand of a magnitude attractive enough to stimulate private research. Moreover, the social pressure that would be exerted over inventors to release the vaccines, in order to allow for diffusion throughout poorer countries, would be such that governments would be forced to resort to compulsory licenses, as exemplified by the celebrated case between South Africa and the pharmaceutical industry over the diffusion of the AIDS anti-retroviral cocktail drug (see Seckinelgin, 2002). If this were to become common practice, potential investors might fear that IPRs would no longer guarantee them an adequate level of protection for their investments. The consequences would be a further discouragement of private R&D in a field already lacking much financial support.

5. Financing vaccine R&D activities

In recent years, despite a common consensus regarding the need to combat these diseases, with both public and private sources arguing in its favour, the International Community has failed to respond accordingly. In 2000 for instance, the UN Secretary General Kofi Annan urged the International Community to fund prevention and treatment against major infectious disease by establishing the Global Fund To Fight AIDS, Tuberculosis and Malaria (GFATM). Similarly, the Commission on Macroeconomics and Health (2001, pp. 81–86) has pleaded for a substantial increase in funding for health care, with particular reference to the creation of a global health research fund. However, to date, these pleas for a constant reliable financial commitment have gone unheard (Tan et al., 2003). Most countries have met only partially their financial obligations to the GFATM. Most of the current funding for vaccine research and development has come from provate pockets and philanthropic foundations. The Bill and Melinda Gates Foundation, for instance, has alone already pledged US $1 billion for the prevention and control of infectious diseases through a number of national and international programmes. Other public-private partnerships have also been created with a view to providing financial support for vaccine R&D activities. Yet, as will be discussed in more detail in section 7.5, despite good intentions, the temporary mandate and limited financial assets they are constrained by, makes philanthropic public-private partnerships far from being a desirable political solution. As will also be argued later, an international fund would appear to be a much more desirable mechanism for the promotion of preventative immunisation. Although currently the Global Fund to Fight Aids, Tuberculosis and Malaria focusses solely on the prevention and treatment of these diseases, given an adequate financial capacity, there would be nothing to prevent it from directing additional resources also towards vaccine R&D.

As to what these resources would entail practically, estimates concerning the costs of drug development are very heterogeneous. Figures vary from US $50 million (UNICEF and WHO, 1996) to almost US $900 million (Frank, 2003; Tufts Center for the Study of Drug Development, 2003) and this appears to depend on whether the costs of clinical, pre-clinical and post-approval tests are all accounted for (for a complete overview see

UNICEF and WHO, 1996; TB Alliance, 2001; Miller, 1998; DiMasi et al., 1991; Frank, 2003; and Tufts Center for the Study of Drug Development, 2003). The Commission on Macroeconomics and Health (2001, p. 81) estimates that the cost of developing a vaccine for HIV/AIDS, Malaria and TB would require roughly a yearly R&D budget of US $1.5 billion - though the Commission fails to provide an indicative research time frame for this.[5] As mentioned earlier, experts are of the opinion that a HIV/AIDS, Malaria and TB vaccine is still ten to fifteen years out of reach (Kaufmann, 2000; WHO and UNICEF, 2002; MVI, 2003), an opinion that is also supported by evidence in the pharmaceutical and medical field. Grabowski and Vernon (1994) have shown that research projects take, on average, about 10 years to reach completion.

According to these estimates therefore, the cost of vaccine development for AIDS, Malaria and TB would amount to US $1.5 billion a year, every year, over a 15-year-period. This would add up to a total R&D budget of US $22.5 billion. In the event that any, or all, of the vaccines were found earlier than anticipated, resources could be re-directed towards: vaccine R&D for any of the other diseases under investigation; diseases other than those investigated; or the diffusion of the vaccine developed.

Understandably, US $22.5 billion is a substantial amount of resources, compared to the current patterns of vaccine R&D expenditure—which according to the estimates here provided does not exceed more than US $600 million a year—it is an affordable sum for most countries in the North.

Although part of the sum could be raised by diverting resources from other destinations (eg. military expenditure), the aim of the proposal would be to *increase* rather than *re-locate* current R&D expenditure patterns. This would imply a major shift in the direction of scientific and technological advance, and also the addition of a third priority to the existing leading fields of military and space R&D (among those publicly funded) and electronic and communications R&D (among those privately funded). The fight against infectious diseases would be comparable in size to the Manhattan project, but with a much more socially constructive output.

Regrettably though, vaccine R&D does not figure amongst the top priorities of most governments agendas. Just as with Nelson's metaphor over the moon and the ghetto (Nelson, 1977), we share the view that it is merely a matter of irrational priority setting. Since budget priorities are a public concern, there is no reason as to why they cannot be re-directed by adequate pressure from civil society and the academic community. The most efficient and pragmatic way of addressing this health issue would be to strengthen the already existing international funds dedicated to vaccine R&D. Such funds would serve the purpose of financing international vaccine research in different countries via a variety of experimental collaborations. Both final and intermediate results, including the vaccines discovered, would be considered the patrimony of all humanity and a global public good, with the United Nations acting as the main coordinator, given its legitimate mandate and competencies necessary for the fund's management. The following section argues this position.

6. Arguments for a global R&D vaccine fund

6.1. A tentative distribution of the contributions to the fund

Recall the uneven distribution of resources and disease burden between the North and the South (see Fig. 1). Here we consider how the total bill for this R&D commitment should be distributed among countries. Unfortunately for vaccine research, nations' commitment to vaccine development has not experienced the same kind of enthusiasm that has distinguished space research or military technology. Vaccine research appears to have been distinguished by a free-rider's logic, by which many governments, especially in Europe, have favoured, financially, the R&D of non-targeted academic activities and commercial areas to stimulate competitiveness among national firms, rather than towards long-term basic research (European Council, 2002). The issue of competitiveness is especially relevant to the European pharmaceutical industry, which

[5] The estimate provided by the Commission on Macroeconomics and Health does not apply exclusively to vaccine R&D, although vaccine R&D would account for the greatest share of the total costs. The figure of US $1.5 billion is therefore taken as a rough indication of the desired resources necessary for developing a successful vaccine for the communicable diseases here mentioned, namely HIV/AIDS, Tuberculosis and Malaria.

in recent years has experienced a loss of competitiveness against its US counterpart (Orsenigo et al., 2000). Replacing this competitive spirit with a cooperative approach would require on the one hand, greater coordination between the initiatives currently underway and, on the other hand, the institutionalisation of a formal system of global governance. If this were achieved, countries would find it much harder to neglect their international commitments. Yet, even if a cooperative approach were to be promoted, a question more ethical than political in nature would still need to be answered: by what criteria should the share of contribution between countries of the North and the South be determined? There are three dimensions that are worth considering:

1. The benefit that each country shall derive from an eventual vaccine development, connected to the estimated number of patients that would benefit from its treatment;
2. the ability of a state to contribute financially to the vaccine development – which is assumed to be linked to a country's income;
3. the availability of medical and scientific infrastructures able to sustain research activities.

Given that there is a strong, positive correlation between points 2 and 3, we can assume that if a high income country is able to contribute significantly to the financing of a vaccine's development, it will also be able to support its research activities.[6] Thus, we are left to focus on two contrasting criteria: 1) either on the basis of the population benefiting from the development of a vaccine; or 2) on the basis of the country's capacity to contribute financially (we assume that the financial contribution of each will be associated to the performed R&D in the country).

The first criterion places the greatest burden of responsibility on the South. Realistically though, this hypothesis is not feasible, since countries in the South lack the resources, infrastructures and expertise necessary to provide contribution proportional to their share of the disease burden—the acquisition of knowledge is in fact a long process that requires learning capacity, absorption of competencies and the building of local know-how (e.g., Polanyi, 1962; Pavitt, 1987; Lundvall and Johnson, 1994; Cockburn and Henderson, 1998).

The second criterion instead, places the greatest share of responsibility upon the shoulders of the North which, in contrast with the South, holds both the financial resources and the infrastructure necessary to perform R&D exercises. Though, how could an argument in favour of the application of criterion 2 possibly be justified? No doubt, OECD countries would never allow Malaria or Tuberculosis to claim as many lives in their own countries with the same disinterest they have shown towards Southern peoples, and it is not a coincidence that out of the eleven HIV/AIDS clades found, the one to receive greatest research attention has been the clade afflicting the North – despite it accounting for just 4% of the world's entire infected population. Whether countries in the North have a rational and ethical responsibility to finance and perform research activities for diseases which do not threaten them directly, depends very much on individual ethical and ideological considerations. In this respect, there are two complementary rationales that can provide a justification: the concept of global public good, and Rawls' (1971) artifice of the "veil of ignorance".

6.2. *Vaccines as global public goods*

By definition, public goods exhibit the following characteristics (for an in depth analysis see Kaul and Mendoza, 2003):

- either they exhibit non-excludable benefits (public good),
- or they provide non-rival benefits (public good),
- or both (pure public good),
- in the instance where such benefits extend to all countries, people and generations, public goods can be considered *global* (Global Public Goods).

Essentially, Global Public Goods (GPGs) can be understood as public good that provide benefits to a community larger than an individual state. We discussed earlier how vaccine knowledge is *de facto* non-rival and non-excludable and, if freely available, there is a greater chance it will be effectively used. These characteristics imply that, according to the definition

[6] Hypothetically, countries with the largest disease burden will finance R&D performed in the countries with the best medical and scientific infrastructures (such as Uganda financing R&D performed in the Harvard Medical School). But since the countries with the disease burden are also the poorest ones, this option is not realistic.

provided above, vaccines could classify as a public good. To qualify as a *global* public good however, vaccines would need to benefit more than one group of countries, populations and generations (Kaul and Mendoza, 2003). From a purely technical viewpoint, it can be argued that the "global" and "public good" labels could be employed each time the "community of fate" of potential beneficiaries encompasses more than one state or a group of states. Since the definition provided by Kaul and Mendoza (2003) also includes inter-generational benefits, the list of public goods that could qualify as global may increase substantially. In a more pragmatic way, the definition provided by Kaul and Mendoza (2003) combines an analytical and a normative component: goods that are public, and whose benefits will potentially go beyond the boundaries of defined political communities, *should* also be provided at the global level (and possibly through global institutions). For the purpose of our argument, Kaul's definition of GPGs will set the frame within which it shall be argued that both the control of communicable diseases, and the knowledge necessary to develop a vaccine for their eradication, can be considered global public goods (for a discussion, see Bizzarri, 2004).

Since health issues such as HIV/AIDS, Malaria and TB bring countries into a shared fate, they should also bring countries together as partners in appropriately reforming their public policy choices (Kaul et al., 2003). After all, one of the main rationales for the existence of the State is its role in providing those socially indispensable goods that, either for one reason or another, are not effectively managed by the market (Desai, 2003). Undeniably, countries at diverse levels of development have different preferences for assigning national and global public goods; yet, even the lives of the richest individuals depend on these preferences. From an economic point of view, excessive disease burden creates negative global externalities (often defined as public bads), including the undermining of past and present development achievements in the South, and curtailing future economic development prospects for Northern industries in Southern regions. Moreover, international travel and trade are causing an increase in prevalence within industrial countries of diseases previously endemic to the South (Kaul and Mendoza, 2003). In Switzerland, for instance, new HIV infections are exhibiting similar characteristics to those fuelling the AIDS epidemic in Africa (Tenkorang and Conceicao, 2003). Similarly, since the early 1970s, 20 diseases have either re-emerged or spread, often in more virulent or drug-resistant forms (Kaul and Faust, 2001). The recent appearance of the West Nile virus in the USA is a reminder that not all diseases will necessarily remain confined to the South.

The development of a vaccine would therefore protect currently disease-free regions in the North from the expansion of Southern epidemics, as well as reducing, or even eliminating, the expenses associated with the current and/or future treatment of these diseases. The UN has estimated that the United States recoups the costs incurred from smallpox eradication programmes once every 26 days. That is every 26 days the benefits accruing from *not* having to deal with smallpox equal the US's total eradication costs (Tenkorang and Conceicao, 2003). The funding of vaccine research for global pandemics and neglected diseases appears therefore to be both rational and necessary, even if only in terms of the preservation of the well being of the North.

6.3. *The veil of ignorance*

A second justification for the North's involvement in the financing of vaccine R&D can be found in Rawls' (1971) artifice of the "original position" and the "veil of ignorance"[7]. Lets assume, for the sake of the argument, that the world is split into two communities, the North and the South, and that a "selfish" individual were asked to distribute the resources of an hypothetical R&D budget between these two halves. The individual must take a decision *prior* to it being revealed in which of the two communities he/she will reside – thus prior to being informed about his/her risk of contracting the diseases. Let us also assume that the individual has access to the data relative to each half and that he/she is aware that the North holds both abundant financial and scientific resources for R&D activities and a low risk of contracting the diseases, whilst in contrast the South exhibits opposite characteristics. Will the individual choose to

[7] In reality, Rawls' limited himself to considering the original position in a given community and he has not extended it to the world community as such. However, we apply here the extension of Rawls' ideas by some of his followers. In particular, Charles Beitz (1979) and Thomas Pogge (2002) have convincingly extended Rawls' theory of justice also to the international arena.

direct R&D towards cosmetic research, or will he/she privilege those scientific programmes that will aim at the eradication of diseases? Let us assume that a *rational* individual would selfishly choose the second option.

6.4. Developing countries' contribution to vaccine development

Although Rawls' artifice of the Veil of Ignorance and the GPGs' rationale entail a predominant commitment of the North, this should not exempt the South from any responsibility, nor that vaccine R&D should be performed in the North only. Despite the fact that vaccines can be transferred more easily than other technologies (say machinery or software, for instance) they still require a local learning capacity in order for their diffusion to take place (Woodle, 2000). Even Coca Cola, which advertises itself as the producer of the global (private) good for excellence, has research laboratories in all parts of the world charged with the responsibility to adapt the product to local taste preferences, conditions and markets. In the case of vaccines, the need for local research would certainly be more categorical. The South could contribute to the local development of a vaccine by devising tax incentive mechanisms, reducing military expenditure, or by increasing tax burden on the richest part of the population. There are, of course, enormous variations in scientific and technological expertise in the South, but many countries have managed to achieve significant scientific results when considered as national priorities (as, for example, in the case of nuclear programmes).

6.5. A proposed distribution of the resources

How should this financial commitment be distributed across countries? Table 1 illustrates a proposed distribution of the financial burden according to the "ability to pay principle", or rather, countries financial contribution proportional to their GDP. The United States would provide the largest contribution, followed by the European Union. Developing countries would also provide a substantial contribution and perform significant shares of R&D. In real terms, these countries would be able to hire a proportionally larger number of researchers since salaries per scientist are substantially lower. It is also likely that countries in the North will be prepared to subcontract parts of the R&D to labs in the South. Indeed clinical trials require indeed on-site analysis.

An input of financial resources alone is not necessarily able to generate the desired competencies. The already existing competencies in the field of immunology, in fact, depend on the already available financial resources. A substantial part of the funding in the first years should therefore be devoted to creating human skills, in particular by promoting training for new researchers in the field.

7. Discussion—implementation and implications

7.1. International coordination

From what has been argued, it follows that research activities require international coordination. This will include:

Table 1
A tentative distribution of requirements for vaccine R&D

	2001 GDP (billion US $)	Vaccine R&D requirements (total 15 years)[a] (billion US $)	Vaccine R&D requirements (average per year)[a] (billion US $)
World total	31400.0	22.5	1.50
High income countries *of which*	25372.0	18.2	1.12
USA	9780.8	7.0	0.47
European Union 15	7181.7	5.1	0.34
Japan	4523.3	3.2	0.22
Low and medium income countries	6025.0	4.3	0.29

Source: World Bank and elaborations.
[a] Proposals for pledges to an International Vaccine Fund Proportional to GDP.

(1) *A central funding organisation* - this organisation should decentralise funding decisions at the national or regional level. However, it should keep control of the various decisions taken. Although we acknowledge growing disillusionment in governments and formal institutions, such as the UN and the WHO in recent years,[8] these nevertheless play a critical role with respect to global health. The WHO is the only global institution that benefits from the mandate to oversee international health cooperation and is responsible for the protection and promotion of global goods. Its role derives from its ability to assemble a broad array of actors, develop consensus, and mobilise resources. With respect to legitimacy, the WHO is currently made up of 191 member states, all of which have equal voting rights, irrespective of size of their population or of their financial contribution (Buse and Walt, 2000). No other institution can claim near universal membership of nation states, nor benefit from a technical network-support as extensive as that of the WHO. The WHO could also act as a catalyst and coordinator for, say, activities across the Global Fund to fight AIDS, Tuberculosis and Malaria, the Global Alliance for Vaccine Initiative (GAVI), International Aids Vaccine Initiative, UNAIDS and Médecins Sans Frontières' Drugs for Neglected Diseases initiative (DNDi). The coordination of finalised research should *not* prevent duplication, since it is widely accepted that a certain degree of duplication can be beneficial to scientific enquiry. Indeed, the problem is not duplication, as much as a lack of information exchange;

(2) *A periodic evaluation of the results* – its aim is to increase funding to those groups obtaining more encouraging results. This evaluation would be performed by scientific peer review—this is now common practice within many research-funding bodies, such as the US National Institutes of Health and the UK Medical Research Council, where funding for research is based on a scientific peer-review process. Members of the scientific community should also be encouraged to continuously exchange information with other research groups. Preliminary and intermediate results could be widely disseminated through typical academic channels (scientific journals, conferences, academic courses, Internet and electronic fora).

(3) *An evaluation from subjects that do not belong to the scientific community* - This is meant to avoid targeted research being transformed into disciplinary research. A periodic external control by stakeholders would help to keep the research activity within the scope of its target. Stakeholders would include government officials, NGOs, health associations and firms working in the pharmaceutical sector—this would also allow taxpayers to exert a greater control over the funding of public research.

7.2. The role of public contracts to the private sector

There is no requirement that the financial commitment of the public sector should also be performed inside public institutions. Policy makers, at both national and international levels, can decide as to whether R&D should be contracted to private organisations or carried out in public infrastructures. Certainly, this would not be unprecedented. In the case of space and defence for instance, it is common to contract out R&D to private research centres, especially in the United States. There are of course a number of risks in outsourcing to private contractors. Outsourcing efficiency is entirely dependent on the capability of the public contracting party to manage the contract and to demand specific results from its contractor. Research contracts are very different from any other procurement for their high degree of incertitude. Private contractors tend to disclose the minimum information, especially if they can trade any additional or unexpected result achieved via separate contracts. This would appear a major obstacle since the dissemination of preliminary and intermediate results is an important component of the R&D activity. The public contracting party should master a high degree of competence in contract-dealing and a strong leadership in directing research. Successful examples of public-to-private contracts have been provided by military research activities, especially within the USA, though the transposition of competencies within the

[8] Think of Jonathan Mann's resignation from the WHO in 1990 as a symbol of protest against what he defined "a lack of commitment" and unimaginative leadership fighting global diseases (Goodle, 1994).

Pentagon and Ministries of Defence to the Health sector would take time and much effort.

7.3. The supposed inefficiency of the public sector

It is often argued that the efficiency of public research in targeted R&D is scarce due to a lack of incentives (Suarez-Villa, 2000, p. 196). There is no evidence that documents the inferiority in efficiency of public research as opposed to private. The public sector has often distorted incentives, but this is a problem that should be addressed by finding suitable mechanisms to stimulate its productivity rather than by turning to the business sector for functions that do not necessarily belong to its scope. With an appropriate system of incentives (based, for example, on yardstick competition), an increase in the range of publicly funded R&D institutions would also increase competition among public laboratories. Each would be competing to secure funding on the ground of the results achieved. Also within the public sector there is the risk that useful intermediate research results may be kept secret in order to ensure funding, though this is a problem that can be easily solved by acting upon incentive mechanisms. It would be sufficient that evaluation criteria privilege the diffusion of research results, for instance by taking into account the number of scientific publications produced by each research team.

7.4. Privately funded research

There is also the case of privately financed and profit-seeking R&D.[9] Although we are advocating a greater public commitment towards vaccine research, we do not aim at impeding the private, and profit-seeking, funding of scientific research in the field. Nevertheless, the rules of the game for businesses should be explicit: should private investors be granted IPRs over the results of their research in the field of immunisation? Or, alternatively, what type of remuneration (or compensation) should be provided to them in exchange of the expropriation of their knowledge?

There has been widespread concern over the exclusive nature of IPRs that has ranged from governments of developing countries (Shiva, 2001), to civil society (Médecins Sans Frontières, 2001) and academia (see, for example, May, 2002; Thurow, 1997; Mazzoleni and Nelson, 1998; Coriat and Orsi, 2002; Heller and Eisenbergv, 1998). These different institutions and scholars have stressed the risk of proprietary knowledge dangerously excluding vast numbers of the world's population from benefiting from newly developed vaccines. We agree with the view that IPRs increase social exclusion from life saving drugs, and that weakening IPRs might enable a greater access to drugs globally. In the short term, it is relevant to challenge these companies in order to reduce their monopoly over essential drugs, but the pressure from large corporations to enforce their IPRs even in the field of life-saving drugs simply reflects the fact that profit-seeking agents *have* generated new knowledge. In a slightly different vein, we argue that the problem to be addressed. It is not so much the proprietary nature of the already existing knowledge, as much as devising new mechanisms for the public ownership of newly generated knowledge.

The proposal we are here advocating would therefore put profit-seeking R&D – at least for vaccine R&D – in a residual position, since the public financing of vaccine research would lessen the bargaining power of business investors, on the one hand, and their ability to charge monopoly pricing on the other. Yet, even in a residual position, the outcome of business funded R&D could prove crucial to medical research, and thus, if limited, it should not be discouraged entirely.

7.5. Public-private partnerships

Public-private partnerships (PPPs) offer a new form of network society in which states and non-state actors, for-profit and non-profit organisations, engage in less hierarchical and less bureaucratic horizontal collaborations. The main advantage that partnerships offer is the potential to combine government funding and public health priorities with private sector efficiency and expertise. Indeed, public research institutes often lack the competencies and the resources necessary to manufacture drugs and carry out the complex and costly clinical studies necessary for their commercialisation. Thus, whilst privates hold the means and know-how to manufacture a vaccine, governments have the capacity to innovate as well as the power to dilute appropriability mechanisms, direct research and guarantee a

[9] Privates' donations for non-profit cases do not belong to this category and are more likely to be in the same category as publicly funded R&D.

market for drugs and vaccines. By linking funding to pricing and intellectual property provisions, the sharing of technological innovation and progress is maximised whilst allowing companies a reasonable level of ownership over the products and technologies developed (see Buse and Walt, 2000; Buse and Waxman, 2001). Moreover, the experience of the drug industry has already indicated that the R&D productivity of the business sector increases when connected to public institutions and facilities (see, for example, Cockburn and Henderson, 1998).

As argued extensively throughout the paper, there are however a number of hurdles associated with private involvement in knowledge production. Particularly with reference to PPPs, the public sector must master a high degree of expertise in contract dealing in order to avoid the risk of losing ownership over valuable knowledge produced. To date, the examples of the International AIDS Vaccine Initiative (IAVI) and the Global Alliance for Vaccines and Immunisation (GAVI) have proved very successful public-private partnerships. Nevertheless, as discussed earlier in the paper, despite their admirable intentions and achievements, most PPPs are characterised by a temporary mandate and limited financial capabilities. Given the long-term and large amount of investments required to develop an effective vaccine for major communicable diseases, PPPs do not represent the ideal, nor the only, policy solution to communicable disease control.

7.6. Purchasing commitments

Another alternative to publicly funded vaccine R&D has been that of "purchasing commitments". As described by Kremer (2003), a purchasing commitment would act as a "pull" research mechanism, or rather, it would issue a "prize" upon the development of successful vaccine in an attempt to stimulate private investment in neglected areas of medical research. This will allow the creation, through public procurement, of a market demand of interest to the business sector. According to Kremer, purchasing commitments would offer the advantage of placing the entire costs and the risks associated with R&D on the shoulders of the private sector, whilst taxpayers would be required to contribute solely in the event that successful vaccines were developed. Moreover, purchasing commitments are compatible with public-private partnerships, and allow the business sector to benefit from the collaboration with in-house publicly performed R&D, whilst retaining intellectual property rights.

The rationale upon which Kremer's proposal rests is similar to the one argued here, in as much as it vests the public sector with the prime responsibility for funding research. However, purchasing commitments rely on the confidence that competition-based market devices are stronger than public direct intervention in shaping scientific breakthroughs. Our proposal, on the contrary, relies more on the direct involvement of the public sector through an internationally coordinated effort. In this respect, "purchasing commitment" present an important hurdle in using public procurement. Basing incentives exclusively on the winner's remuneration entails an entirely competitive spirit between the various research groups. Although on the one hand such an approach would stimulate competition between firms in previously neglected medical areas, the exclusivity of the prize would force the various competing agents to keep secret all intermediate results of their research. As we have argued extensively in this paper, competitiveness and secrecy are detrimental to the social optimality of knowledge production.

8. Concluding remarks

Vaccines hold the capacity to eradicate diseases affecting millions of people, and experts in the field argue that there is a certain degree of confidence that the target could be achieved by investing adequate resources. Although uncertainty is endemic to scientific investigation, there is a strong rationale for investing much more heavily in vaccine R&D than is currently the case. We have demonstrated that the reason behind this lack of financial enthusiasm is traceable to a lack of adequate incentives for both the private and the public sector. Business sources have limited interest to invest, given the lack of profitable markets for communicable diseases, whilst governments in the South lack the necessary resources to address them, and in the North they lack a direct health threat. Not surprisingly, the largest amount of R&D is focussed on AIDS, which, compared to TB and Malaria, is the only disease to exert a substantial direct health threat to the North.

Given this scenario, only a major shift in the science policy priorities of governments in the North can

solve this paradox. The paper has argued in favour of an international vaccine fund as representing the most effective and efficient mechanism to manage an international research activity. The financial commitment and research coordination necessary to ensure the effectiveness of the fund would be ensured by charging supra-national agency such as the WHO with key responsibilities. The paper has also provided some suggestions as to how the fund should operate, arguing in favour of publicly performed R&D involving an international effort.

The paper has moreover provided a tentative distribution of the desired fund's resources across countries on the grounds of their economic welfare, implying a significant but feasible increase in the R&D budget of industrially advanced countries.

Is such a proposal feasible? In spite of official commitments agreed within inter-governmental summits, national authorities have been very reluctant to open up new lines of economic resources—this is clearly illustrated by the steep decrease in Official Development Aid since the fall of the Berlin Wall (World Bank, 2003, p. 13). We believe, nevertheless, that there is nothing inevitable in these trends; on the contrary, they are merely the outcome of policy decisions (Archibugi and Lundvall, 2001). Governments in the North have often shown themselves to be attentive to public opinion, and the latter has been sensitive to a number of global campaigns, as the South African case over the diffusion of the AIDS cocktail drug has illustrated. We therefore address, in particular, three different communities: the global movements, the academic community and the restricted but influential community of science policy analysts.

Global movements have already played a crucial role in steering government priorities in key areas such as environment, disarmament, and human rights (see, for example, Glasius et al., 2001, 2002, 2003). Concerning the health agenda, global movements have heavily criticised the privatisation of knowledge and implications for its diffusion (see Shiva, 2001). We would urge these movements to reconsider their priorities and focus on the need to increase publicly funded R&D as much as on the issues of access to drugs for neglected diseases. With reference to vaccines, IPRs are just a consequence of knowledge development, whilst the resources to fund the production of knowledge is the issue at stake.

The other community we address are scientists, a category of individuals whose work is, or rather should be, performed on moral and ethical grounds. In many cases scientists hold the ability to strategically direct the priorities of their research. Governments do not have the information to direct scientific investigation unless there are scientists providing the technical expertise. Scientists could therefore devote increasing attention to the welfare implications and consequences of their work and induce governments to devote more resources to global health priorities. Governments need to adapt their funding and administrative priorities to support the emergence and healthy growth of research networks (Geuna et al., 2003).

Last but not least, we address the small community of science policy analysts and advisors. In the last two decades there has been a growing focus on science and technology as shapers of economic performance, rather than enhancers of social well-being. The circle of scholars of science and technology policy has been a close advisor to policy makers. If today, so much attention has been placed upon technologies for industrial innovation, and so little towards medical research for developing countries, it is due, in part, to the choices and priority setting of this community.

Whether governments will listen to a request for a change in priority setting will depend on the ability of global movements, scientific communities, and science & technology policy advisors to pursue the same objectives. If this were to be achieved, policy makers will have no other option but to act.

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