Horizon Scan Report

iMed: Innovating

Medical Entrepreneurship and Delivery

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Contents

Executive Summary

This horizon scan reviews existing ideas and proposals for innovative financing mechanisms in health-care. Our research is based on the following question, which underpins our entire effort:

> What funding mechanisms would maximise access to medicines *and* incentivise innovation based on cost effective health impact and at a level of innovation funding at least as high as today?

This question is, in turn, based on the following summary of the motivation for change:

> **The situation**: Millions of people need medicines. Medicines are cheap to copy and potentially expensive to research. Meanwhile funding mechanisms are not directly linked to health impact, profits are based on prices, and the existence of monopoly patents supports prices well above the cost of manufacture.
>
> **The complication**: Funding mechanisms, especially monopoly patents, limit access to medicines for millions of people through inflated prices and lack of innovation in non-profitable areas, and fail to incentivise for health impact and efficiency of drug manufacture.

Mechanisms

There are four main kinds of funding mechanism for medical R&D:

- **Grants:** unconditional, upfront funding for research.
- **Monopoly rights**: where an innovator may obtain a temporary monopoly (a patent) for a new discovery (such as a drug), and which allows them to set prices

at the profit maximising point rather than health impact maximising point or linked to cost of research and manufacture.

- **Prizes**: pre-defined payments for specific one-off innovations or interim achievement, for example a new vaccine for HIV, or a new drug for Hepatitis C. Often, prizes require the winner to make their discovery public and open.
- **Remuneration rights:** where innovators receive a "remuneration right" entitling them to payment from a dedicated fund on a predefined basis related to desired outcomes (or, possibly outputs) – for example proportional to the number of lives saved by their innovation relative to all other innovations covered by the fund. In return, innovators make their discoveries public and open.

Our focus

Of these four mechanisms, grants, prizes and remuneration rights all have the potential to simultaneously improve access and incentivise innovation based on health impact. We have further narrowed our focus to proposals of either a) on remuneration rights or b) active mixed mechanism efforts which innovatively combine two or more of these three.

Remuneration rights

There have been many remuneration right style proposals, none of which have so far been implemented. The main proposals are the Medical Innovation Prize Fund (MIPF), the Health Impact Fund (HIF), and the Cancer Innovation Fund (CIF). CIF and MIPF are both active proposals in 2017.

While remuneration rights seem the most promising mechanism, there are a number of open questions regarding the technicalities and implementation of such a system.

Technical issues

- Scope: should a remuneration rights system cover medicines relating to diseases of the poor or of the rich or both?
- Scale: should a remuneration rights system be national or international, and what are the governance mechanisms for such a system (especially at an international level)?
- Relation to monopoly rights: should a remuneration rights system substitute or complement the monopoly rights system?
- Selection criteria: when measuring health impact in order to allocate remuneration rights, are QALYs alone sufficient or would multiple selection criteria be more powerful?

These technical issues should be examined in detail in a feasibility study.

Implementation issues

Remuneration rights can act as comprehensive alternative to patents, and have been framed that way in the past. This makes them politically ambitious – any major change from the status quo is difficult, and this one especially so. It is perhaps therefore unsurprising that, so far, no remuneration rights system has been implemented since they were first formally proposed approximately fifteen years ago. Nevertheless, if remuneration rights are to be considered to have potential it is necessary to show their political feasibility. This horizon scan will not look at this in detail – but this subject will be examined further in later work.

Mixed mechanisms

While it is helpful for organising purposes to classify mechanisms and proposals, in the real world many proposals are hybrids. This is a promising approach, as it allows both pull and push funding to be employed and can target the whole research cycle. We

therefore have considered several particularly promising recent mixed proposals such as the 3P Project, the Health Product Research and Development Fund and the AMR Review proposals.

Introduction

The problem

Millions of people need medicines, which are cheap to copy and potentially expensive to research. However, profits are based on prices, and monopoly rights result in prices well above the cost of manufacture and research. In addition, current funding mechanisms are not directly linked to health impact - that is, to the quantity and quality of health produced by a given medicine. Funding mechanisms, especially monopoly rights, thus limit access to medicines for millions of people through high prices, and fail to incentivise important health innovations in non-profitable areas.[1]

There are then two interrelated problems to solve: the problem of access, and the problem of innovation. We need to find a funding mechanism which maximises access to medicines and incentivises innovation based on health impact.

In a monopoly rights based system, there is a fundamental tension between access and innovation: monopoly rights support innovation via high sale prices, which in turn restrict access. In a system where innovation and access are in direct tension having both must appear unrealistic. However, this tension isn't fundamental to creating and sharing information (in this case, pharmaceutical research) - it is merely a feature of the particular funding system that exists now. In investigating alternative approaches, we are seeking a funding mechanism which removes the tension between innovation and access and allows for both simultaneously.

[1] For detailed criticism of the current funding system, see Stiglitz, "Economic Foundations of Intellectual Property Rights"; Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*; Love and Hubbard, "The Big Idea;" Ravvin, "Incentivizing Access and Innovation for Essential Medicines."

Approach

We identified existing proposals and funding mechanisms based on interviews with experts together with a literature search. This produced a database of existing proposals.

To shortlist these proposals for further analysis, we examined existing mechanism classifications,[2] and then sorted proposals into mechanism types. The funding mechanism types used in this paper are grants, monopoly patents, prizes, and remuneration rights. We selected at least one proposal from each mechanism type for further analysis, to ensure sufficient breadth.[3]

As well as this minimum selection, we chose additional proposals for analysis on the basis of two criteria: whether the proposal increased access, and whether the proposal incentivised innovation in relation to health impact.

This paper is based on the research process described above, and summarises our conclusions first on mechanisms in general and then on remuneration rights, which we identified as the most promising funding mechanism available.

It is important to note that today all healthcare systems used a mixture of funding mechanisms, combining two or more of the above mechanisms. For example, countries have both grants and monopoly rights. Any future system would also likely be mixed –

[2] See Hecht, Wilson, and Palriwala, "Improving Health R&d Financing for Developing Countries", p. 977; Stiglitz, "Economic Foundations of Intellectual Property Rights", p. 1722; Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*, Ch. 9; Ravvin, "Incentivizing Access and Innovation for Essential Medicines"; "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination", pp. 50-51; Hoffman and So, "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally", p. 433; Renwick, Brogan, and Mossialos, "A Systematic Review and Critical Assessment of Incentive Strategies for Discovery and Development of Novel Antibiotics", p. 3.

[3] With the exception of grants, which for reasons given below seemed outside the scope of this project.

for a variety of reasons including the fact that different mechanisms work better at different stages of R&D; that globally it is important to have both push and pull mechanisms in place;[4] and to have funding mechanisms which suit both small and large innovators.[5] As we currently operate in a mixed system, it is not necessary for remuneration rights or any other proposal recommended to be used exclusively: only that they could be used to improve the current funding landscape.

[4] See for example Renwick, Brogan, and Mossialos, "A Systematic Review and Critical Assessment of Incentive Strategies for Discovery and Development of Novel Antibiotics," p. 3; Hecht, Wilson, and Palriwala, "Improving Health R&d Financing for Developing Countries," p. 977; Dalton, "Should You Fund Research into Tropical Diseases?", p. 42.

[5] For an illustration of how incentives affect small and large companies differentially, see "Health Product Research & Development Fund: A Proposal for Financing and Operation", p. 38.

Results

Mechanisms

There are many possible ways of classifying funding mechanisms for medical R&D, and no standard approach. For example, Joseph Stiglitz uses a broad categorisation of patents, prizes and government funding.[6] Steven Hoffman and Karen So classify funding mechanism reform into five classes: intellectual property reforms, regulatory reforms, financing reforms, market reforms, and legal reforms.[7] Many researchers simply separate mechanisms into 'push' and 'pull',[8] or add a third category, such as drug price reduction[9] or hybrid mechanisms.[10] This lack of uniformity in describing kinds of funding mechanisms is reflective of a space which is in reality multidimensional and messy. There are many axes on which to position a funding mechanism (funding source, funding purpose, exclusive or competitive manufacture, compulsory or optional system, etc.) and these axes cut across one another. What is important is to find a usable categorisation that fits the purpose of inquiry.

Other investigators have focused on reform area like Hoffman and So, or incentive structure, as with the push and pull classification. In classifying funding mechanisms, we chose to focus on the mechanism itself. Our categories thus answer the question: under this mechanism, how is R&D actually financed? This emphasis means that some areas which are often considered as a part of the solution to the problem of access and innovation, like open source platforms, fall outside the scope of our study. The

[6] Stiglitz, "Economic Foundations of Intellectual Property Rights", p. 1722.
[7] Hoffman and So, "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally", p. 433.
[8] See Hecht, Wilson, and Palriwala, "Improving Health R&D Financing for Developing Countries", p. 977; Dalton, "Should You Fund Research into Tropical Diseases?".
[9] Ravvin, "Incentivizing Access and Innovation for Essential Medicines."
[10] Renwick, Brogan, and Mossialos, "A Systematic Review and Critical Assessment of Incentive Strategies for Discovery and Development of Novel Antibiotics", p. 3.

classification does have the advantage of simplicity, and also ensures that everything in our purview genuinely influences funding structure, rather than peripheral (though perhaps important) areas. Our mechanism classification is contained in Table 1 below.

Table 1: R&D funding mechanisms

The column entitled 'Example proposal types' contains families of proposal which aim to improve either access or innovation or both, under the relevant mechanism

Mechanism	Description	Example proposal types
Grants[11]	A mechanism which funds medical R&D through unconditional, upfront funding. Grants are unconditional in that there is no direct conditioning of payment on outputs or outcomes, i.e. the researcher is paid irrespective of what their research produces. They are upfront in that the researcher is paid or promised payment prior to the work being done. Almost all university research is grant-based, and grants account for a good portion of all research funding and the majority of funding for basic research.	- Direct grants to companies, especially in low-income countries - Traditional research grants to universities
Monopoly rights[12]	A mechanism which funds medical R&D by granting innovators a temporary monopoly (a patent) for a new discovery (such as a drug), and which allows them to set prices at the profit maximising point rather than health impact maximising point or linked to cost of research and manufacture. There are many small variations that can be made to improve an essentially monopoly rights based mechanism. We have included all such proposals under monopoly rights.	- Bulk buying - Compulsory licensing - Equitable access licences (EAL) - Foreign filing licence approach (FFL) - Patent buyouts - Patent donations - Regulatory harmonization - Differential pricing - Patent pools - Transferable Fast Track (TFT) - Transferable Intellectual Property Rights (TIPR) - Volume-based pricing
Prizes[13]	A mechanism which funds medical R&D through pre-defined payments for specific one-off innovations	- End prizes - Milestone prizes

[11] See Ravvin, "Incentivizing Access and Innovation for Essential Medicines."
[12] See Hoffman and So, "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally", Towse, "A Review of IP and Non-IP Incentives for R&D for Diseases of Poverty. What Type of Innovation Is Required, and How Can We Incentivise the Private Sector to Deliver It?", "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination", Love, "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D."
[13] See "Selected Innovation Prizes and Reward Programs", Paul Wilson and Amrita Palriwala, "Prizes for Global Health Technologies."

	or interim achievement, for example a new vaccine for HIV, or a new drug for Hepatitis C.	- Tournaments - Advanced Market/Purchase Commitments (AMC/APCs)
Remuneration rights[14]	A mechanism which funds medical R&D through the allocation of payments upon creation of a product. Innovators receive these payments according to some set of principles or conditions based on outcomes, usually including health impact and access provision. In return, innovators make their discoveries public and open	- Prize funds

There are some limitations to this classification. Firstly it is important to note that the mechanism types are not mutually exclusive: a prize system can coexist with a monopoly rights system, grants with remuneration rights, and so on. But it is not just that all mechanisms can be operative at a given point in time in a given society: in some cases, features of each mechanism type are operative within a particular funding proposal. A good example of a hybrid proposal type is Public-Private Product Development Partnerships (PDPs), which often bring together various and sometimes complex funding sources.[15] We will return to such mixed proposals in the section below on Mixed Mechanisms.

There are also kinds of proposal which fall outside this schema. For example, we have excluded tax relief, which incentivises R&D through tax relief. Tax relief and could operate alongside any of the mechanisms in our typology. It is very difficult to design a mechanism typology which genuinely captures all possible proposals, and those which fall outside our typology are small-scale and have not been suggested as comprehensive funding measures. Another limitation of our typology is that there is a certain fuzziness between prizes and remuneration rights. The latter term is used infrequently, and is more often referred to as prize funds.[16] In using remuneration rights, we seek to draw a

[14] See Love and Hubbard, "The Big Idea", Love and Hubbard, "Prizes for Innovation of New Medicines and Vaccines", Hollis and Pogge, The Health Impact Fund: Making New Medicines Accessible for All.
[15] See Ravvin, "Incentivizing Access and Innovation for Essential Medicines", pp. 115-116.
[16] For more on terminology, see Appendix 1.

distinction between one-off prizes for individual innovators, and comprehensive systems which regularly reward any innovator in a certain class.

These limitations notwithstanding, we believe that the classification of grants, monopoly rights, prizes and remuneration rights is a good approximation of the funding mechanism space. We will now examine each mechanism in terms of access and innovation.

Grants

Grants are a push funding mechanism, unlike the others we considered: grants fund research upfront, rather than after the fact.[17] Currently, grants are a very widely used form of funding in medical R&D, and are uncontroversial. Even strong opponents of the current system agree that grants should continue to operate as a funding mechanism.[18] Grants are the most suitable mechanisms for early stage research, as information remains open for others to build upon and funding is not tied to specific outcomes, allowing exploratory work. Among the many proposals to improve the current state of medical R&D, few proposals concern improving the grants system, which also suggests that this funding mechanism is working reasonably.[19] However, as a funding mechanism, grants have little to do with access. They provide no incentive to translate research into a marketable product, so this stage in development is usually undertaken by commercial firms who then patent the results.[20] This makes grant funding poorly suited to dealing with the problem of access. Grant funding does provide a significant boost to innovation, but does not exert strong incentives regarding health impact. This is because grants are provided upfront, and it is very difficult to predict health impact before the fact. It might also be undesirable for all funding to be directly tied to health

[17] Ravvin, "Incentivizing Access and Innovation for Essential Medicines", p. 115.
[18] Stiglitz, "Economic Foundations of Intellectual Property Rights", p. 1724; Love and Hubbard, "The Big Idea", p. 1553.
[19] An exception is the recent development of direct government grants to small and medium companies, especially in developing economies, for R&D and capacity building. See Paul Cunningham, Abdullah Gök, and Philippe Laredo, "The Impact of Direct Support to R&D and Innovation in Firms."
[20] Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*, p. 102; Ravvin, "Incentivizing Access and Innovation for Essential Medicines", pp. 115-116.

impact: we need basic research, and grant funding is excellent at resourcing this. Essential though grant funding will remain, its functioning is only distantly related to the problems of access and impact-based innovation. This being the case, we did not investigate grant funding proposals (of which there are in any case very few) in further detail.

Monopoly rights

A large proportion of medical R&D is currently funded via our second mechanism type, monopoly rights. There are numerous examples of proposals of this kind which have been successfully implemented.[21] However, while monopoly rights based proposals can improve access and increase innovation, they tend not to do both. It is more common for proposals in this group of this mechanism type to focus on increasing access rather than improving incentives for innovation based on health impact. Examples are patent pools, differential pricing, patent donation, patent buyout, FFL, EAL and compulsory licensing, all of which can reduce the cost of drugs but do not provide strong incentives for innovation based on health impact.

On the other hand, where monopoly rights based proposals *do* incentivise innovation strongly, they often fail to address the problem of access, as is the case with tax relief, TFT and TIPR. In a monopoly rights based system, there is a fundamental tension between access and innovation: monopoly rights support innovation via high sale prices, which restrict access. While many of the individual reform proposals mentioned here have had a very positive health impact, it is hard to resolve this fundamental tension at the heart of the monopoly rights system. Such proposals are valuable but they are limited and essentially act as small patches on a faulty system, and are pursued because of their near-term political feasibility. We therefore concluded that this was not the most promising area for further investigation, and focused our attention on more

[21] See the Proposals Database.

ambitious proposals which offer the potential of systematic change and large-scale improvement.

Prizes

Prizes as a funding mechanism also boast many implemented proposals.[22] Prizes take many forms, including milestone prizes, end prizes, tournaments and AMCs. In terms of access and innovation, there is a disjunct between the technically possible and the actually implemented where it comes to prizes. Prizes can be made conditional on access provisions, and there is no reason that a prize should not be made conditional on health impact and thus provide an efficient incentive. However, while prizes often come with access requirements, they are not usually set in relation to health impact because of the difficulty of measuring these same. Instead, prizes tend to focus on a specified research achievement. This means they do not necessarily incentivise innovation in relation to health impact, and so are only a partial solution to the access and innovation problem.

Remuneration rights

This leads us to consider remuneration rights. Under remuneration rights, innovators are rewarded in a reliable and repeated manner from a fund, in accordance with a set of criteria. In most proposals, these criteria contain both some commitment to open licensing and/or explicit price commitments; and health impact. This means that remuneration rights both promote access and incentivise innovation directly based on health impact. We therefore selected remuneration rights as the most promising mechanism for further investigation.

[22] See Appendix 2.

Mechanism: Remuneration rights

There have been suggestions for alternatives to monopoly rights almost since patents were introduced.[23] From the 1990s, with the rise of the internet, economists became increasingly interested in the funding of knowledge goods which are nonrival. Nonrival goods can be used again and again at little additional cost, and so are particularly badly suited to the monopoly rights funding system, which ensures a high cost for every use.[24] This was followed in the 2000s by a flurry of proposals dealing with medical R&D in particular. Here we shall focus on those proposals which relate to remuneration rights-like systems, but there have also been many proposed and implemented systems of other mechanism types.[25] Much of this initial work took place in the United States, which is the single largest producer and consumer of medical R&D.[26] In 2002, work began on what would become the Medical Research and Development Treaty (MRDT), orchestrated by James Love. This proposal was submitted to the World Health Organisation (WHO) in 2005, the same year that Bernie Sanders first brought the Medical Innovation Prize Fund Act (MIPF) to the House of Representatives. The WHO agreed to a global framework for essential health R&D in 2006, in 2007 MIPF was brought to the Senate, and in 2008 the WHO agreed a global strategy and plan of action on medical R&D funding and coordination. Also in 2008, Thomas Pogge and Aidan Hollis proposed the health impact Fund (HIF). MIPF was brought again in 2011 and 2013, and preliminary proposals on a Cancer Innovation Fund (CIF) were made in 2008, 2009 and 2014. Further proposals can be seen in Table 2.

[23] Wei, "Should Prizes Replace Patents - A Critique of the Medical Innovation Prize Act of 2005", p. 29.
[24] As knowledge goods are nonrival, it costs very little or nothing to copy them. Monopoly rights restrict access to knowledge goods which in an efficient market would be freely or nearly freely available at point of use. Love and Hubbard, "The Big Idea", p. 1528.
[25] See Appendix 2.
[26] See "Worldwide Pharmaceutical Sales by Region 2014-2016 | Statistic" for consumption and "Science,technology and Innovation : Gross Domestic Expenditure on R&D (GERD), GERD as a Percentage of GDP, GERD per Capita and GERD per Researcher" for production.

The most important of these proposals, and the ones which will be focused upon in what follows, are MIPF, HIF and CIF. CIF and MIPF are currently active, so merit attention. HIF is unusually detailed as a proposal and has received more extensive critical attention.[27] Of the remaining proposals, PDP+ and the Australian Democrat Prize Proposal have left very little evidence behind them and so are unsuitable for detailed investigation. FRIND has slightly more surrounding evidence, but remains a minor proposal. The WHO proposals are so wide-ranging and contain so much which is outside the scope of remuneration rights that they have been deprioritized as unwieldy.

Table 2: Remuneration rights proposals

Proposal	Description	Status
Cancer Innovation Fund (CIF)[28]	A proposal to delink R&D costs from drug and vaccine prices in the case of cancer. Proposed by various actors in 2008, 2009, 2014 and 2017.	Currently under discussion.
Medical Innovation Prize Fund (MIPF)[29]	A proposal for a compulsory fund to replace the monopoly rights system in the US and remunerate innovators on the basis of the health impact they create. Presented by Bernie Sanders to the House of Representatives in 2005 and the Senate in 2007, 2011, 2013 and 2017.	Currently under discussion.
Health Impact Fund (HIF)[30]	A proposal to create an optional fund which would remunerate medical R&D according to health impact. Proposed by Hollis and Pogge in 2008.	Discussed largely in academic circles.
Global framework for essential health R&D[31]	A series of proposals to the WHO to create a global framework committing states to contribute a certain level of funding into a	A process which still has repercussions today but whose vision has not been

[27] See for instance Hecht, Wilson, and Palriwala, "Improving Health R&D Financing for Developing Countries"; Ravvin, "Incentivizing Access and Innovation for Essential Medicines"; Hoffman and So, "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally."
[28] See "Resolution On Cancer Hailed By WHO Members, Easily Adopted In Committee", "Geneva Technical Workshop on Proposals for a Cancer Innovation Fund (CIF) – Union for Affordable Cancer Treatment."
[29] See "The Medical Innovation Prize Fund: A New Paradigm for Supporting Sustainable Innovation and Access to New Drugs: De-Linking Markets for Products from Markets for Innovation."
[30] See Hollis and Pogge, The Health Impact Fund: Making New Medicines Accessible for All.
[31] See "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination", "WHA59.24: Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action", "Global Strategy on Public Health, Innovation and Intellectual Property."

	pooled fund, which would be disbursed in a variety of ways including remuneration rights. The 'global framework' in particular refers to a 2006 resolution, but here shall be used as an umbrella term for the process relating to such proposals which began in 2005, included the 2008 global strategy and plan of action on medical R&D funding and coordination and culminated in 2012.	fully realised. There is still no global pooled fund.
PDP+ Fund[32]	A proposal for a fund for R&D into neglected diseases, which awards remuneration to innovators on condition of pro-access measures. Proposed by Novartis, the George Institute, and IAVI in 2010.	A one-off proposal.
Fund for Research and Development in Neglected Diseases (FRIND) [33]	A proposal for an optional fund for R&D into neglected diseases which awards remuneration to innovators provided that their drugs are sold affordably. Proposed by Novartis to the EWG in 2009 and the CEWG in 2011.	A one-off proposal.
Australian Democrats Prize Proposal[34]	An optional, international public good patent scheme, where innovators are rewarded from a fund in relation to health impact. Proposed in 2007 by the Australian Democrats.	A one-off proposal.

Moreover, there is considerable current interest in remuneration rights proposals. Two proposals in particular are currently under consideration. MIPF was raised again by Sanders in March 2017, and has been referred to the Senate's Committee on Health, Education, Labor, and Pensions.[35] Meanwhile, a CIF proposal has been under discussion in 2017. This led in May to a WHO resolution on cancer, which contains many actions including a commitment to a feasibility study into full delinkage.[36] With this current momentum, now is a good time to build consensus and raise the profile of remuneration rights as a possible funding mechanism for medical R&D.

It is important to survey the criticisms that have been made of remuneration rights proposals, to avoid the issues they raise. It is however striking that most of the

[32] See "The PDP+ Fund."
[33] See "Fund for Research and Development in Neglected Diseases."
[34] See "Selected Innovation Prizes and Reward Programs."
[35] Sanders, "Text - S.495 - 115th Congress (2017-2018)."
[36] "WHA70.12: Cancer Prevention and Control in the Context of an Integrated Approach."

objections made are at a detailed level. No-one seems to dispute academically that theoretically a remuneration rights system would improve access, innovation and incentives: there is simply disagreement on the feasibility of such a system. Because criticisms tend to focus on detail, most of them do not apply to every version of remuneration rights proposals. For instance, the problem of influence over the selection procedure,[37] while potentially serious for MIPF, is much less grave for HIF, which uses a single technical measure to allocate funding. Similarly, the difficulty of setting the level of funding is alleviated under the HIF proposal because the fund is voluntary, so prices would be market regulated.[38] Other proposals like CIF do not yet have a concrete form, and could steer around such problems.

There are also a cluster of criticisms surrounding governance, some of which can be set to one side, while others require further investigation. Remuneration rights systems are sometimes criticised because they require complex new administrative structures.[39] As the patent system itself is hugely complex to administer, this does not seem like a fair standard to hold an alternative proposal to. Another related criticism is that a remuneration rights fund would be expensive to run.[40] Figures are not usually given to substantiate this claim or make clear to what remuneration rights systems are being compared unfavourably. Given that the efficiency savings of such a fund are estimated to be high,[41] this criticism also seems safe to put to one side. A final general criticism is that the governance structures required for a remuneration rights system are

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[37] Faunce and Nasu, "Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/ Competitive Tender Treaty", p. 149; Wei, "Should Prizes Replace Patents - A Critique of the Medical Innovation Prize Act of 2005," p. 40.
[38] Wei, "Should Prizes Replace Patents - A Critique of the Medical Innovation Prize Act of 2005", p. 32.
[39] Faunce and Nasu, "Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/ Competitive Tender Treaty", p. 150.
[40] "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination", p. 55; Hoffman and So, "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally", p. 439.
[41] For saving estimates, see "The Medical Innovation Prize Fund: A New Paradigm for Supporting Sustainable Innovation and Access to New Drugs: De-Linking Markets for Products from Markets for Innovation", p. 2; Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*, pp. 93-94.

underdeveloped.[42] HIF lays out a rough structure of advisory boards, MIPF proposes six expert committees, and CIF has not got to this stage yet. Nevertheless, it seems clear that further work is needed on governance, as coalitions are built and a more concrete system becomes feasible. We return to this issue of governance below in discussing implementation issues.

The key criticisms of a remuneration rights system then relate to detailed technical issues and broader implementation issues, rather than fundamental conceptual flaws. This does not make such criticisms trivial: on the contrary, it is essential moving forwards that such technical and implementation issues are investigated further and satisfactorily resolved. We have identified the principal technical issues outstanding to be scope, scale, relation to monopoly rights and selection criteria. There remains a considerable range of opinion on the best way to deal with these issues.

Technical issues

Scope

Should a remuneration rights fund target diseases of the poor or of the rich, or both? Innovation incentives and access levels are worst for diseases of the poor, and proposals relating to such diseases may be easier to implement politically and have a higher health impact, at least in the short-term. On the other hand, Love and Hubbard prefer proposals which tackle diseases of the rich or general diseases, as they argue that the spillover effects from a remuneration rights fund affecting medicines in the US would be greater than one targeting say tropical diseases. It is important to note that here disease scope is interacting with geographical scope and also with R&D system.

The principal remuneration rights proposals are split on this issue. MIPF would cover all diseases, giving special provision to neglected diseases of the poor. The HIF proposal

[42] This criticism was made of HIF in particular, but can be applied to a lesser extent to other proposals. "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination", p. 56.

would be open to diseases of any sort, but because the fund is optional in practice it would favour diseases of the poor, where health impact related remuneration would exceed monopoly rights profit margins. CIF of course focuses on cancer.

It seems likely that a pilot remuneration rights fund for any disease or set of diseases would be potentially beneficial for all areas of medical R&D as setting an example of how such funding can function. The urgent question then becomes not which disease area the most impactful long-term, but which is the most tractable to implement as a pilot scheme at this moment in time. There are also technical questions about which medicines are easy to make generically. Further research is needed into the most tractable disease area and geographical area for such a fund.

Relation to monopoly rights

Should a remuneration rights system complement or replace the monopoly rights system in the area(s) it operates? Love and Hubbard argue for a compulsory system, as a voluntary system would have to be competitive with monopoly rights and so would be more expensive to run.[43] It is worth noting that if one's conclusion on scope as an underlying issue was that diseases of the poor matter more, then this drawback of a voluntary system would become less salient: the monopoly rights system offers almost no reward for developing medicines for the poor, so competing with this level of remuneration would not be difficult. MIPF and probably CIF are compulsory schemes. HIF is optional, which provides an adjustment mechanism for pricing.[44] It is also possible that an optional system would be much more feasible politically, especially at pilot stage.

[43] Love and Hubbard, "The Big Idea", p. 1535.
[44] Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*, p. 6.

Selection criteria

Should remuneration rights be allocated according to QALYs or to some composite metric? MIPF employs composite metrics, which is endorsed by Love and Hubbard on the argument that there are other important factors besides QALYs. Criteria used by MIPF include number of patients, incremental therapeutic benefit, relation to priority health needs, efficiency of manufacturing, and openness of data.[45] HIF suggests using QALYs alone because as a metric they are the least open to political influence and the most correlated with health impact. Academically, the use of QALYs has now become widespread, and it seems unlikely that a group of legislators or fund designers could come up with a metric that approximates health impact better than the metric honed by academics worldwide. It is not clear how CIF would remunerate based on health impact.

Scale

Should a remuneration rights fund be national or international? MIPF is a national proposal, while HIF and CIF would involve international cooperation.

Any fund would need to have sufficient scale to ensure supply. This means that a national approach is only feasible for big drug producers and consumers like the US. With scale, there is fundamentally a trade-off between the feasibility of the agreement and the workability of the system itself. More research is needed into where the sweet spot is. There is also the additional and critical consideration of which nations are amenable to such a proposal.

Implementation issues

It is helpful to distinguish between the technical issues cited above and implementation issues. The technical issues are questions of design which require technical solutions.

[45] Sanders, "Text - S.495 - 115th Congress (2017-2018)."

Implementation issues are more political. Fundamentally, we need to answer the questions: why have remuneration rights proposals failed to be implemented in the past, and what prevents them from being implemented now? It is not clear from current research what the answers to these questions are, so going forward it is critical that these issues are given deeper consideration. A preliminary sketch of possible implementation issues is that a lack of powerful stakeholders, robust feasibility studies (including more thorough governance plans in response to criticisms) and crucially empirical evidence have hampered remuneration rights proposals.[46] Further research in these areas is necessary to gain a more complete understanding of remuneration rights.

Mechanism: Mixed

While within the parameters of our mechanism classification there is reason to believe that remuneration rights offer the most promising solution to the problems of access and innovation, it is important not to disregard mixed mechanisms. In the real world, many proposals incorporate elements of multiple mechanism types, for instance by combining a prize fund with a patent pool, or grants with an advanced market commitment.

As well as investigating remuneration rights, we will continue to research promising mixed proposals, where such proposals address both access and innovation, and have received recent interest. Table 4 shows the principle mixed mechanisms we shall consider.

Table 3: Mixed proposals

Proposal	Description	Status
3P Project[47]	A package of incentives to encourage the creation of an	Currently

[46] A lack of empirical evidence in the form of a pilot scheme is one of the criticisms of remuneration rights given by Wei in "Should Prizes Replace Patents - A Critique of the Medical Innovation Prize Act of 2005," pp. 31-32.
[47] See "THE 3P PROJECT. Better TB Treatment. Faster."

	affordable one-month TB regimen. Proposed in 2015 by MSF, the 3P Project is seeking funding in 2017 and is now run by a consortium of anti-TB organisations, led by the International Union Against Tuberculosis and Lung Disease (IUATLD). The incentives include grants and prizes. All recipients would be mandated to join the Medicines Patent Pool to ensure access.	seeking funding.
AMR Review[48]	A report commissioned by the British Government and presented in 2016. It proposed a Global Innovation Fund of $2bn over 5 years for early-stage and non-commercial research; and a system of market entry rewards of around one billion USD per drug for effective treatments. These rewards would be allocated conditional on affordable access and in proportion to social value. The idea behind this fund is similar to that of the WHO Global Consortium,[49] proposed in 2014, and GUARD,[50] proposed in 2017.	Report process completed. No fund implemented.
Health Product Research and Development Fund[51]	A pooled fund proposed to the WHO in 2016 for Type II and III diseases, which would allocate funding to health product R&D via a variety of mechanisms. Extent of delinkage would be one of the selection criteria.	No pooled fund implemented to date.

[48] See Jim O'Neill, "Tackling Drug-Resistant Infections Globally: Final Report and Recommendations", "Home | AMR Review."
[49] "A Publicly Financed Global Consortium for R&D to Fight Antibiotic Resistance."
[50] Selma Stern et al., "Breaking through the Wall: A Call for Concerted Action on Antibiotics Research and Development."
[51] See "Health Product Research & Development Fund: A Proposal for Financing and Operation", "TDR | New Approach Proposed for Funding and Managing Health Product R&D."

List of Abbreviations

Abbreviation	Definition
AMC	Advanced Market Commitment
AMR	Antimicrobial Resistance
APC	Advance Purchase Commitment
CIF	Cancer Innovation Fund
CEWG	Consultative Expert Working Group on R&D Financing and Coordination
DALY	Disability Adjusted Life Year
EAL	Equitable Access Licensing
EWG	Expert Working Group on R&D Financing and Coordination
FFL	Foreign Filing Licensing
FRIND	Fund for Research and Development in Neglected Diseases
GDP	Gross Domestic Product
GUARD	Global Union for Antibiotics Research and Development
HIF	Health Impact Fund
IAVI	International AIDS Vaccine Initiative
IUTLD	International Union against Tuberculosis and Lung Disease
MIC	Medical Innovation Convention
MIPF	Medical Innovation Prize Fund
MPP	Medicines Patent Pool
MRDT	Medical Research and Development Treaty
MSF	Medecins sans frontieres
PDP	Public-private Product Development Partnership

QALY	Quality Adjusted Life Year
R&D	Research and Development
TFT	Transferable Fast Track
TIPR	Transferable Intellectual Property Rights
WHO	World Health Organisation

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Appendix 1: Terminology

Just as with the classification of mechanism types, terminology is also non-standard in this field. Here we present some of the key terms along with their usage.

Term	Description
Delinkage	Any system which separates the cost of R&D from the price of drugs. Used more commonly by activists[52] than academics.[53] Also used by the WHO.[54]
Health Impact Funds	Occasionally used as a general term for remuneration rights systems, with the HIF as its primary example.[55]
Open	Means that anyone is able to use, build on and share information free of charge. In contradistinction to closed approaches like monopoly rights, were data and information is held privately.
Pay-For-Performance	Used as a descriptor of the HIF, in that it rewards successful research only.[56] Also used by Mossialos and Outterson to describe a general approach involving paying for performance rather than quantity or some other factor.[57]
Prizes	Usually refers to one-off milestone or end prizes. Sometimes includes

[52] Especially Love. See for example Love and Hubbard, "Prizes for Innovation of New Medicines and Vaccines."
[53] For exceptions see Renwick, Brogan, and Mossialos, "A Systematic Review and Critical Assessment of Incentive Strategies for Discovery and Development of Novel Antibiotics" and Hoffman and So, "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally."
[54] "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination."
[55] Faunce and Nasu, "Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/ Competitive Tender Treaty"; Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*.
[56] Hollis and Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*.
[57] Kevin Outterson, "New Business Models for Sustainable Antibiotics"; Renwick, Brogan, and Mossialos, "A Systematic Review and Critical Assessment of Incentive Strategies for Discovery and Development of Novel Antibiotics."

	prize funds like HIF[58] and MIPF.[59] At other times, used to describe a pull funding mechanism in contradistinction to patents.[60]
Prize funds	Usually used synonymously with remuneration rights, to describe a fund which remunerates innovators on registration of their innovation. [61] Can also describe one-off milestone or end prizes.[62] Sometimes used for MRDT.[63] Many initiatives include 'prize fund' in their title.[64]
Remuneration rights	A system where innovators are awarded repeated remuneration rights after registering their innovation. Remuneration rights are so-termed because innovators are granted a "remuneration right" that entitles them to be paid from the central fund. The term is rarely used in relation to medical R&D.[65] Approximately synonymous with the usual usage of prize fund, but excluding any one-off milestone or end prizes. All remuneration rights systems are prize funds; not all prize funds are remuneration rights systems.

[58] Hecht, Wilson, and Palriwala, "Improving Health R&d Financing for Developing Countries"; Love and Hubbard, "Prizes for Innovation of New Medicines and Vaccines."
[59] Wei, "Should Prizes Replace Patents - A Critique of the Medical Innovation Prize Act of 2005."
[60] Stiglitz, "Economic Foundations of Intellectual Property Rights", p. 1722.
[61] Love and Hubbard, "The Big Idea."
[62] "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination."
[63] Faunce and Nasu, "Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/ Competitive Tender Treaty."
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[65] A Google scholar search shows that it is more commonly used in relation to copyright, especially digital copyright. See Hancock, "1997 Canadian Copyright Act Revisions"; Kretschmer, "Digital Copyright"; Wan, "Legal Protection of Performers' Rights in the Chinese Copyright Law"; Wolke, "Some Catching Up To Do"; Xue, "One Step Ahead, Two Steps Back."

Appendix 2: Proposals Database

This spreadsheet displays all of the proposals which our research uncovered along with basic information relating to each proposal.