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## **ANALYSIS**

# Twenty criteria to make the best of scarce health resources in developing countries

The needs of developing countries are so great and potential interventions so numerous that priorities are essential. **James D Shelton** suggests a simple checklist for deciding on priorities and improving implementation

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It is difficult to exaggerate the health needs of developing countries. Consider the formidable core list of priorities in President Obama's Global Health Initiative: maternal health, diarrhoea, pneumonia, routine immunisable diseases, family planning, nutrition, sanitation, malaria, HIV, tuberculosis, and priority neglected tropical diseases—and each has multiple interventions. Yet, numerous other worthy health conditions clamour for attention. These include infectious diseases such as influenza, meningitis, cholera, and emerging zoonoses but also injuries, mental illness, surgery, palliative care, and chronic diseases. The immense needs dwarf the available resources and fragile overloaded systems. Even basic infrastructure is often lacking—for example, national service provision assessments from Uganda and Tanzania indicate that only 24% and 35%, respectively, of health facilities have regular electricity and only 31% and 34%, respectively, have regular water supply. 12 Health worker shortages and related system dysfunctions have been described as a "slow-burning crisis." Health workers can perform only a limited number of tasks, and organisational system structures are fragile as well. Accordingly, many effective public health approaches such as water and sanitation, food fortification, or alcohol taxation bypass clinical services entirely.

So what is the best use of resources? Much of the advocacy for health interventions stresses the importance of a particular health problem and the clinical efficacy of proposed interventions. However, true success on a large scale in resource constrained environments requires much more. To help a more systematic approach, I suggest some key criteria that should help both to inform priorities and to improve interventions.

#### Criteria for effective interventions

Health burden—This fundamental criterion includes the extent and severity of the problem but also equity considerations, especially towards the most vulnerable. Incidence, prevalence, mortality, morbidity, and disability adjusted life years (DALY) are a good start in evaluating burden. Problems such as

diarrhoea, pneumonia, tuberculosis, malnutrition, HIV, maternal health, and family planning are priorities in almost all developing countries. Others, such as malaria and tropical diseases, are localised.

Individual level efficacy— Such efficacy means performance in the best circumstances, usually assessed in circumscribed clinical trials, but trial evidence is only part of the story. Oral contraceptives, for example, are almost 100% efficacious in clinical trials but in actual use effectiveness is closer to 91% because of imperfect adherence. Conversely, efficacy need not be perfect. Although male circumcision provides only about 60% protection from HIV infection for individual men, solid population level evidence shows than in areas where male circumcision is very common, HIV does propagate enough to reach epidemic proportions. So, given its other benefits, circumcision warrants priority. Other interventions, such as coronary bypass surgery, may be highly effective but cost constraints and relatively small numbers of beneficiaries militate against them being a high priority.

Scalability—To merit priority, an intervention must benefit a substantial population. But mass multiplication is but one way to achieve scale. Thus, elimination of smallpox or polio can provide immense global impact even though relatively few people are vaccinated; or a tobacco tax can discourage smoking throughout the population. Some interventions like immunisation and malaria control produce herd immunity that exceeds the linear sum of individual efficacy once high coverage is reached. Although provision of antiretroviral drugs for treatment has reached large scale, mass provision to a substantial proportion of all those who are HIV positive for the purpose of prevention faces major constraints of programme reach, logistics, cost, acceptability, adherence, and potential drug resistance.

Low cost—Limited resources and vast health needs mandate extremely low cost. Many vaccines cost only pence for each dose. Some behavioural interventions such as exclusive breast feeding, kangaroo care, alcohol reduction, or limiting sexual

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partners have no product cost or can save money for the individual. But proper assessments must include other costs such as service delivery and organisational costs.

Simplicity—Fragile health systems and lack of resources make this criterion critical. Hence many successful interventions in the developing world are rather simple compared with those in Western medicine. Examples include insecticide treated bed nets, breast feeding, vitamin A, oral rehydration therapy, hand washing, latrines, condoms, simple neonatal resuscitation, and manual vacuum aspiration and misoprostol for post-abortion care. Simpler regimens of antiretroviral drugs, such as fixed dose combinations of three drugs, promote better adherence. Single encounter interventions such as "see and treat" approaches to cervical cancer work better than conventional smear tests, which require later follow-up for treatment.

*Safety*—The risk-benefit balance for interventions must be strongly positive. For example, giving isoniazid to prevent clinical tuberculosis risks hepatic toxicity, but the benefits far exceed the risk.

*Individual acceptability*—If individuals don't like an intervention, they tend not to use it. Thus condoms have acceptability limitations. And a new strain of rice may be more nutritious but can fail if it tastes strange or cooks differently.<sup>11</sup>

Family support—Similarly, families have a strong influence on the effect of interventions, especially in tightly knit developing world cultures. Examples include prioritising bed nets<sup>12</sup> and food<sup>13</sup> towards the most vulnerable household members, negotiating condom use with partners, and supporting drug adherence.<sup>14</sup> Conversely, injectable contraceptives have the advantage that partners need not be aware of their use.

Social norms—Cultural influences are also important. Male circumcision has strong traditional support among some groups but not others. <sup>15</sup> Breast feeding is strongly supported in virtually all cultures. Social stigma about AIDS impedes prevention and treatment, <sup>16</sup> and rumours about the polio vaccine have stymied elimination efforts in Nigeria. <sup>17</sup> Political will towards an intervention is another key component.

Compatibility with provider attitudes, medical culture, and organisation of work—Why would overstretched and poorly paid health staff be motivated to deliver something new? Understanding their perspective and medical culture is crucial to successful delivery of an intervention.<sup>18</sup> Thus, intrauterine devices are underused, partly because insertion is complicated and time consuming compared with other methods of birth control.<sup>18</sup> Similarly, medical staff tend not to provide extensive counselling, and thus interventions that require less counselling or for which information can be provided in other ways ( such as through mass media) are preferable.

Potential for integration—The way services mesh together is crucial. For example, it makes sense to provide family planning with infant immunisation but less so with antenatal care. <sup>19</sup> Integration also takes place outside the clinical arena. For example, distribution of bed nets can be integrated with large scale efforts such as national immunisation days, <sup>20</sup> and mass treatment of several tropical diseases can be provided concurrently. <sup>21</sup> Likewise, a coordinated package of behaviour change interventions aimed at many health problems, including chronic disease, makes intuitive sense.

Relation to alternative interventions—An intervention must be evaluated relative to other interventions it may displace or affect. For example, a new contraceptive implant may offer little advantage over an existing one. Or a combination of biomedical, behavioural, and structural approaches may synergistically improve HIV prevention.<sup>22</sup> Conversely, some preventive

approaches, such as condoms, are susceptible to behavioural risk compensation whereby those using them may increase risky sexual behaviour.<sup>23</sup>

Regulatory and policy limitations—Donors and countries typically require that drugs and devices are approved by international bodies such as the European Medicines Agency and are increasingly requiring individual country approval.<sup>24</sup> These processes can be very cumbersome. Drug regulatory approval typically extends to labelling, packaging, and manufacturing. Policy constraints include needless restrictions on who can provide services such as injections, antibiotics, antiretroviral drugs, and simple surgery.

Procurement, supply chain, and logistical requirements—Forecasting, budgeting, procurement, warehousing, and transportation of consumable products at global or national scale are all hugely demanding. Consumables such as injections, oral rehydration salts, antibiotics, surgical supplies, and vitamins are susceptible to being out of stock and product expiration as well as diversion and corruption. Products with short shelf lives or that require continuous cold storage pose further challenges.<sup>25</sup>

Timing dependence—Some interventions have to be applied at specific times. Obvious examples are safe delivery of babies, post-abortion care, and response to outbreaks of infectious disease. Seasonality affects some diseases, including malaria. Smallpox eradication was successful, partly because it focused intensive containment vaccination at the seasonal low of transmission. The first few days post partum are critical for both maternal and neonatal interventions. Yet because so many deliveries occur at home, reaching mothers and babies during that narrow time is especially challenging.

Durability—Long term durability is especially important for systems ill equipped to provide services repetitively and consistently. Interventions such as circumcision, immunisation, long acting contraceptives, and bed nets all possess this advantage.

Behavioural dependence—Healthy behaviours such as exclusive breast feeding or hand washing have many advantages; they are inexpensive, simple, efficacious, potentially highly durable, free from regulation, and can bypass the clinical system. But achieving consistent, long lasting behaviour change at scale can be difficult. Sometimes structural approaches (such as tobacco taxation, food fortification, removal of lead from petrol) are more effective. Likewise, adherence to long term drug regimens such as those to treat HIV infection or tuberculosis is challenging.<sup>27</sup>

Commercial sector compatibility—The commercial sector contributes substantially to the distribution of many interventions. Successful product development, manufacturing, and marketing require profitability and other incentives, although global companies can also respond to social responsibility.<sup>28</sup> Collaboration, for example, for a fixed dose antiretroviral combination that includes drugs from more than one company, needs nurturing in the commercial environment. At country level, marketing interventions such as micronutrient fortified foods, oral rehydration salts, or low emission cooking stoves must be commercially viable.

Collateral benefits—Some interventions have benefits beyond their main health objective. Family planning has substantial additional benefits, including personal fulfilment, economic wellbeing, and women's empowerment.<sup>29</sup> Reduction in malaria burden seems to reduce susceptibility to other infectious diseases.<sup>30</sup> Male circumcision prevents not only HIV but several

other sexually transmitted diseases and probably cervical cancer

by preventing human papillomavirus infection.<sup>31</sup>

Sustainability and other future considerations—Sustainability (not necessarily reaching complete self reliance) relates to many other criteria—for example, simplicity, low cost, acceptability, compatibility, and profitability. However, other dimensions include how well an intervention is introduced, vulnerability to future events such as emergence of drug resistance, resilience of the health system, political commitment, energy and enthusiasm of proponents, and ability to continue when donor assistance diminishes.

### Three examples

To illustrate, I have applied the above criteria to three interventions, rotavirus vaccine, insecticide treated bed nets against malaria, and tenofovir gel vaginal microbicide for HIV prevention. I have assigned a maximum score of 10 for each criterion, yielding a simple total up to 200. Rotavirus vaccine has many positive qualities (table 111). It prevents severe diarrhoea, a major killer of children. It is likely to be durable, highly acceptable, safe, and compatible with existing immunisation programmes, and costs for poorest countries are subsidised by the Global Alliance for Vaccines and Immunization (GAVI.) However, it has limited efficacy in the poorest settings, does not prevent all causes of severe diarrhoea, has a complex and narrow administration schedule, requires a cold chain, and has uncertain sustainability, thus presenting substantial challenges for weak health systems. Its overall score is a respectable 131.

Bed nets against malaria (table  $2\Downarrow$ ), an extremely successful intervention, score a much higher 171. They are highly efficacious, very scalable, simple, inexpensive, durable, acceptable, relatively free from regulatory and clinical service delivery constraints, and have collateral benefits against other infectious disease. However, they do have some logistical and behavioural constraints. Conversely, the tenofovir gel microbicide for HIV prevention (table  $3\Downarrow$ ) scores a much lower 96. Though the gel meets a critical health need, it has low efficacy, high behavioural requirements, formidable regulatory, cost, and logistical challenges and its scalability is severely limited by the restriction to delivery through clinics and current requirement for periodic HIV testing.

The point is not to assert correctness for these somewhat global assessments. Indeed, differing perspectives, including those of communities and consumers that reflect differing country situations, are essential. Moreover, clearly no single summary number suffices. Some attributes are more critical than others. They overlap and interact in complex ways. Inevitably overall judgment is required.

#### Conclusion

The global marketplace of innovation and advocacy for health interventions will continue to be dynamic, turbulent, and often passionate. That is a good thing. Improvement must occur on many fronts. Strengthening health systems is a major priority, but absorptive capacity remains severely limited. And the developing world's vast and varied health needs only heighten our responsibility for prudent decision making. In the end, hopefully informed by the criteria in this checklist, we must select priorities, and try to improve key interventions to make our best effort to improve global health.

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### ANALYSIS

**Tables** 

	Score	
Criterion	(0-10)	Comment
1. Health burden	10	Rotavirus is a leading cause of severe diarrhoea and death in young children
2. Individual efficacy	4	Efficacy only 40-50% against rotavirus and 25% against all severe diarrhoea in poorest parts of sub-Saharan Africa <sup>32</sup>
3. Scalability	8	The live oral vaccine can be delivered at some scale alongside other childhood vaccinations, 33 and high vaccination levels produce strong herd immunity 34
4. Low cost	6	Expensive but costs for poorest countries currently underwritten by the Global Alliance for Vaccines and Immunization
5. Simplicity	8	Simple modality but complex administration schedule with 2-3 doses
6. Safety	8	Safe (though some concern about intestinal intussusceptions)
7. User acceptability	9	Vaccines generally highly acceptable
8. Family acceptability	9	Vaccines generally highly acceptable
9. Social norms	9	Vaccines generally highly acceptable
10. Provider/medical culture	10	Well established process and acceptability for providers
11. Potential for integration	8	Fits well with existing vaccine infrastructure but immunisation schedule differs
12. Alternative approaches	8	Complements other interventions against diarrhoeal disease
13. Regulatory and policy requirements	6	Some local regulatory approval generally needed
14. Procurement/logistics	3	Substantial supply chain required and narrow temperature requirements
15. Timing dependency 3		Very precise timing required with complex administration schedule—too late risks infection and too early interference from maternal antibodies <sup>34</sup>
16. Durability	8	Protection durability appears good, including extrapolation from durability of natural immunity
17. Behaviour dependency	8	Behaviourally independent once given, but presentation for routine immunisation is often late
18. Commercial amenability	3	Country level commercial viability appears remote
19. Collateral benefits	0	None obvious
20. Sustainability	3	Significant ongoing cost and effort needed especially if donor subsidy diminishes
Raw sum	131	

Table 2 | Table 2 Checklist for long acting insecticide treated bed nets

Criterion	Score (0-10)	Comment	
1. Health burden	10	Malaria's health burden is vast	
2. Individual efficacy	9	Efficacy is high	
3. Scalability	10	Amenable to very rapid and wide scale-up. Some herd immunity from reduced mosquitoes in environment	
4. Low cost	10	Low cost for both product and distribution	
5. Simplicity	9	Simple design and usability	
6. Safety	9	Very safe	
7. User acceptability	8	Generally acceptable, though some issues related to comfort	
8. Family acceptability	8	Acceptable, but children, who are at most risk, may not always get preference	
9. Social norms	8	Seem positive	
10. Provider/medical culture	10	Can bypass clinical service environment. Worker friendly	
11. Potential for integration	8	Fairly easily integrated with several service delivery modes	
12. Alternative approaches	9	Complements other malaria interventions to reduce population risk	
13. Regulatory and policy requirements	9	No drug or device regulatory approval required	
14. Procurement/logistics	7	Requires procurement and logistics but relatively simple to carry out; bulky	
15. Timing dependency	9	Can be initiated for ongoing use at any time	
16. Durability	8	Insecticide typically lasts for at least three years	
17. Behaviour dependency	7	Requires nightly behaviour to use, which seems largely acceptable	
18. Commercial amenability	8	Can be profitable enough for commercial sales and distribution	
19. Collateral benefits	7	Considerable effect on other childhood infectious diseases	
20. Sustainability	8	Highly sustainable because of simplicity, low cost, etc, but insecticide resistance a problem	
Raw sum	171		

Table 3 | Table 3 Checklist for tenofovir gel vaginal microbicide for HIV prevention

	Score	
Criterion	(0-10)	Comment
1. Health burden	10	HIV is a high priority and women are vulnerable
2. Individual efficacy	4	Efficacy only 39% in pivotal clinical trial
3. Scalability	3	Likely to be difficult; for intermediate term only and requires clinical provision with repeat HIV testing foreseen
4. Low cost	4	Uncertain, but cost of active ingredient, gel, applicator, packaging, and ongoing service delivery is likely to be appreciable
5. Simplicity	6	Simple product concept but vaginal self administration and possible need to administer before and after sex,* as well as service delivery process add to complexity
6. Safety	8	Fairly safe. But if antiretroviral resistance develops it could jeopardise future antiretroviral treatment
7. User acceptability	4	Vaginal administration, and possible need to administer before and after sex are problematic
8. Family acceptability	7	Probably generally good but partners may not always be supportive
9. Social norms	7	Probably generally good but HIV stigma even regarding prevention remains problematic
10. Provider/medical culture	6	Probably fairly positive but may entail a significant increased workload for providers, including counselling
11. Potential for integration	6	Additional tasks including repeat visits and periodic HIV testing challenging for weak systems
12. Alternative approaches	6	Fills a major void but has potential for reduced use of condoms and possible increase in risky sex
13. Regulatory and policy requirements	3	Full scale regulatory approval required
14. Procurement/logistics	3	Rather onerous: a relatively bulky consumable product requiring repeated clinical distribution and testing. Shelf life not completely established but probably good
15. Timing dependency	4	Must be used either before and after sex or daily continually
16. Durability	2	Requires consistent ongoing administration
17. Behaviour dependency	2	Highly behaviourally dependent
18. Commercial amenability	4	Possibly commercially viable in longer term, but costs and price acceptability are key challenges
19. Collateral benefits	2	Prevents HSV as well as HIV
20. Sustainability	5	Costs appear considerable; HIV has high proponent enthusiasm
Raw sum	96	

<sup>\*</sup>Potential regimens include both daily administration and administration before and after sex.