

What's In, What's Out: Ethics & Equity Considerations for Health Benefits Design

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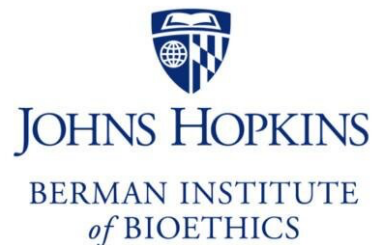
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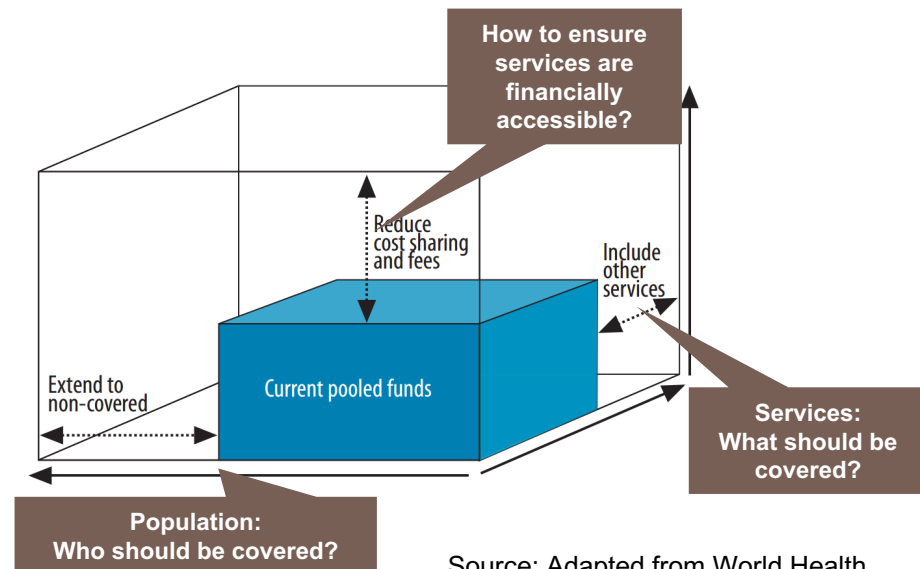


Dispelling Myths about Ethics

- *“Ethics is an afterthought”*
 - *“Ethics is the enemy of cost-effectiveness”*
 - *“Ethics is not evidence-based”*
 - *“Ethics is not useful or important”*
-
- Ethics is all about pursuing what is right – making good decisions, fulfilling duties we have to other humans

The Pursuit of UHC: A value-laden endeavor

- Whose health will be improved and does the mix of services represent a fair distribution of health benefits across the population?
- Does the plan address the needs of populations that have been historically disadvantaged or overlooked?
- Do the interventions covered and the cost-sharing arrangements offer financial protection for those most-at-risk of catastrophic health expenditure?
- Does the package of services represent good “value-for-money”?
- Do covered interventions align with social values/priorities?
- How does the mix of services shape patients’ experience of dignity and respect in the health system?
- How fair and transparent are the processes for HTA? How do interventions get on the policy agenda for evaluation?



Source: Adapted from World Health Organization, World Health Report, 2010

Ethics Analysis: Part of the Toolbox

Enables policymakers to examine policy options, processes and outcomes through a different lens – evaluating them against principles, norms and values.

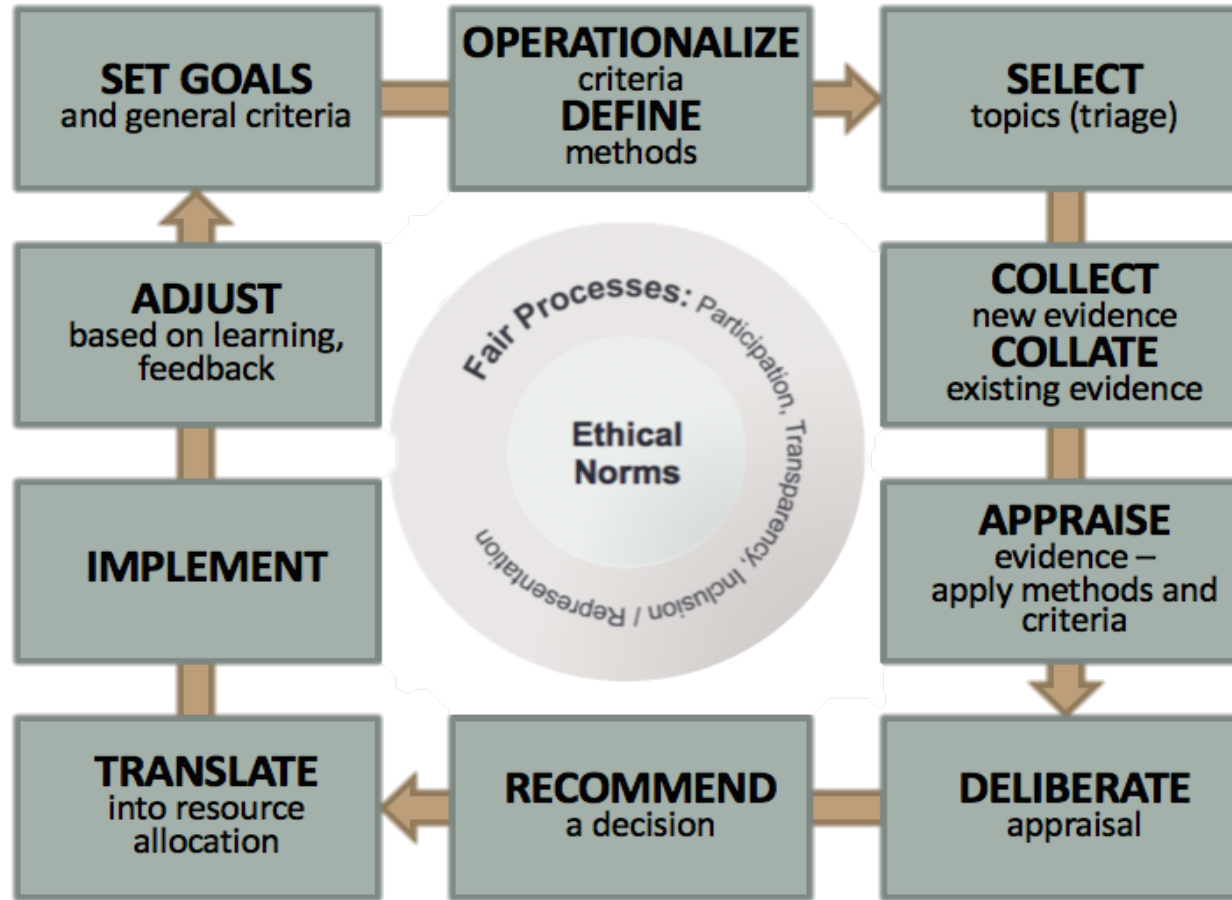
Can support priority-setting decisions that:

- cohere with public health goals and societal values
- are publically justifiable and morally defensible
- protect against serious moral harms and contribution to gross inequities



Explicit HBP:

Not just “What’s In or Out” but “*Why*”



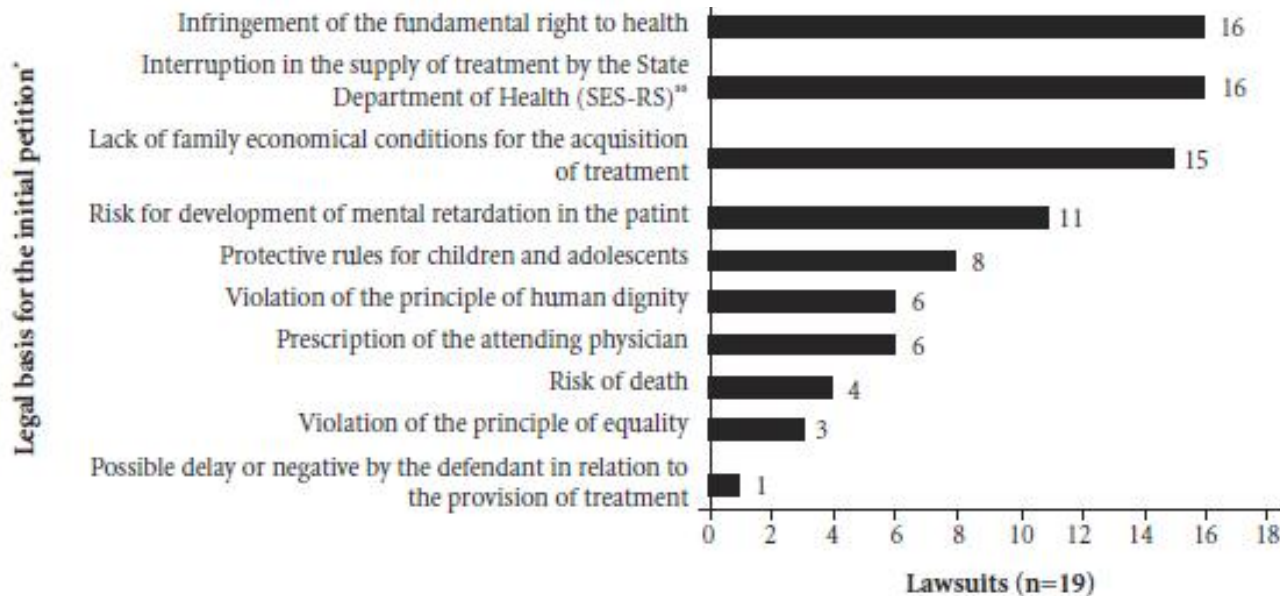
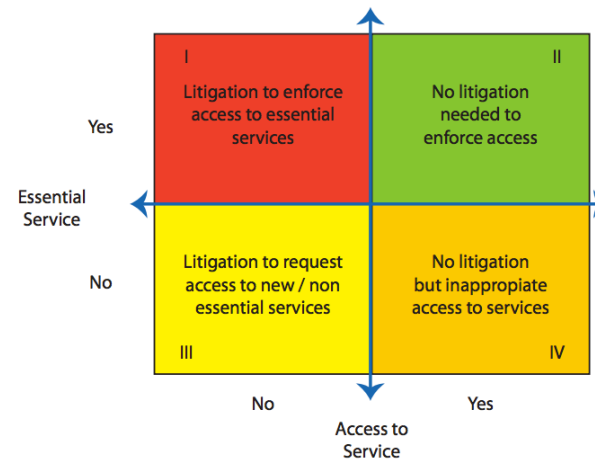
Pitfalls of overlooking ethics in health priority-setting

- Unintentional and avoidable harms
- Potentially reinforcing/worsening systematic disadvantage and health inequities
- Inefficient allocations that could have been used for important gains in health and wellbeing
- Loss of public trust in the government and health system, political and public backlash

Protest in the streets



Protest in the courts



Source: Manguiera TL, et al. Access to treatment for phenylketonuria by judicial means in Rio Grande do Sul, Brazil. Ciênc. Saúde Coletiva. 2015 May; 20(5): 1607-1616. Figure 1. Access to PKU treatment by judicial means in Rio Grande do Sul, Brazil: legal basis for the initial petition.

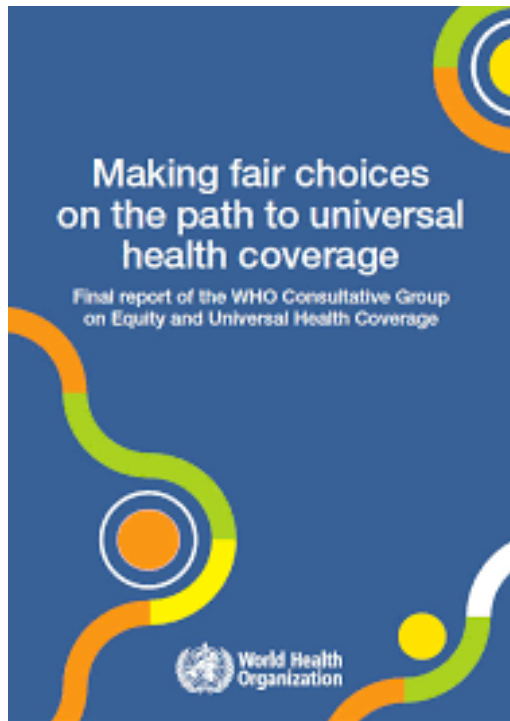
ETHICS CONSIDERATIONS FOR DESIGNING HEALTH BENEFITS

What does ethics analysis look like in priority-setting?

Various Ethics Frameworks on Priority-Setting: Broad and Narrow

- Most ethics frameworks consist of:
 - Foundational principles (e.g., health maximising, avoiding harms, justice & fairness, respect)
 - With guidelines, considerations or questions
 - Plus procedural norms (participation, transparency)
- Some are meant to apply broadly to the UHC plan or policy
- Others focus on specific assessment of a health technology or intervention

Example: Broad Ethics Guidance



- Guiding Principles:

- Cost-effectiveness/Max. Health Benefits
- Priority to the worst off
- Financial protection

- Process

1. Categorize interventions into priority categories: High, Medium, Low
 - *Based on 3 guiding principles*
2. Expand coverage for high-priority services to everyone
3. Ensure that disadvantaged groups are not left behind (e.g., poor or rural populations)

WHO Fair Choices: *Unacceptable Trade-offs*

1. Do not expand coverage for low- or medium-priority services before there is near universal coverage for high-priority services.
2. Do not start by including only those able to pay, while excluding the poor, even if it would be easier
3. Do not give high priority to very costly services (whose coverage will provide substantial financial protection) when the health benefits are very small compared to alternative, less costly services.
4. Do not expand coverage for well-off groups before doing so for worse-off groups when the costs and benefits are not vastly different.
5. Do not shift from OOP payment toward mandatory prepayment in a way that makes the financing system regressive/less progressive

Ethics Framework in Sweden

Human Value Principle

All human beings are of equal value and have the same right independent of personal characteristics or function in society.

The principle determines primarily what factors that should *not* determine the priority setting, e.g. chronological age, social and economic situation, previous life-style etc. But it does allow these factors to be taken into account if they affect the effectiveness of the treatment, e.g. biological age and future life-style.

Need and Solidarity Principle

Resources should be distributed according to need.

When it is necessary to prioritise among effective interventions – more of health care’s resources should be given to those in greater need, meaning those with the most severe conditions, and those with the lowest quality of life. This applies even if it means that everyone cannot have their needs met in part or at all.

Cost-effectiveness Principle

In choosing between different interventions one needs to strive for a reasonable relationship between costs and effects, measured in terms of improved health and quality of life.

The relationship between the Need and Solidarity Principle and the Cost-effectiveness Principle is such that patients with severe diseases and substantially impaired quality of life should take precedence over milder cases, even if this care involves “substantially” greater costs for a given health benefit.

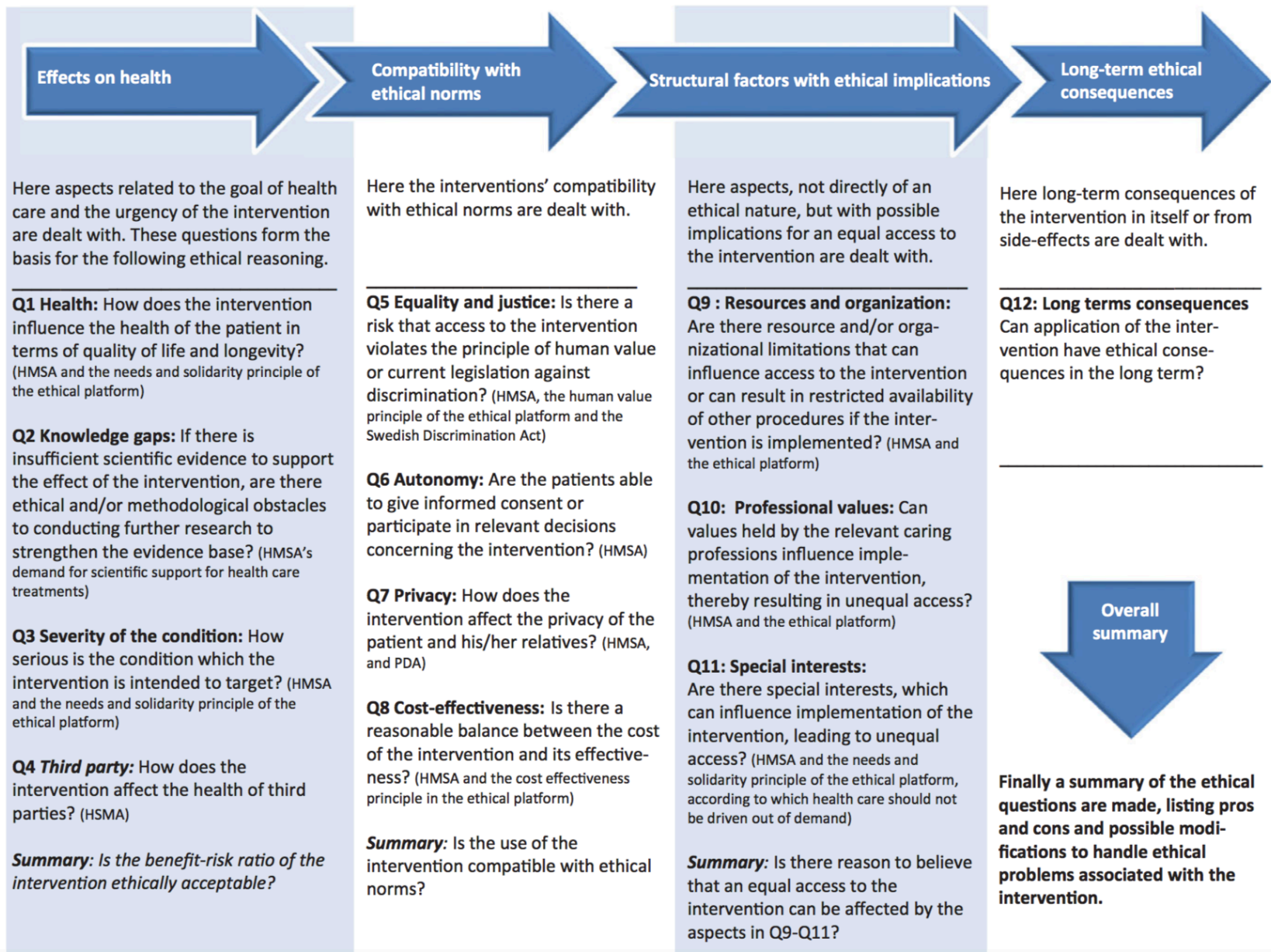


Figure 2 Overview of the structure of argumentative priority of the framework assessment as a basis for such decisions. HMSA: Swedish Health and Medical Services Act, PDA: Patient Data Act.

Examples: Narrower Ethics Guidance

Hofmann B, Toward a Procedure for Integrating Moral Issues in HTA

- Questions checklist (see right)

EUnetHTA Core Model

<https://mekat.thl.fi/htacore/model/HTACoreModel3.0.pdf>

- Principles with questions
 - Benefit/Harm Balance
 - Autonomy
 - Respect for Persons
 - Justice & Equity

Table 1. Morally Relevant Questions with Respect to Assessing Health Technology

| | |
|-----|---|
| Q1 | What are the morally relevant <i>consequences</i> of the implementation of the technology? |
| Q2 | Does the implementation or use of the technology challenge patient autonomy? |
| Q3 | Does the technology in any way violate or interfere with basic human rights? |
| Q4 | Does the technology challenge human integrity? |
| Q5 | Does the technology challenge human dignity? |
| Q6 | Will there be a moral obligation related to the implementation and use of a technology? |
| Q7 | Does the technology challenge social values and arrangements? |
| Q8 | Does the widespread use of the technology change our conception of certain persons (e.g., with certain diseases)? |
| Q9 | Does the technology contest religious, social, or cultural convictions? |
| Q10 | Can the use of the technology in any way challenge relevant law? |
| Q11 | How does the assessed technology relate to more general challenges of modern medicine? |
| Q12 | Are there any related technologies that have turned out to be morally challenging? |
| Q13 | Does the technology in any way challenge or change the relationship between physician and patient? |
| Q14 | How does the implementation of the technology affect the distribution of health care? |
| Q15 | How does the technology contribute to or challenge professional autonomy? |
| Q16 | Can the technology harm the patient? |
| Q17 | What patient group is the beneficiary of the technology? |
| Q18 | Are there third-party agents involved? |
| Q19 | What are the interests of the users of the technology? |
| Q20 | What are the interests of the producers of technology (industry, universities)? |
| Q21 | Are there moral challenges related to components of a technology that are relevant to the technology as such? |
| Q22 | What is the characteristic of the technology to be assessed? |
| Q23 | Is the symbolic value of the technology of any moral relevance? |
| Q24 | Are there morally relevant issues related to the choice of end points in the assessment? |
| Q25 | Are there morally relevant issues related to the selection of studies to be included in the HTA? |
| Q26 | Are the users of the technology in the studies representative of the users that will apply it in clinical practice? |
| Q27 | Are there morally relevant aspects with respect to the level of generalization? |
| Q28 | Are there moral issues in research ethics that are important to the HTA? |
| Q29 | What are the reasons that this technology is selected to be assessed? |
| Q30 | What are the interests of the persons participating in the technology assessment? |
| Q31 | At what time in the development of the technology is it assessed? |
| Q32 | Are there related technologies that have or have not been assessed? |
| Q33 | What are the moral consequences of the HTA? |

From Broad to Narrow:

Ethical Considerations for Health Benefits Design

- Equity
- Efficiency
- Individual Benefits and Harms
- Respect and Dignity of Patients/Citizens
- Respect for Clinician Judgment
- Evidence-Informed Action and New Health Systems Knowledge
- Procedural Fairness for Decision-Making

*A framework for specifying what is most important and relevant in a particular context – starting with goals and objectives, then using those to inform priority setting of services, cost-sharing arrangements, M&E and adjustment

Equity: Fair and Just Distribution

- Positive action to address current disparities (differences that are unfair and avoidable)
- Negative action: Avoid creating new inequities or reinforcing existing

| Commitments to Equity | Explanations |
|--|---|
| Equity in Financial Protection and Cost-Sharing | Ensuring that the burdens of out-of-pocket payments and plan contributions are fairly distributed across the population, so that no one experiences an undue financial burden in accessing services |
| Equity in Access to Care | Ensuring that all beneficiaries experience both coverage and availability of health services |
| Equity in Quality of Health Care | Ensuring that all beneficiaries have access to high quality services and respectful treatment regardless of personal circumstances (geography, socio-economic status, gender, ethnicity, age, etc.) |
| Equity in Outcomes | Ensuring comparable improvements in health status (morbidity, mortality, burden and severity of disease) among different groups within the population |

What specific equity objectives are relevant in your context?

- Are you trying to cover all people with a basic minimum or developing a population for an underserved population?
- Which inequities are you most concerned about?
 - Gender
 - Ethnicity
 - Geographic location
 - Socioeconomic status
 - Sexual orientation
 - Religion
- “Horizontal equity” – treating like cases like
 - E.g., closing gaps between what people with same illness receive on a public scheme vs private?

What specific equity objectives are relevant in your context?

- A clear conception of what the top “equity objectives” for a benefits are will inform:
 - What populations are covered
 - What services should be included
 - What cost-sharing arrangements should be adopted
 - What evidence needs to be considered and/or generated
 - What outcomes should be measured to track HBP progress
 - What adjustments should be made when equity objectives are not being met or when new equity objectives need to be adopted

Efficiency: Maximizing Population Health

Not just an economic concern, but a ethics concern:

- Limited resources ought to be used efficiently to achieve greater gains in population health
- Investment in high-cost, low-value services will result in morally relevant opportunity costs – foregoing important health gains in favor of expensive interventions that have little associated benefit
- Failure to steward resources efficiently can also threaten progress on all objectives of the HBP – leading to sustainability issues and erosion of public trust

Efficiency and Equity: Are they at odds?

- While many focus on tradeoffs between equity and efficiency, the two often co-travel
 - Many of the most cost-effective interventions are ones that benefit the most disadvantaged, and many interventions that are essential for the most disadvantaged are cost-effective
 - The opportunity costs of inefficient allocations often fall disproportionately on the most disadvantaged (particularly when coverage of these interventions are driven by those who have greater wealth and/or political influence) – widening disparities
 - Inefficient allocations are often significant impediments to progress toward equitable HBPs and universal health coverage

While CEA can capture some equity & ethics considerations, it cannot “do it all”

Guidance on priority setting in health care (GPS-Health): the inclusion of equity criteria not captured by cost-effectiveness analysis

[Ole F Norheim](#) ✉, [Rob Baltussen](#), [Mira Johri](#), [Dan Chisholm](#), [Erik Nord](#), [DanW Brock](#), [Per Carlsson](#), [Richard Cookson](#), [Norman Daniels](#), [Marion Danis](#), [Marc Fleurbaey](#), [Kjell A Johansson](#), [Lydia Kapiriri](#), [Peter Littlejohns](#), [Thomas Mbeeli](#), [Krishna D Rao](#), [Tessa Tan-Torres Edejer](#) and [Dan Wikler](#)

Cost Effectiveness and Resource Allocation 2014 12:18 | DOI: 10.1186/1478-7547-12-18 |

Priority-setting criteria to be considered in conjunction with cost-effectiveness results (Norheim et al. 2014)

| Group 1: disease and intervention criteria | |
|--|--|
| Severity | Have you considered whether the intervention has special value because of the severity of the health condition (present and future health gap) that the intervention targets? |
| Realization of potential | Have you considered whether the intervention has more value than the effect size alone suggests on the grounds that it does the best possible for a patient group for whom restoration to full health is not possible? |
| Past health loss | Have you considered whether the intervention has special value because it targets a group that has suffered significant past health loss (e.g. chronic disability)? |
| Group 2: criteria related to characteristics of social groups | |
| Criteria | Question |
| Socioeconomic status | Have you considered whether the intervention has special value because it can reduce disparities in health associated with unfair inequalities in wealth, income or level of education? |
| Area of living | Have you considered whether the intervention has special value because it can reduce disparities in health associated with area of living? |
| Gender | Have you considered whether the intervention will reduce disparities in health associated with gender? |
| Race, ethnicity, religion and sexual orientation | Have you considered whether the intervention may disproportionately affect groups characterized by race, ethnicity, religion, and sexual orientation? |
| Group 3: criteria related to protection against the financial and social effects of ill health | |
| Economic productivity | Have you considered whether the intervention has special value because it enhances welfare to the individual and society by protecting the target population's productivity? |
| Care for others | Have you considered whether the intervention has special value because it enhances welfare by protecting the target population's ability to take care of others? |
| Catastrophic health expenditures | Have you considered whether the intervention has special value because it reduces catastrophic health expenditures for the target population? |

Individual Benefits and Harms

- While we are are concerned about population health, we have to remember that individuals are going to be impacted by priority-setting decisions
 - Real consequences (+/-) of adopting, denying and delisting
 - What are those impacts?
 - If negative, how severe are they?
 - What can be done to minimize individual harms?
 - What, if any, provisions can be made to address the concerns of those with more specialized needs?
- *Keeping in mind that looking solely at the aggregate can lead to prioritizing small benefits to the many over large benefits to the few – “the aggregation problem”*

Individual Benefits and Harms: An example

Epilepsy, Neuropathic Pain and HLA-B*1502 Gene Screening

- 1st line therapy, while generally safe and cost-effective, has severe, life-threatening complications or risk of permanent disabilities for <1% patients
- Alternative therapies would be extremely costly if given to the entire patient population
- Personalized medicine and advances in screening can help detect those most likely to have complications
- With HLA-B*1502 screening can identified those that should go straight to second line options – reducing complications by 88%

Adapted from: Rattanavipapong W, Koopitakkajorn T, Praditsitthikorn N, Mahasirimongkol S, Teerawattananon Y. Economic evaluation of HLA-B* 15: 02 screening for carbamazepine-induced severe adverse drug reactions in Thailand. *Epilepsia*. 2013 Sep 1;54(9):1628-38.

Individual Benefits and Harms: An example

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Additional Notes:

- **Risk is higher in populations who are immunocompromised** (e.g., cancer patients, people living with HIV, lupus), with higher associated mortality rates in these groups
- Screening HLA-B*1502 in neuropathic pain patients **is cost-effective** at 3,900 USD/QALY but **not cost-effective** in epilepsy patients at 6,700 USD/ QALY

Should it be covered? For whom?

Adapted from: Rattanavipapong W, Koopitakkajorn T, Praditsitthikorn N, Mahasirimongkol S, Teerawattananon Y. Economic evaluation of HLA-B 15: 02 screening for carbamazepine-induced severe adverse drug reactions in Thailand. Epilepsia. 2013 Sep 1;54(9):1628-38.*

Individual Benefits and Harms

- Engagement as a critical tool for understanding patient needs, preferences, what would be most beneficial, what harms are most important to mitigate
- “Patient-centered outcomes”
 - Disability community preferences for greater investments in assistive devices over novel/experimental approaches to restore function; paraplegics more concerned with restored sexual function than walking
 - ESRD preferences for pain management, social supports and EOL counseling

Respect & Dignity

- Respecting the autonomous choices of individuals
 - Some care choices engage important decision for self-determination and others don't
- Eliminating discrimination based on group membership (e.g., ethnicity/race, religion, gender, etc.)
- Reducing sources of stigma
- Sensitivity to cultural and religious norms
- Preserving human dignity
- Privacy and Confidentiality

Respect & Dignity: Examples

- Home-based HIV Counselling & Testing in areas with levels of stigma
 - Data showing increased testing rates, reduced stigma-related harms and intimate partner violence, and + impacts of counselling
- Youth Clinics & Corners for Reproductive & Sexual Health
 - A safe space to receive “non-judgmental” care
- Choice between different modes of family planning methods: L-T (IUD, injectables) vs S-T (ring, patch, pill)
- End-of-life counseling to discuss options and support dignity
- Dentures and restoring “self-worth”, social bases of respect (Chile case)

Respect for Clinician Judgment

- Providers in are often in the best position to promote the best interests of individual patients, and they have role-specific obligations to do so
- They are also critical to a well functioning health system
- Engaging providers and respecting their role in meeting health objectives and delivering services should be a key consideration in decision-making
- *But this does not mean giving practitioners discretion over every domain of health care decision-making*

Respect for Clinician Judgment

- Some priority-setting decisions impact providers' ability to carry out their obligations to patients more than others
- Some physicians are also not up-to-date on the latest evidence and best practice – “the bench to bedside lag”
- Also a matter of politics and pragmatics:
 - If physicians do not feel adequately respected or free to practice on their own terms through the public system, they may challenge the plan and its legitimacy, or seek opportunities in the private sector that offer greater liberty in how they care for their patients.

Respect for Clinician Judgment

- Some considerations:
 - How do design decisions for the HBP, including but not limited to which interventions are included, affect providers' ability to care for their patients?
 - Would excluding certain interventions meaningfully constrain important choices for physicians to provide care?
 - If so, are there good moral justifications for doing so?
 - Could the exclusion of an intervention threaten provider-patient trust?
 - If so, are there good moral justifications for doing so?
 - What can be done to engage providers in the decision making process, to build legitimacy and buy-in for decisions?

Evidence-Informed Practice

- Evidence on disease burden and *distributions* of ill health
- Evidence on interventions
 - Including cost-effectiveness, comparative effectiveness, and data on patient-centered outcomes
 - Evidence on externalities – other non-health benefits for patients and benefits to other persons not directly receiving services
 - Evidence on social values in the particular context

“...securing just health care requires a constantly updated body of evidence about the effectiveness and value of health care interventions...”

~ Faden et al. (2013)

Tough Choice & Trade-offs

- No health system can provide everything to everyone
- When applying these ethics considerations, there will often be conflicts that arise across different commitments
 - Efficiency/maximizing population health & meeting individual needs
 - Evidence-informed practice & respect for clinician judgment
 - Efficiency & equity

Capturing Multiple Considerations and Visualizing Tradeoffs

Financial Protection

How well does this reduce catastrophic health expenditures? How well does it reduce OOP?

Respecting Clinicians

How well does this align with meaningful provider choice?

Efficiency & Population Health Impact

What is magnitude of impact on public health?
How efficient or cost-effective is the intervention?

Respecting Patients & Preserving Dignity

How much does covering this service contribute to meaningful self-determination interests, reducing stigma, and enhancing dignity?

Social Value

How does this rank on expressed public preferences? Is demand high?

Affordability

How well does this fit with budgetary considerations and constraints?

Low

High

Equity

How well does this address health disparities and the needs of the disadvantaged?

Supply Side Capacity

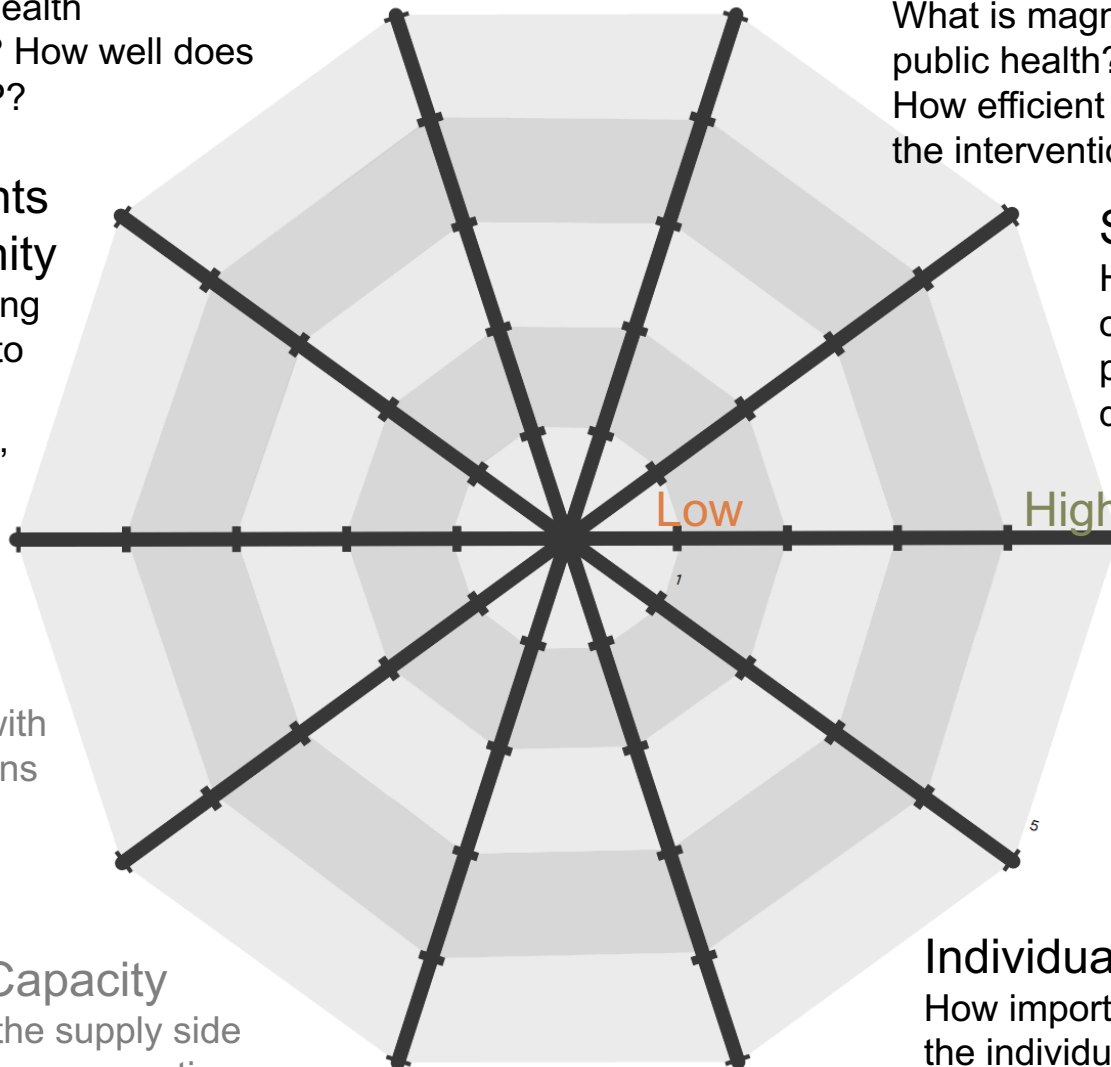
How prepared is the supply side to deliver on the programmatic feature of the package?

Political Feasibility

How likely to have support from important political actors?

Individual Wellbeing

How important is this service to the individual wellbeing of those who need it? How severe are the consequences of not providing the service?



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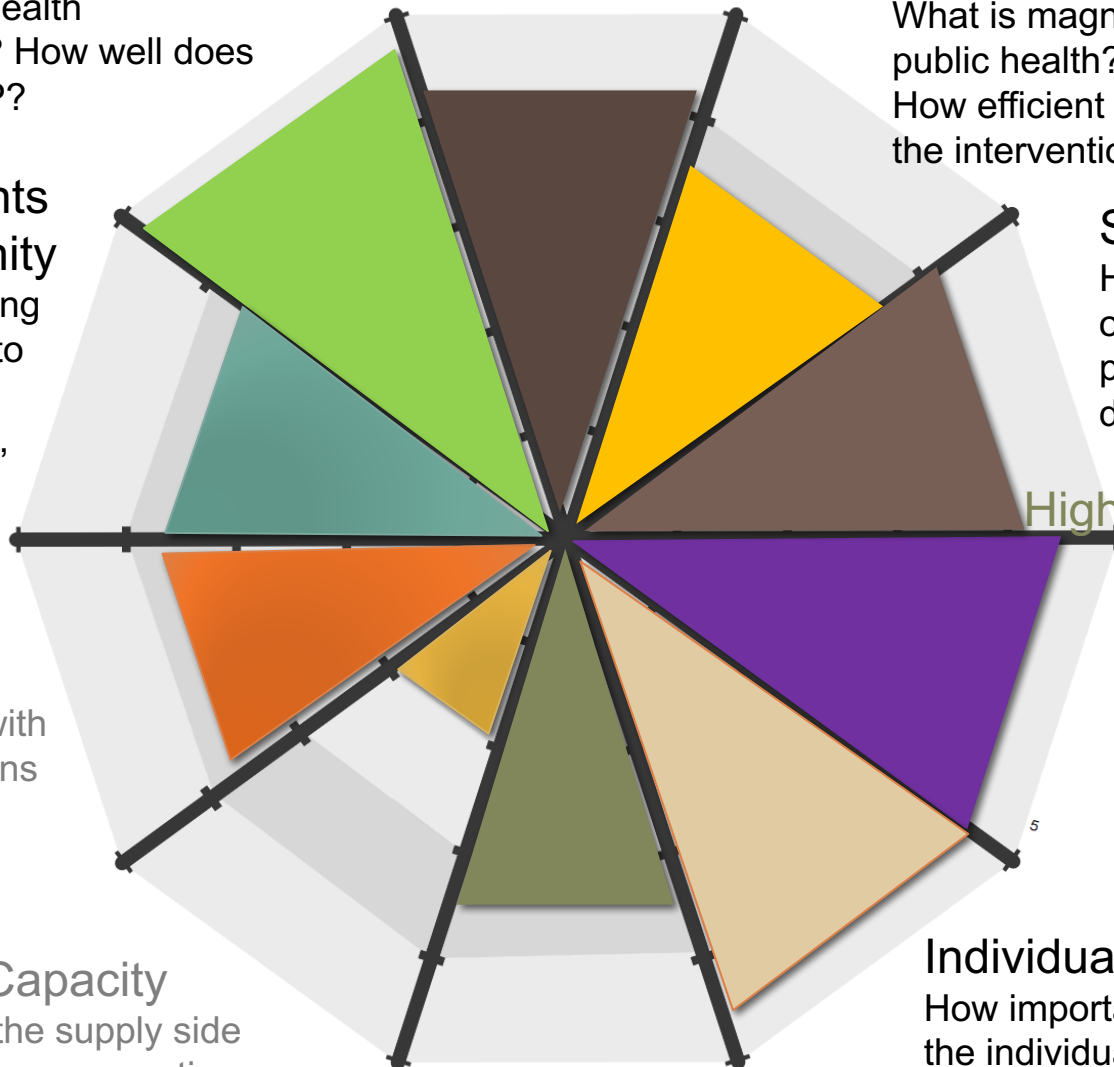
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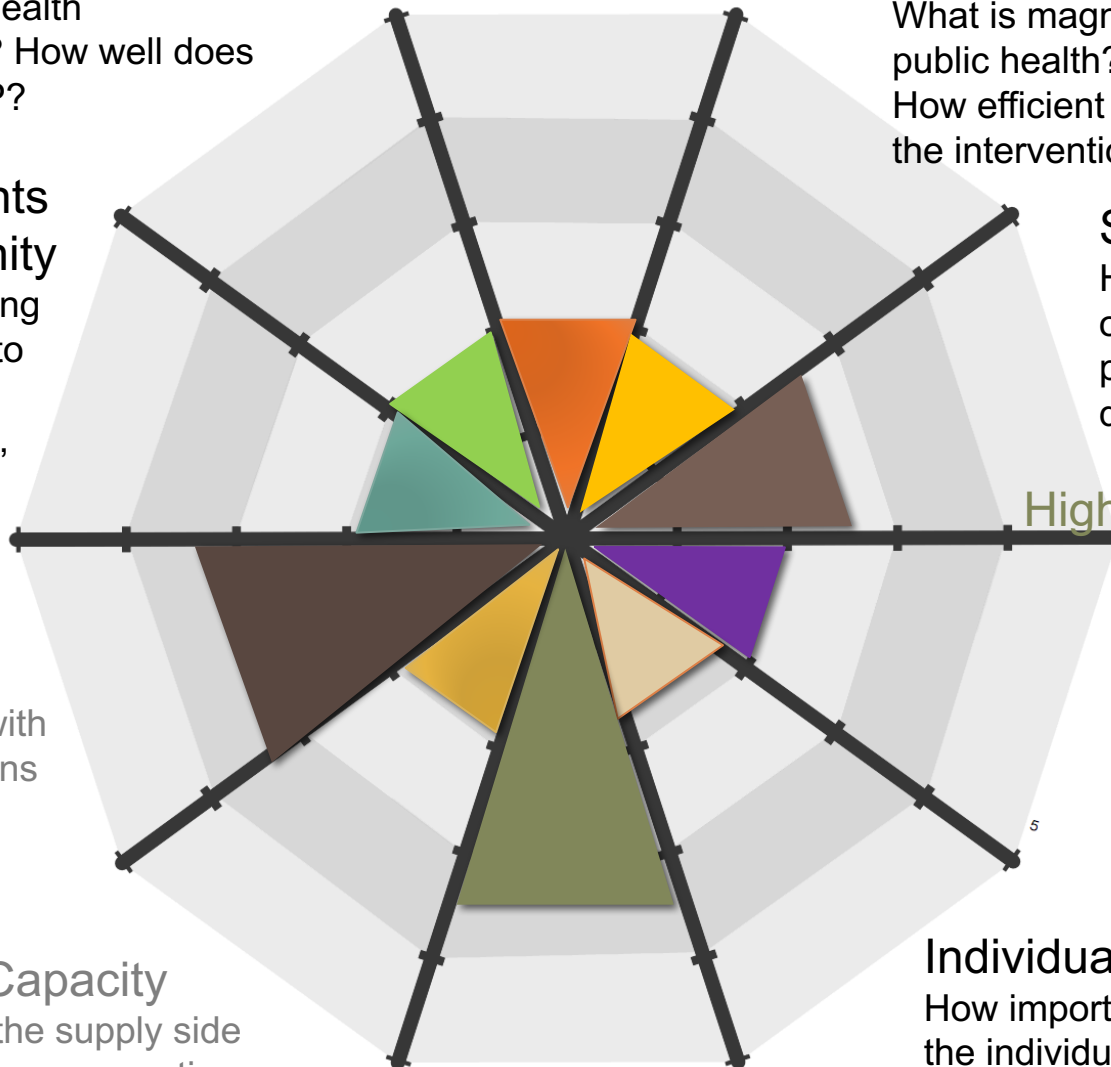
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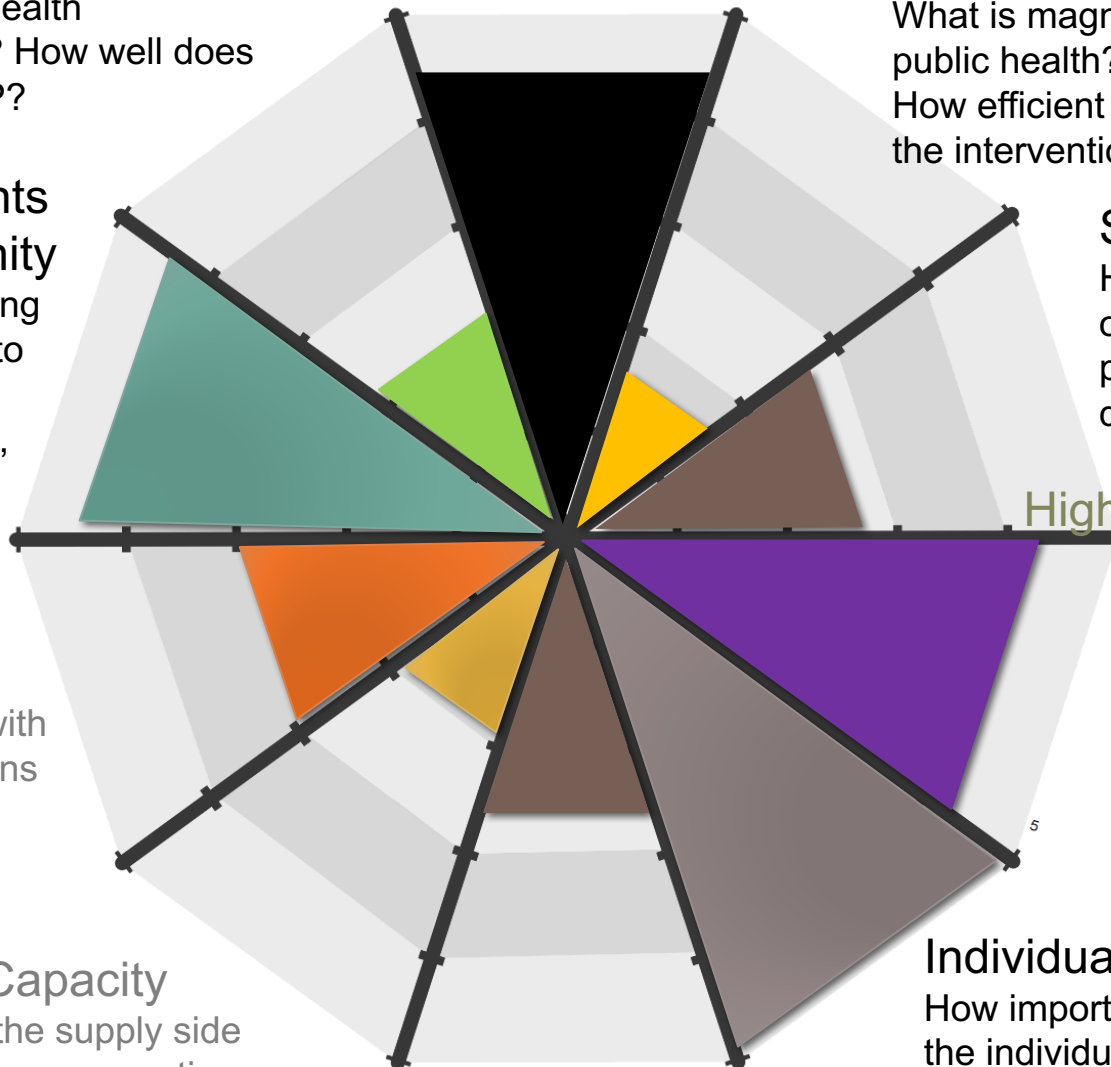
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Tough Choice & Trade-offs

- In some cases, there may be solutions to better align these commitments
- Often, avoiding tough tradeoffs will not be possible
- The important thing is to be able to justify the decisions taken, providing morally sound arguments for tradeoffs, and minimizing negative impacts wherever possible

Fair Processes and Procedures

- Given that reasonable people will disagree about which tradeoffs ought to be made, a commitment to fair processes can help navigate these tradeoffs and result in fairer and more legitimate decisions
- This includes:
 - participatory processes with relevant stakeholders
 - transparency about the decisions being made and the rationales for adopting them
 - accountability mechanisms to ensure the plan delivers on its promises,
 - opportunities for stakeholders to participate in and influence revisions to the plan

Fair Processes: Public Engagement

- Engagement not only builds trust but can provide a valuable source of information to feed into the priority-setting process - including on social values.
- Many approaches to public engagement
- Appropriate methods for engagement should depend on:
 - Context
 - Aims of engagement

Public Engagement: Rules of Thumb

- Ensuring participants have adequate information to meaningfully contribute
- Having authentic and balanced representation of key stakeholder groups
 - includes safeguarding against disproportionate influence of powerful interest groups and ensuring representation of the interests of marginalized and disenfranchised populations
- Attention to eliciting social values, not merely individual interests (not just what they want but why)
- Conducting engagement activities at relevant stages in the processes, allowing adequate time for input to inform decision-making

Ethics Analysis in Practice: Case Studies

Group Case: Novel Tx for MDR-TB

- Despite global declines in TB rates, MDR-TB on the rise
 - Up from 250,000 in 2009 to 480,000 in 2016.
- MDR-TB tends to co-travel and reinforce disadvantage
- Standard tx for MDR-TB requires a 20-month regimen with 2nd-line drugs
 - Daily injections for 8 months in “intensive period”, then 4 oral drug cocktail in continuation phase
- Toxicity is high, includes hearing loss, psychiatric effects, physical discomfort, elevated risks of cardiac and liver failure
- >50% complete regimen
- In South Africa, major gaps between diagnosis and tx initiation (only 41%)

Source: Derek J. Sloan, Joseph M. Lewis; Management of multidrug-resistant TB: novel treatments and their expansion to low resource settings. *Trans R Soc Trop Med Hyg* 2016; 110 (3): 163-172. doi: 10.1093/trstmh/trv107

Group Case: Novel Tx for MDR-TB

- Novel MDR-TB regimens with 6 or 9 month regimens in pipeline (Phase IIb and III)
- May improve cure rates, shorten treatment duration - awaiting more data on toxicity (including in PLWHIV)
- Likely to increase treatment costs compared to current standard
 - In UK, a 24-week course of bedaquiline is £18,700 (US\$ 28,400)
 - But may be cost-effective when downstream benefits of improved TB control are also considered – plus other social and economic benefits

Source: Derek J. Sloan, Joseph M. Lewis; Management of multidrug-resistant TB: novel treatments and their expansion to low resource settings. *Trans R Soc Trop Med Hyg* 2016; 110 (3): 163-172. doi: 10.1093/trstmh/trv107

A Framework for A Single Intervention

- **Impacts on Individual Wellbeing (+/-)**

- What positive impacts does the intervention provide to those who receive it?
- What negative outcomes may occur if this intervention is not covered?
- Are there any groups of individuals who are likely to have adverse reactions to or complications from this intervention, even if most will benefit from it?

- **Population Health Gains**

- How well does this intervention support high-priority public health goals and objectives?
- What, if any, negative population health consequences could arise if the intervention is not provided?

A Framework for A Single Intervention

- **Equity**

- Does the intervention promote equity and/or address disparities?
 - Will it help meet health needs for a group that is somehow worse-off, disadvantaged, or in greater need?
- Is the intervention likely to work comparatively well for all those affected by the health condition, or will it work better or worse for certain sub-groups of the affected population?
 - How are the benefits (or harms) distributed? Who wins/who loses?

- **Efficiency and Affordability**

- Does this intervention represent a good value for money?
- How much would adoption of this intervention affect the overall budget for health?
 - If adopted, what other services might not get covered? How does this intervention perform across all ethics considerations as compared to other services that could be displaced?

A Framework for A Single Intervention

- **Respect and Dignity**

- Does the intervention address or protect against any sources of social stigma or afflictions that would be damaging to one's dignity?
- How well does this intervention align with the cultural or religious beliefs of those to whom it will be offered?
- Does the intervention have the power to change the way a health condition is viewed socially or change perceptions of a class of people most often associated with a particular health condition?

- **Respect for Clinician Judgment**

- How might restricting coverage of this intervention negatively affect providers' ability to deliver care?
- How might coverage decisions impact provider-patient relationships?
- Is this intervention endorsed by relevant communities of practice?

A Framework for A Single Intervention

- **Evidence**

- What evidence exists to inform assessment for each of these considerations? How robust is that evidence? Can reliable conclusions be drawn from the current sources of information?
- Where there are gaps, what kinds of evidence should be pursued to inform the assessment?
- Which, if any, indicators should be collected routinely in order to inform ongoing coverage decisions?

- **Fair Processes and Procedures**

- Whose interests are most affected by the decision to include or exclude this intervention? Who are the relevant stakeholders?
- Whose interests are most affected by the decision to include or exclude this intervention? Who are the relevant stakeholders?
- How, when, and for which considerations should these stakeholder be included in the ethics assessment?

Group Case:

PrEP for HIV Prevention among Sex Workers

- PrEP a daily pill that has been shown to reduce HIV infection by ~90% when taken as directed by those at-risk
 - High-quality evidence strongly supports use of PrEP by any person at substantial risk of acquiring HIV infection
 - Oral PrEP has an excellent safety profile
- Risk of drug resistance is low
 - Occurred in ~1 in 1000 PrEP users in clinical trials, almost exclusively among people who already had acute undetected HIV infection when they started PrEP. HIV testing before PrEP can help further reduce drug resistance
- Offering PrEP is expected to be cost-effective where the incidence of HIV is greater than 3 per 100 person years
 - It not only averts costs associate with HIV infection for PrEP users, but could produce cost saving by reducing community viral load – averting future infections among partners

Group Case:

PrEP for HIV Prevention among Sex Workers

- Sex workers are highly vulnerable to HIV and STI, with high incidence and prevalence
 - Prevalence as high as 71.8% among FSW in Johannesburg
 - ~6% of new HIV infection in S. Africa were linked to sex work
- Sex workers are also highly marginalized
 - Many enter sex work due to extreme poverty
 - Sex workers face higher rates of violence, murder, and discrimination; Sex work is criminalized in
- A major benefit of PrEP is that it puts prevention in the hands of those at-risk, getting around challenges negotiating condom use with partners
 - Especially important for sex workers also are paid “risk premiums” for condomless sex

Group Case:

PrEP for HIV Prevention among Sex Workers

- As of September 2015, WHO recommends that people at substantial risk of HIV infection should be offered PrEP as part of a comprehensive prevention package.
- In South Africa, the 2016 National Sex Worker HIV Plan recommends PrEP for HIV negative sex workers as part of combination HIV prevention
- Yet some oppose provision of PrEP to sex workers on religious or moral grounds – raising questions about how well this approach coheres with social values

- Should PrEP be expanded to cover all HIV- sex workers?