

## Ethics Framework for Case Analyses

Below you will find a set of ethics considerations to use for your case discussions. They are meant to provide a framework of ethically relevant questions, though there may be additional relevant questions that are not included, and not all the considerations listed will apply in each case. At the start of case discussions, please select one member in your group to facilitate discussion of the questions below and one member to serve as the scribe to report back to the group. For each case, take about 5 minutes at the start to read carefully through the case materials. Then spend ~5 minutes on each category of questions. Allow 10 minutes at the end to discuss the group's overall recommendation.

### Impacts on Individual Wellbeing

What positive impacts does the intervention provide to those who receive it?

- What kinds of health gains are associated with the intervention and how likely are they?
- How large and/or important are these health gains for those who will experience them?
  - Is there a subset of people who are more likely to experience greater benefits from the intervention?
- Will these health gains have other positive effects on wellbeing beyond health?

What negative outcomes may occur if this intervention is not covered?

- How likely are these bad outcomes?
- How severe are these outcomes?
- How long will they impact the wellbeing of those affected?
  - Is there a subset of people who may be more likely to experience severe and/or prolonged adverse outcomes if the 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? (e.g., patients with co-morbidities where there are foreseeable adverse drug interactions; patients with a particular genetic marker that would provide a contraindication)

- What can be done to avoid harms among these patients? What could be offered as an alternative intervention?

### Population Health Gains

How well does this intervention support high-priority public health goals and objectives?

- Will this intervention reduce a high disease burden among the population? How significant are the likely impacts?
- Will there be additional health benefits for those not directly receiving the intervention? Are there positive health externalities?
- How durable are the impacts of the intervention? (e.g., a vaccine that will offer lifelong protection for the immunized cohort vs. an intervention that must be given continuously to sustain impact)

What, if any, negative population health consequences could arise if the intervention is not provided?

### Equity

How well does this intervention align with equity objectives?

- Does the intervention under consideration serve populations that are disadvantaged in one or more dimension of their wellbeing? Does it help address disparities between groups, such as by income, gender, geographic location, age, education, etc.?
  - If so, in what ways?
- Does the intervention under consideration serve populations that are already advantaged? Will coverage of these services exacerbate inequities across the population?
  - If so, in what ways?

- 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?
  - If it works better for some sub-groups, does it tend to favor the comparatively advantaged, or those who are most disadvantaged?
  - If it will not work well or potentially cause harms for certain subgroups, what if any alternatives are (or should) be made available?

### **Efficiency and Affordability**

Does this intervention represent a good value for money?

- How costly is the intervention compared to the associated gains in wellbeing?
- How does the cost-benefit compare to other available interventions for realizing these improvements in wellbeing?

How much would adoption of this intervention affect the overall budget for health?

- If limited resources are used to cover this intervention, what other services might not get covered? What is the opportunity cost of coverage – and how does this intervention perform across these ethics considerations as compared to other services that could be displaced?
- Might this intervention, even if costly and/or beyond the cost-effectiveness threshold, still be affordable and potentially good value for money (e.g. if it offers relief to a small number affected by rare conditions who have few or no alternatives)?

### **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?
  - Does the intervention offer more privacy for those who may face social stigma?
  - Does the intervention offer a cure for a socially stigmatized condition?
  - Does the intervention enable those experiencing the condition to manage their health state with more dignity?
- How well does this intervention align with the cultural or religious beliefs of those to whom it will be offered?
  - Is there something about this intervention that would be unacceptable to certain religious or ethnic groups?
  - Is this intervention more respectful of cultural or religious norms as compared to alternative options?
- 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?
- Does this intervention have the potential to address stigma or social bases of disrespect for a class of people, not just for those directly benefiting from it?
- Does the inclusion or exclusion of this intervention meaningfully impact people's ability to take an active role in decision-making for their care, to work with their providers to get care that most closely aligns with their needs and preferences? (e.g., people may have strong preferences between invasive and non-invasive procedures, and may be willing to make tradeoffs in health gains to avoid surgery)
  - How important is this consideration to patients in the context in which health services are being offered?

## **Respect for Clinician Judgment**

- How might restricting coverage of this intervention negatively affect care providers' ability to exercise their discretion in delivering appropriate care? How stringent are these limitations? Are the restrictions reasonable and justifiable?
- Are there specific ways in which not covering this intervention might negatively impact the provider-patient relationship by limited care decisions? (e.g., if public providers are unable to offer something that is widely covered by private insurers, could that lead to distrust between patients and providers – particularly in cases where many doctors work in both public and private clinics?)
- Does the community of practice (e.g., medical associations, international and national clinical guidelines) support adoption of this intervention?
  - If so, is this intervention the best among available options for the local context, taking into consideration affordability & efficiency, health system capacity, and training level of providers?
  - If this intervention is not supported by evidence-based practice guidelines (or even recommended against), yet remains common practice among care providers, what if anything can and should be done to engage providers advocating for it?

## **Evidence-informed decision-making and evidence generation**

- 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?
- How, when, and for which considerations should these stakeholder be included in the ethics assessment?