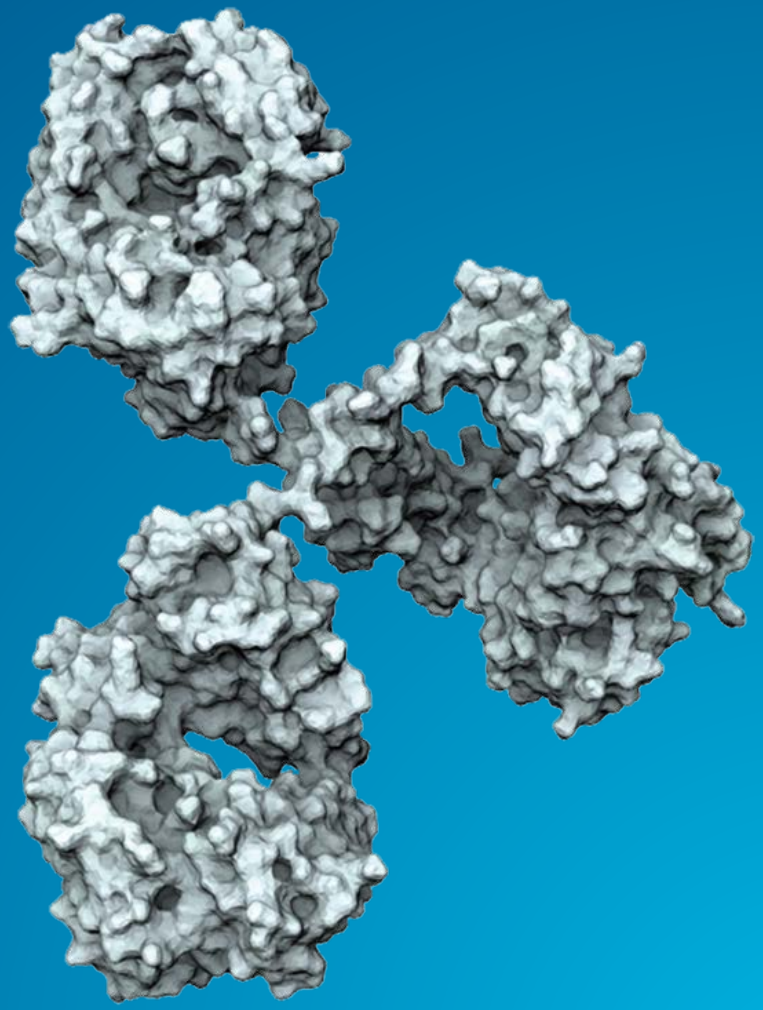
Translating **science** into **global** health impact

Enabling equitable and affordable global access to monoclonal antibodies for COVID-19 treatment



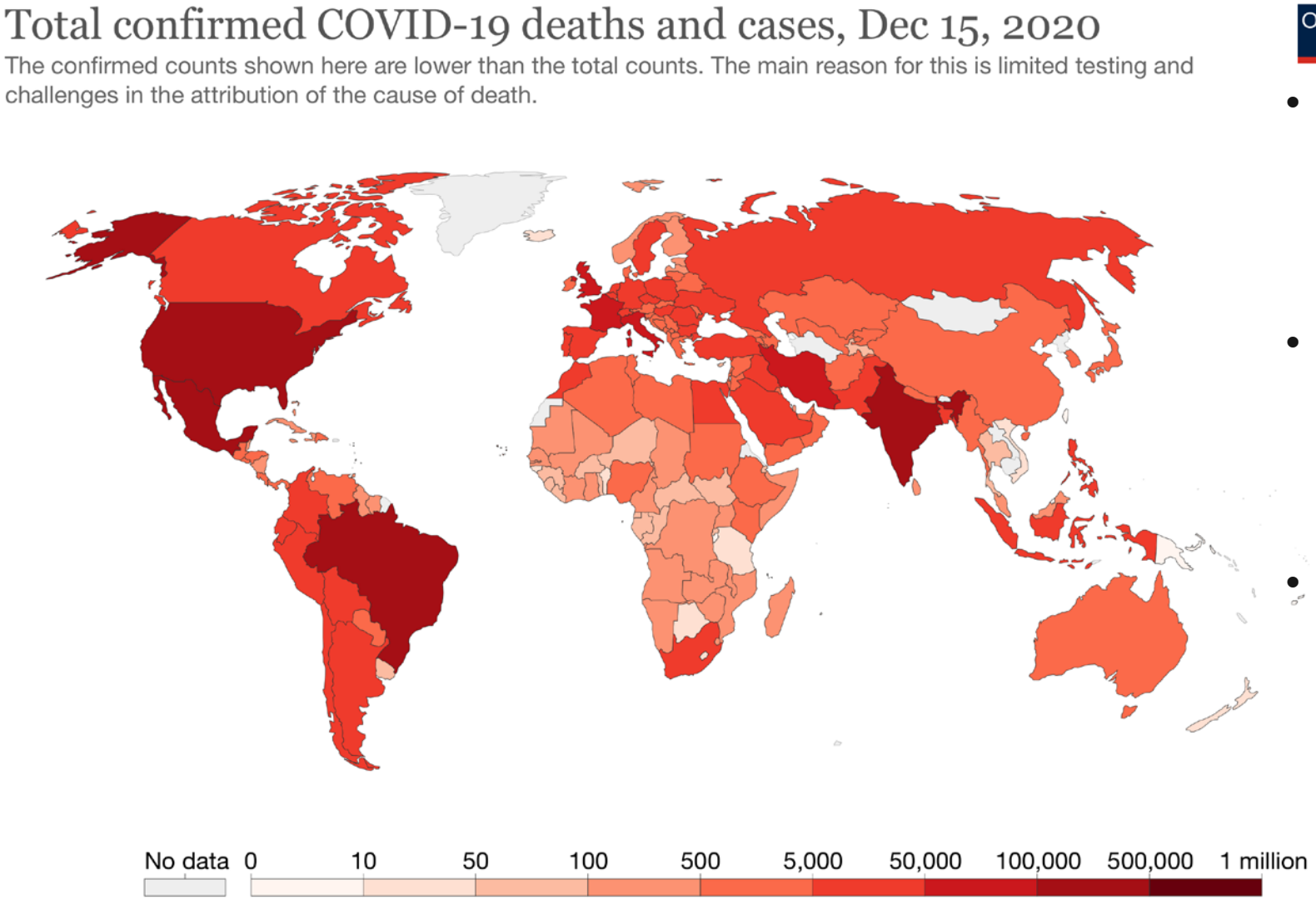
Mark Feinberg, MD, PhD

IAVI

Workshop on Allocation of COVID-19 Monoclonal Antibody Therapies and Other Novel Therapeutics
National Academies

December 17, 2020

By definition, a pandemic is a *global* threat



Our World in Data

- The advent of efficacious vaccines is a tremendous advance but these are projected to have limited near-term availability in low and many middle income countries. If so, the impact of the pandemic will persist in lower income countries
- Most efforts of address COVID-19 treatment needs in LMICs have focused on "repurposing" older, now inexpensive drugs. With the notable exception of dexamethasone, all of these have shown to be inefficacious.
- Innovative, more efficacious and more complex/expensive treatments will likely reach LMICs last, if at all

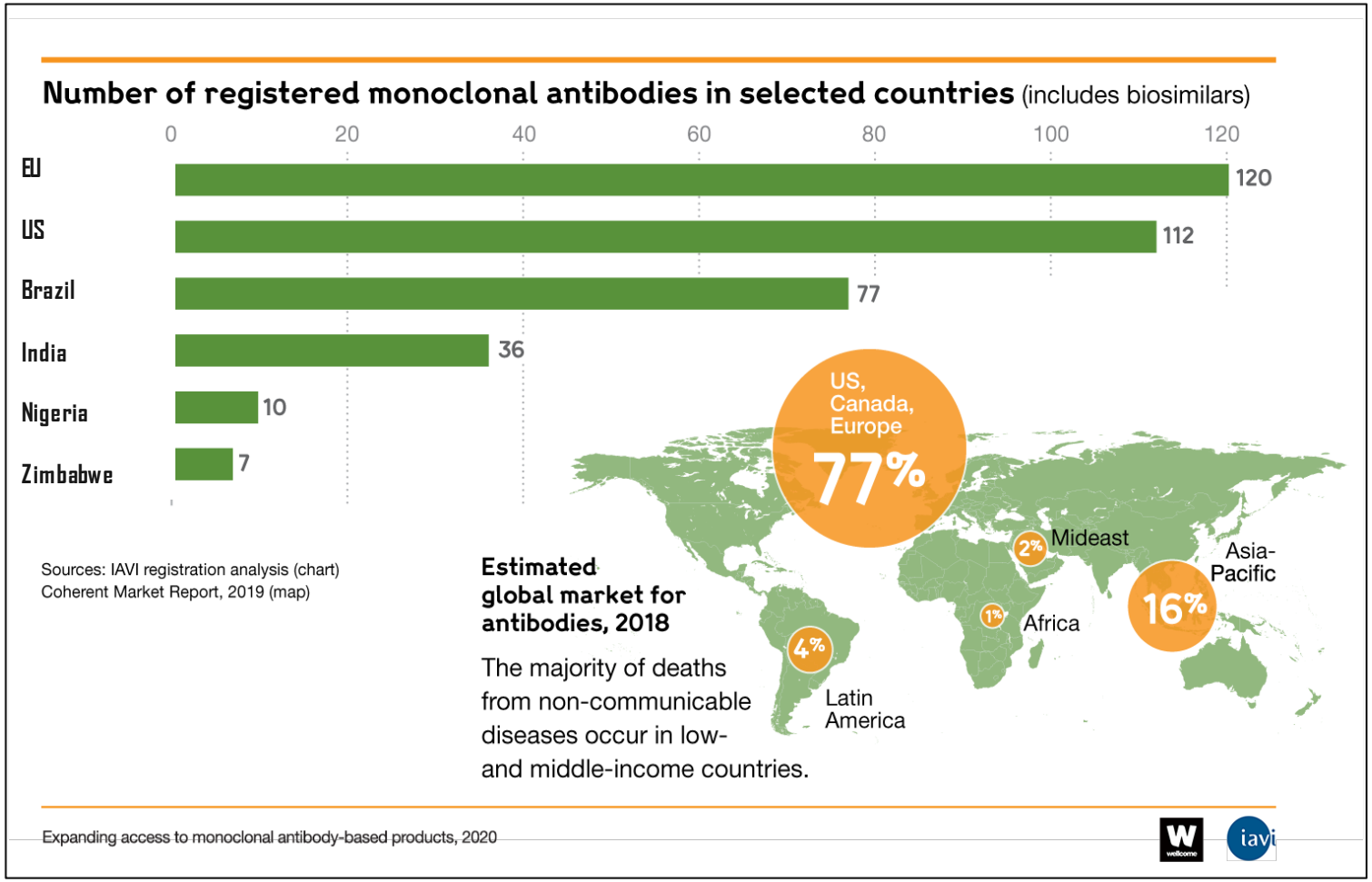
Expanding Access to Monoclonal Antibody-based Products: A Global Call to Action

IAVI-authored, Wellcome-commissioned call to action (published 10 August 2020)

- Analyses of the **gaps and opportunities** for global access to antibodies for all diseases, with a focus on LMICs
- Formulate a **series of recommended actions** to expand global access to antibodies
- **Comes at a critical time**: the pandemic has triggered unprecedented collaboration on mAbs to prevent and treat COVID-19

Available at iavi.org and wellcome.org/reports/expanding-access-monoclonal-antibodies

Monoclonal Antibodies (mAbs) have revolutionized treatment for many diseases, but global access is severely limited



Access gap is expected to widen as the proportion of antibodies in product pipelines continues to increase

Lack of **availability** and **affordability of mAbs in LMICs**

- *limited awareness of the health and economic value*
- *Unclear regulatory processes with limited capabilities*
- *Unclear market size*
- *Process for WHO-prequalification in early stages*
- *Lack of donor-funded procurement mechanisms*
- *Limited business and partnership models with affordable pricing frameworks*

"As the COVID-19 pandemic has shown, no country is immune to the threat posed by emerging infectious diseases. If monoclonal antibodies prove to be effective for COVID-19, ensuring prompt, equitable and affordable global access to these products, as well as others, will be imperative."

IAVI-Wellcome, Expanding Access to Monoclonal Antibody-Based Products: A Global Call to Action, 2020

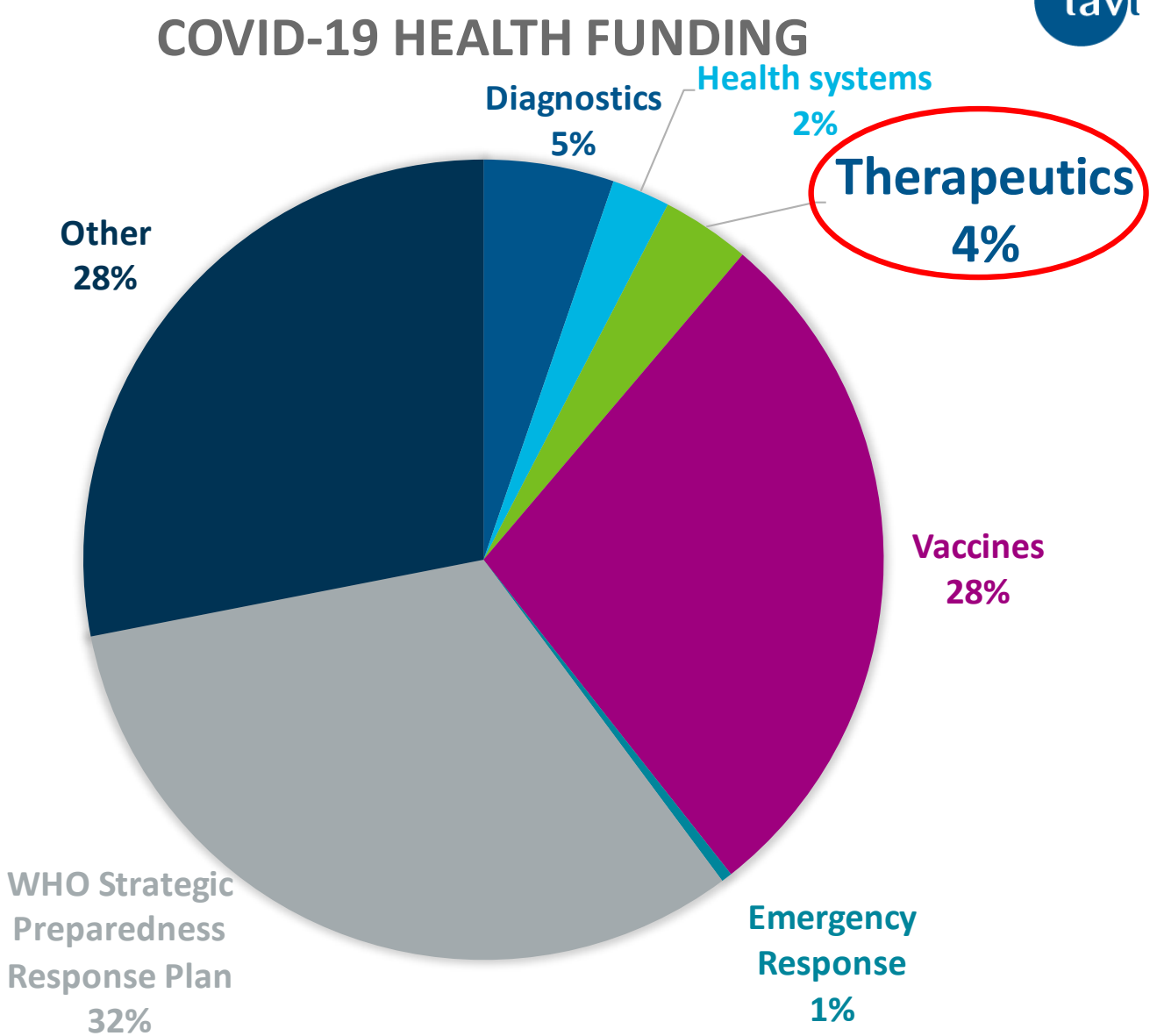
Current barriers to equitable global access to COVID-19 mAbs

- **Product profiles** are currently not amenable to global scale up:
  - High doses utilized in available products
  - Requirement for IV infusion
  - Cold chain
- **Delivery**:
  - Systems for prompt diagnosis and linkage treatment must be developed (given mAb efficacy in earlier, but not more advanced, disease)
- **Affordability**:
  - Cost of mAbs (exacerbated by high doses used)
  - Cost of administration
- **Limited or slow availability** in LMICs:
  - Early supply committed to the US
  - Scale of manufacturing not nearly sufficient to meet global demand (especially given high doses currently required and potential need for more than one mAb)

Investment in COVID-19 therapeutics is lagging

ACT Accelerator Therapeutics Pillar, *revised targets and progress toward goals*

- Target of US $6.6 B through end-2021 (initial projected need almost twice this)
- To date, only $460 M has been raised (of which only ~$150 M have been allocated to increasing mAb supply [but not other needs])
- *Gap of ~$6.1 B of which $750 M is needed "urgently"*



Source: Act Accelerator: Urgent Priorities and Financing Needs, 10 Nov 2020

Source: Economist Intelligence Unit, COVID Health Funding Tracker, https://covidfunding.eiu.com/

Key principles for supporting access to COVID mAbs in LMICs

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1 Product profiles that support uptake in resource-limited settings

Subcutaneous, thermostable formulations to enable administration in range of settings. Fixed dose, single administration to facilitate uptake

2 Affordability

Dose sparing to reduce cost of goods. Leveraging innovation & low-cost manufacturing strategies to reduce costs of production. Pricing strategies that support global access.

3 Alternative business models

Innovative partnership & licensing strategies to catalyze access across LMIC settings

4 Scale up for global supply

Scale up & distribution strategies that are equitable and ensure that supply meets global demand.

5 Strategic clinical & regulatory approaches

Global implementation of clinical trials and use of harmonized regulatory pathways to support timely registration in LMICs.

6 Investment in market preparedness

Collaborative mechanisms to support financing & procurement. Investment in market understanding, delivery pathways and infrastructure to support widespread deployment.

What needs to change to enable equitable access to COVID-19 mAbs?

- Greater political will to champion, and funding to achieve, access to innovative COVID-19 therapeutics beyond wealthy countries
- Definition of an integrated public health response framework for pandemic control that prioritizes, but is not limited to, global access to COVID-19 vaccines
- Greater investment in advancing innovative R&D efforts to optimize product profiles necessary to ease implementation of COVID-19 mAbs in LMICs (which would also be beneficial in higher income countries as well)
- Product and business model innovation to achieve adequate and affordable supply
- Investments in strengthening healthcare delivery systems

Save the date:

Webinar: ***Global access pathways for monoclonal antibodies: Can COVID-19 pave the way?***

Sponsors: IAVI, UNITAID, and Wellcome Trust
Date: January 19, 2021

https://www.wellcomeevents.org/wellcome/frontend/xt/token.csp?token=QBcE34wP2kwOQVQ788g6572848199471