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Fixing the challenges in the diagnostic testing ecosystem post-COVID-19

Special Focus Dialogue

12th November 2020,1600-1700 CET

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Better Testing. Better Treatment.

Jodie Hoyos, Executive Director, Prevent Cancer Foundation

Dan Milner, Chief Medical Officer, American Society for Clinical Pathology

Susanne Munksted, Chief Precision Officer, Diaceutics

Moderated by

Shalini Jayasekar Zürn, Senior Advocacy Manager, Union for International Cancer Control (UICC)

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Fixing the challenges in the diagnostic testing ecosystem post-COVID-19

Susanne Munksted, Chief Precision Officer, Diaceutics

Diaceutics

Better Testing, Better Treatment

The dynamics at play in the delivery of test-dependent Precision Medicine therapies

Non-small cell lung cancer (NSCLC) reveals the complex dynamics at work today in Precision Medicine (PM), including:

- Delayed diagnosis
- New high-volume precision treatments
- Evolving understanding of disease
- Fragmented stakeholders
- Wasted and siloed investment
- Imperfect information flows
- The absence of a standard optimal approach to precision testing for all NSCLC patients

Global Impact

Our analysis suggests that the common pain points and practice gaps are evident in NSCLC in the US beleaguer precision testing globally

The advances in PM cancer care as illustrated by the US NSCLC landscape

Treatment

12 new targeted treatments have been approved during the past 2 decades for second- and first-line treatment options

48% **reduction** in disease progression for patients with access to single and combination immunotherapy

Testing

67% **of labs** in the US offering EGFR testing (the most established NSCLC companion biomarker) are now using an NGS method

14.5% **of tests** for patients who might otherwise miss out on treatment due to tumor sampling difficulties are now delivered by liquid biopsy tests

Biomarker

11.3% **of patients** with metastatic NSCLC were tested for PD-L1 expression prior to receiving nivolumab or pembrolizumab

50% **of the ~8800** oncologists comprising the main segment of HCPs treating patients with NSCLC tested at least one of their patients for PD-L1 expression

Diaceutics Data on File: Diaceutics' proprietary Global Diagnostic Index (GDI) unpublished data, 2020.

Real-world analysis of US NSCLC landscape illustrates the challenges in the clinical diagnostic testing ecosystem

4.5yrs

Today it can take **up to 4.5 years** for a biomarker to reach an 80% testing rate among patients

~80%

Today Pharma spend **~80%** of their PM educational investment on the predictive biomarker phase

40%

40% of all FDA approvals in 2018 were for Precision Medicines with **1000** potential therapies in late phase of development

30%

Up to **30%** of the value of a PM treatment is delivered by the diagnostic test

$5-7bn $$$

The NSCLC testing market is predicted to grow in value from **$5.3 to $7.4bn by 2025**

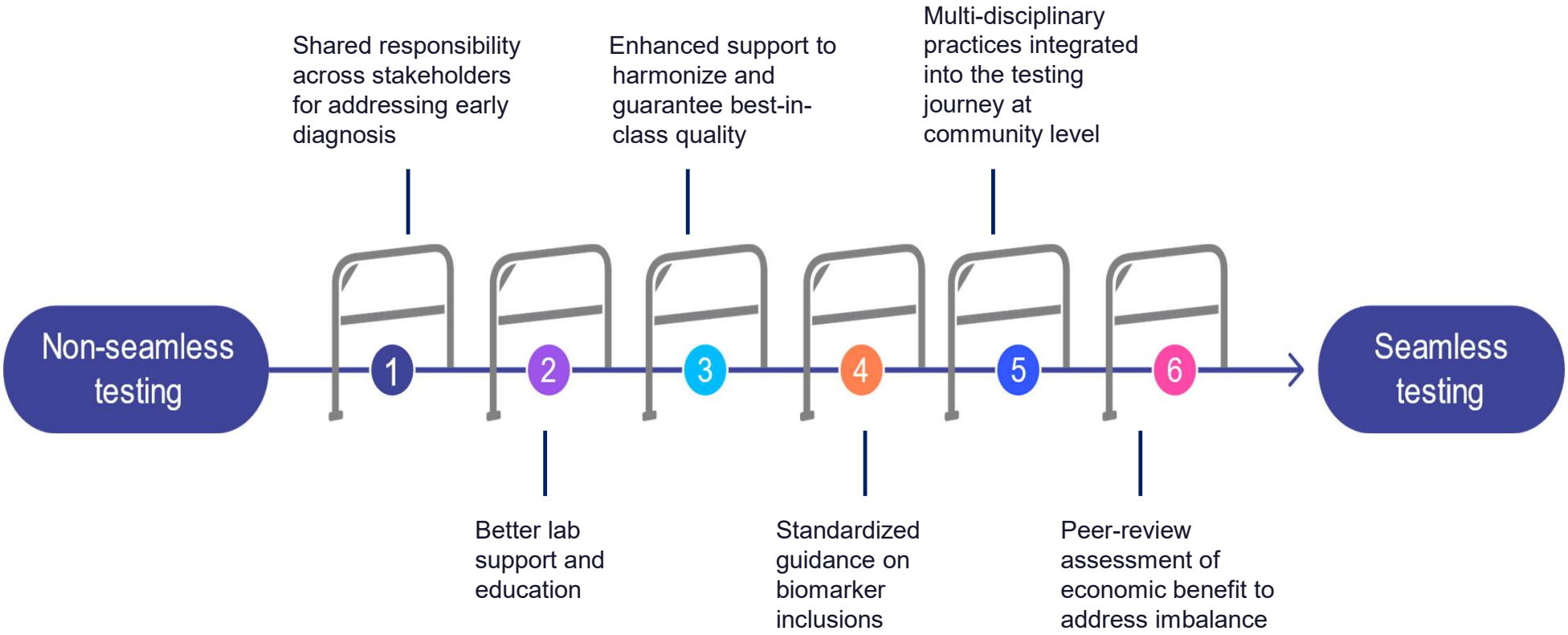
50%

Approximately **50%** of patients with NSCLC in the US currently do not receive appropriate testing at the right time **due to hurdles in the testing ecosystem**

As a result, the majority of NSCLC patients in the US today are still diagnosed in late stage (75%), with only 50% and 22% progressing to 2nd & 3rd-line therapy

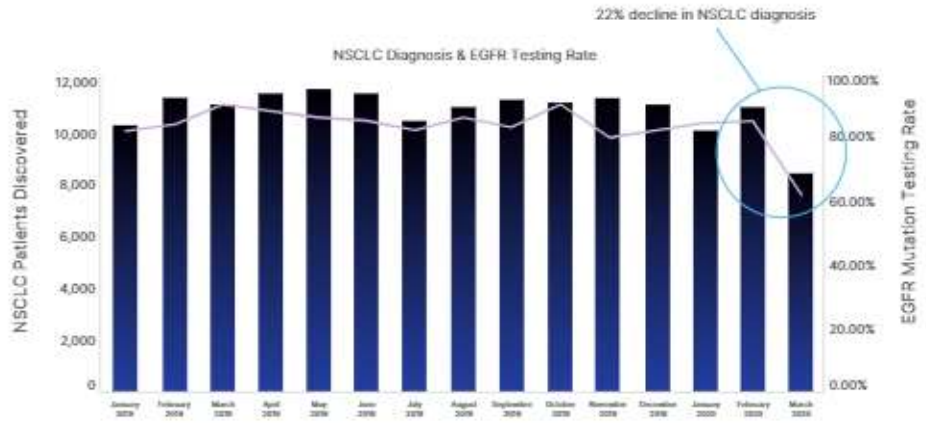
Diaceutics Data on File: Diaceutics' proprietary Global Diagnostic Index (GDI) unpublished data, 2020.

Recommendations to address hurdles in the US NSCLC landscape



Impact of COVID-19 on the NSCLC landscape: US and China data

Figure 6. Diaceutics' COVID-19 Oncology Tracker: Impact of COVID-19 on US NSCLC testing.[43]



EGFR=actionable biomarker in NSCLC; NSCLC=non–small cell lung cancer; US=United States

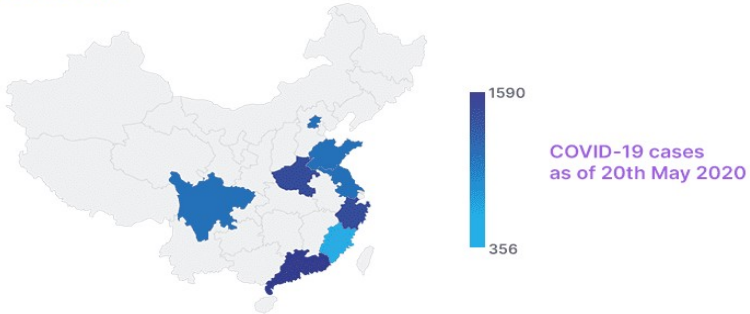
US

31%* decline

Cancer testing rates dropped as much as 31%* between Feb 2020 and March 2020 - setting the stage for a cancer chain reaction in 2021

*Non-small cell lung cancer testing rates

China



Number of COVID-19 cases reported in the 9 provinces covered

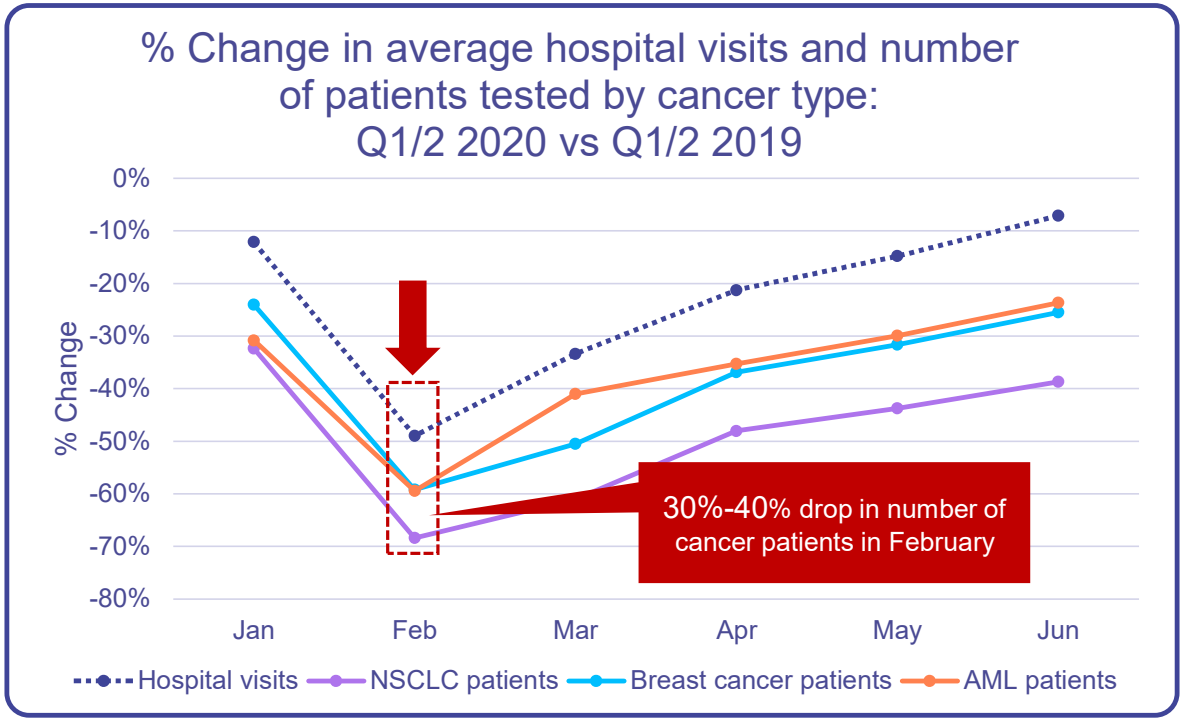
~40% decrease

At the peak of pandemic in Feb 2020, the ~40% drop in overall hospital visits corresponded to a drop in the number of cancer patients tested

A gradual recovery in hospital visits began in March 2020

Diaceutics Data on File: Diaceutics' proprietary Global Diagnostic Index (GDI) unpublished data, 2020.

COVID-19 impacted diagnosis of new cancer cases



Change of biomarker testing rates: March vs February 2020

NSCLC	
KRAS	-7%
EGFR	-13%
BRAF	-11%

CRC	
BRAF	-9%
MSI/MMR	-8%
RAS	-6%

AML	
FLT3	-12%
IDH1	-11%
IDH2	-12%

Change in number of newly diagnosed patients in March 2020 compared to February 2020

-31%

-14%

-12%

Source: National Health Commission and Diaceutics Data Lake

A collaborative solution to the broken clinical diagnostic testing ecosystem

- Collaboration with multiple stakeholders working together to solve the real-world testing challenges to ensure every patient gets the treatment they deserve
- Greater data insights from laboratories to enable efficient decision-making
- Collaboration at biomarker discovery stage to unlock purpose-built testing solutions to solve real-world challenges together
- Enhancing the tracking and monitoring of test quality to improve outcomes
- In-lab solutions for test standardization, training, tech support, regulatory support, and quality assessment

DXRX
The Diagnostic Network

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Thank you

Susanne Munksted, Chief Precision Officer, Diaceutics

Diaceutics

Better Testing, Better Treatment

Challenges in Cancer Screening during COVID-19

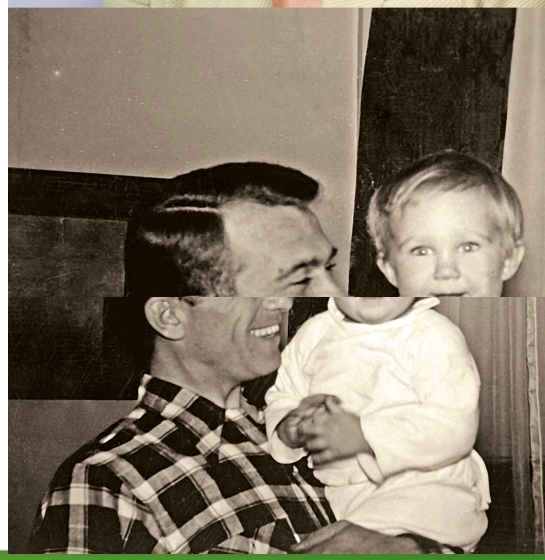
Jody Hoyos, Executive Vice President

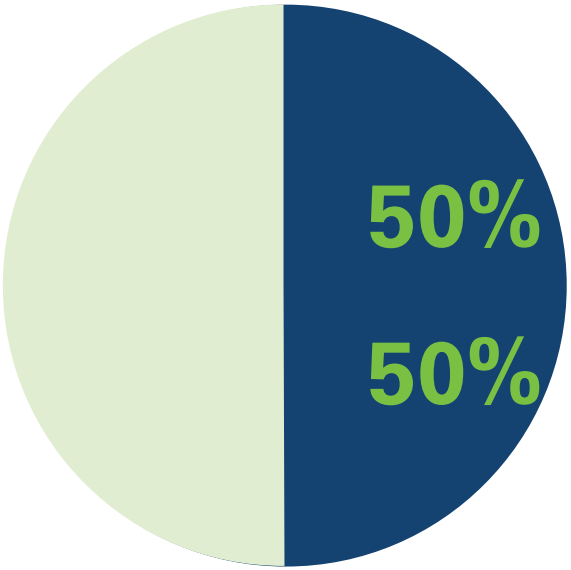
prevent cancer® FOUNDATION

preventcancer.org

Foundation history

- Founded in 1985 by Carolyn “Bo” Aldigé in memory of her father, Edward Perry Richardson.
- Back then, everyone was looking for the “magic bullet” that would cure cancer. Prevention was not the mainstream.
- The Prevent Cancer Foundation remains the only U.S.-based advocacy organization that focuses solely on cancer prevention and early detection.
- Through **research**, **education**, **outreach** and **advocacy** we have helped countless people avoid a cancer diagnosis or detect their cancer early enough to be successfully treated.



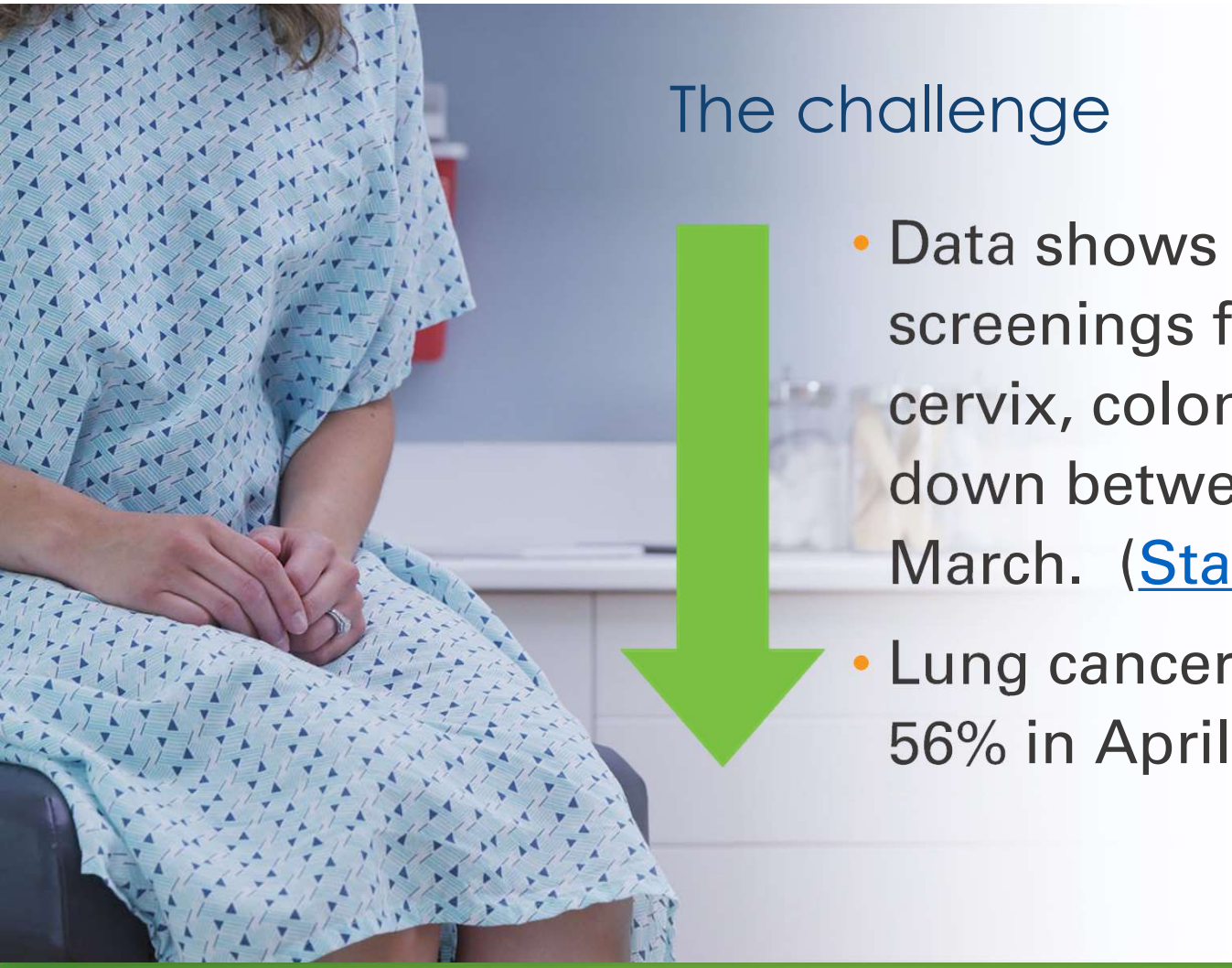


50% of cancer cases are preventable.

50% of cancer deaths are preventable.

Every year, 1.8 million Americans are diagnosed with cancer. More than 600,000 people die from these diseases each year.

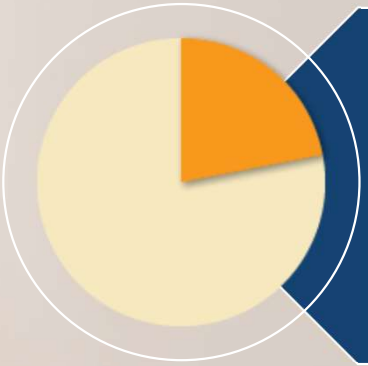
Imagine if all cancers could be prevented or detected early enough to be successfully treated.



The challenge

- Data shows that appointments for screenings for cancers of the cervix, colon, and breast were down between 86% and 94% in March. (Stat News)
- Lung cancer screenings decreased 56% in April. (Avalere Health)

HIGHLIGHTS FROM MAY 2020 PREVENT CANCER SURVEY:



22% said their doctor's or dentist's office was open, but they wanted to minimize their risk of exposure to COVID-19

24% expect their provider to contact them to reschedule missed appointments

preventcancer.org/backonthebooks

prevent cancer® FOUNDATION

Addressing the Challenges-Leveraging Community

- Reaching people through trusted communities
  - Churches and faith-based institutions
  - Gaming communities-Prevent Cancer Foundation and Awesome Games Done Quick

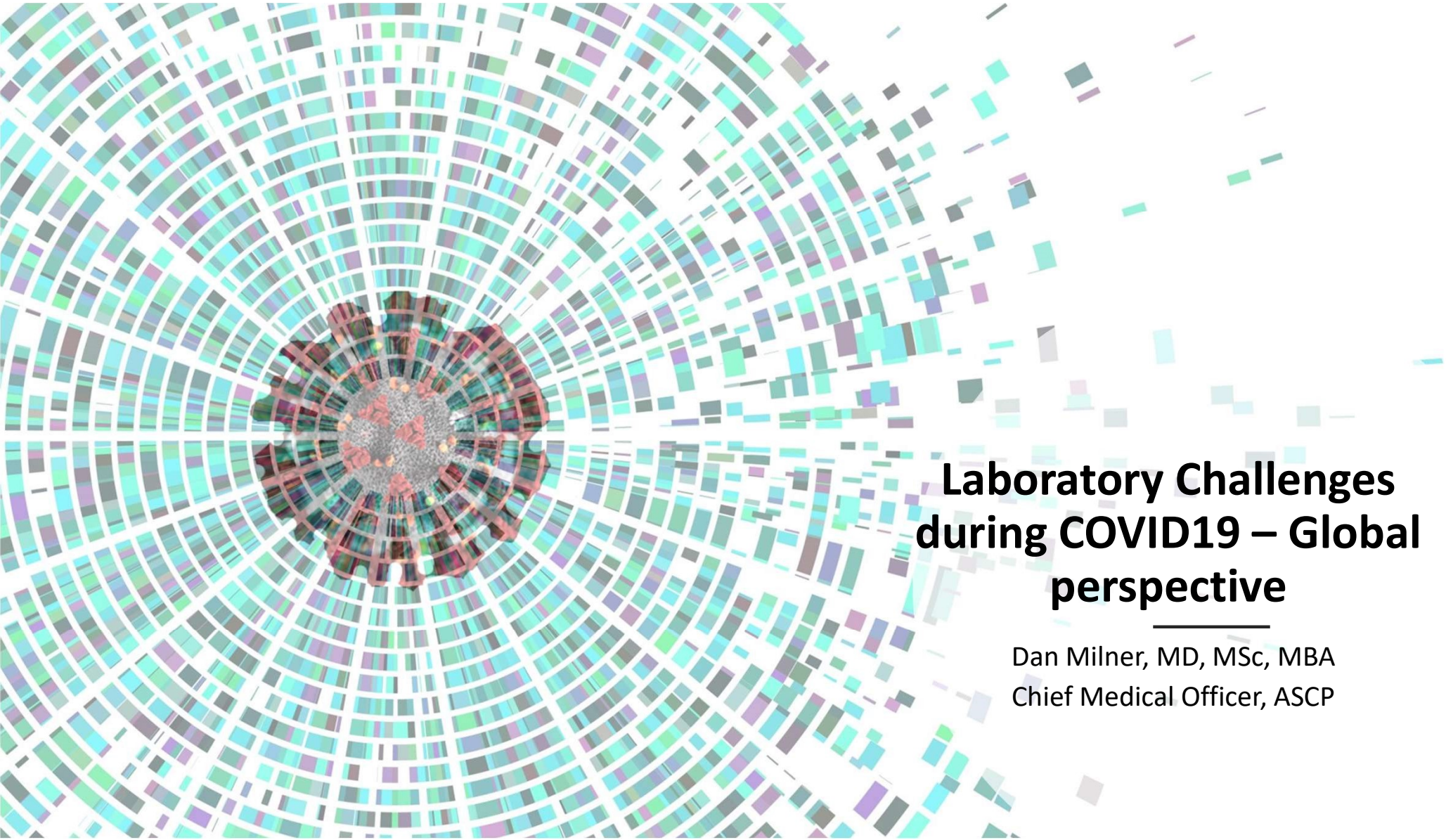
Invite community members to be advisors in outreach efforts

Addressing the Challenges-Leveraging Technology

- Project Echo-the ECHO Model™ connects groups of community providers with specialists at centers of excellence in regular real-time collaborative sessions.
  - MD Anderson Cancer Center program for cervical cancer screening training and case review in medically underserved areas of Texas and Mozambique

Addressing the Challenges-Leveraging Technology

- iBreast-handheld, radiation-free breast screening device that detects abnormal breast lumps as small as five millimeters that can be early signs of breast cancer. It allows health care workers to perform breast exams anywhere, determining within minutes who needs further testing or treatment.
  - Drs. Victoria Mango and Peter Kingham of Memorial Sloan Kettering Cancer Center clinical trial to evaluate the effectiveness of a new low-cost breast cancer screening device in Nigeria, where mammograms can be hard to obtain due to the expense, lack of access and lack of basic resources, equipment and radiologists.
  - The iBreast Exam is the biggest innovation in early breast cancer detection since the mammogram was widely introduced in 1963—and has already been used to screen more than a quarter million women worldwide.



Laboratory Challenges during COVID19 – Global perspective

Dan Milner, MD, MSc, MBA
Chief Medical Officer, ASCP

The Global Laboratory Response



- The initial response of LMIC laboratories to COVID:
  - Awaiting guidance from WHO, CDC
  - Governments enacting restrictions before testing was available
- What did laboratories do?
  - Received rationed supplies for testing initially
  - Received partial orders for testing workflow
- Why?
  - Market priorities, low incidence

- Real challenges created by pandemic pressure:
  - Strained infrastructure
  - Pressure on governments to “act”
  - Demand for testing platforms in countries without
    - specimen transport networks
    - Tracking
    - logistical efficiency
  - Decimation of fragile economy through restrictions on movement and travel

Africa Survey – March 2020

53 laboratories from 10 countries responded

Rwanda

Uganda

Kenya

Ethiopia

Mozambique

Tanzania

Nigeria

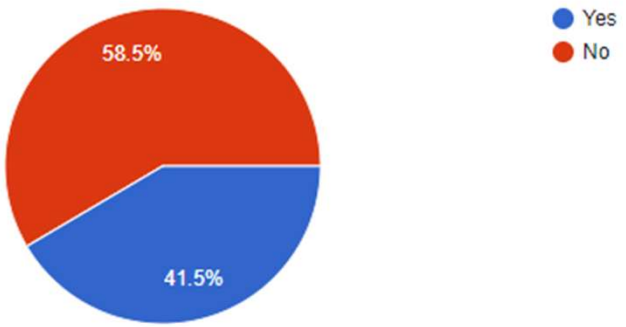
Madagascar

Malawi

South Africa

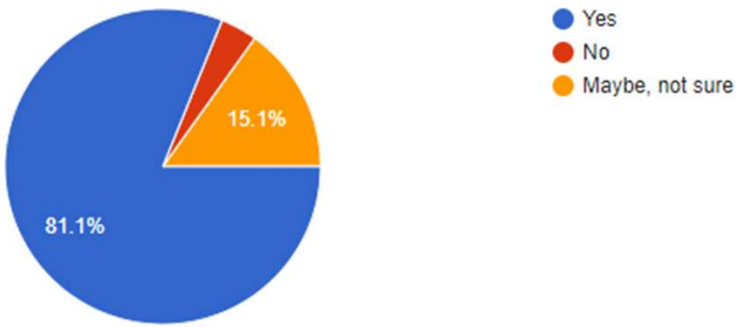
Do you currently have COVID19 testing available?

53 responses



Are you seeing or hearing about clinical cases that could be consistent with COVID19?

53 responses



Africa Dashboard– Oct 2020

Rwanda – 10,000 tests/day (7/27)

Uganda – total tests = 264,162 (7/28)

Kenya – 55,074 tests with 1109 + (5/22)

Ethiopia – 400,000 tests per month (8/2)

Mozambique – Results in 72 hours (9/2)

Tanzania – 652 tests with 509 + (5/19)

Nigeria – 2549 tests/day, 509K in total (9/28)

Madagascar – 304 confirmed (5/19)

Malawi – Received 38,000 test kits (7/23)

South Africa – 3,726,721 tests done (9/2)

African Development Bank bolsters Malawi's Covid-19 battle with $45.07 million support

July 24, 2020 Watipaso Mzungu -Nyasa Times 3 Comments

The African Development Bank (AfDB) is set to release $45.07 million to help boost the Malawi National COVID-19 Preparedness and Response Plan by financing the government's response to the health, social and economic impacts of the COVID-19 pandemic.

The Minister of Finance Felix Mlusu confirmed the development with *Nyasa Times* in a telephone interview a short while ago.

The bank, through a statement issued on Thursday night and made available to *Nyasa Times*, says the package comprises a loan of $24.48 million, and a grant of $20.59 million as direct budget support, and complements an earlier sum of $8.9 million to six countries in the region, including Malawi, under the Bank's COVID-19 Response grants to the Southern African Development Community (SADC) countries last month.

The budget support int
Preparedness and Res
including government,

The Acting Bank Coun
to protect lives; strengt
jobs.

COVID-19: Uganda to benefit from sh36b AfDB funding

tgwambe@newvision.co.ug (Tracy Gwambe) 2020-07-01

Uganda is among the 12 African countries that will benefit from the $9.52m (over sh36b) that the African Development Fund (AfDB) has approved to enhance coordinated COVID-19 response.

Funding will also go toward the procurement of essential medical supplies, including testing kits and to train health workers in East Africa and the Horn, and in Comoros, according to a statement from AfDB.

The beneficiary countries are; Uganda, Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Somalia, Kenya, Rwanda, South Sudan, Sudan, and Tanzania.

"The funds will be used to bolster health systems and disease surveillance, enhance infection prevention and control, and improve regional coordination," the AfDB statement said.

The grant, approved on June 26, is part of the $10 billion (sh38 trillion) COVID-19 Rapid Response Facility approved by the AfDB Board of Directors in April this year and complements the Bank's direct support to regional member countries across the continent.

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Global Numbers (Oct 4 2020)

Incidence Rates

Rwanda – 37.46 per 100,000

Uganda – 19.26 per 100,000

Kenya – 73.32 per 100,000

Ethiopia – 67.73 per 100,000

Mozambique – 28.95 per 100,000

Tanzania – 0.85 per 100,000

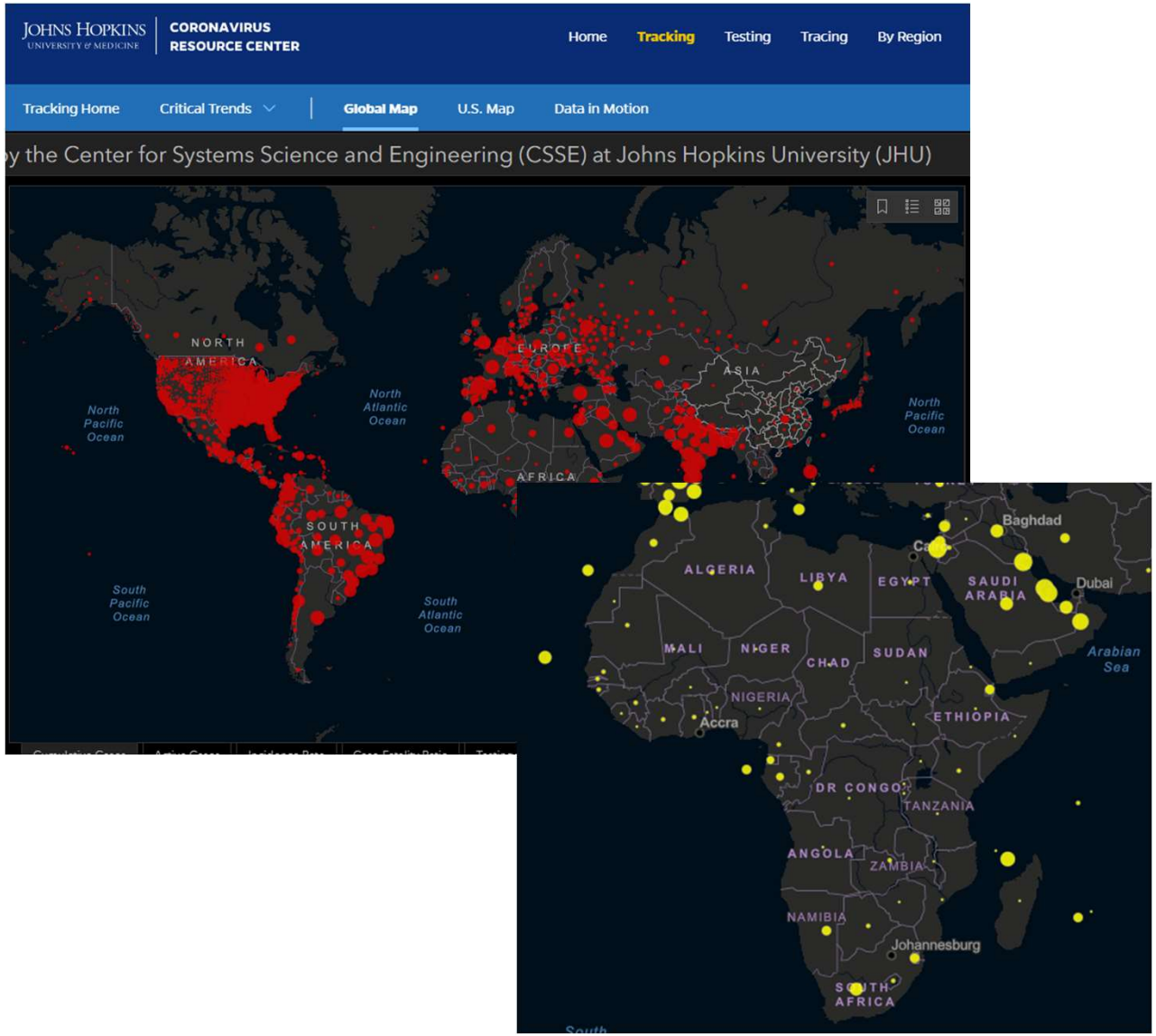
Nigeria – 28.76 per 100,000

Madagascar – 59.80 per 100,000

Malawi – 30.23 per 100,000

South Africa – 1146.06 per 100,000

US – > 2500 per 100,000



Impact on Diagnostics from COVID19

- In a follow up survey, 57% of laboratories reported affects on their other laboratory services (especially AP):
  - Surgeries cancelled, medical staff infected, other medical staff afraid to work
  - Patients afraid to go to hospital
  - Hospital mission switched purely to COVID19
  - Costs of labs increase, volume decreased, massive loss of revenue
  - Further delays in supply chain
  - Performing post-mortems without proper PPE or clinical data
  - around 80% to 90% reduction in the incoming volume of both cytology and biopsy specimens
- More than 90% reported adequate hand sanitizer and cleaning supplies and more than 85% require mask to work in the lab (and hospital) beginning as early as March

Global Cancer Burden

Cervical Cancer and Prostate Cancer have the highest incidence and mortality in developing nations with specific risk factors being:

-HIV positivity

-Low income/poverty

-Black African origin

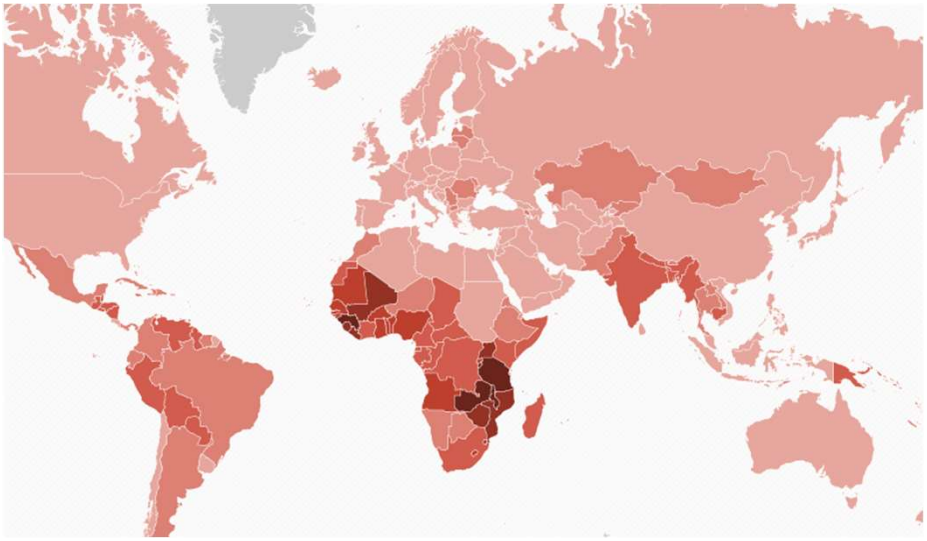
No infrastructure for screening prior to 2018 WHO Program for Cervical Cancer

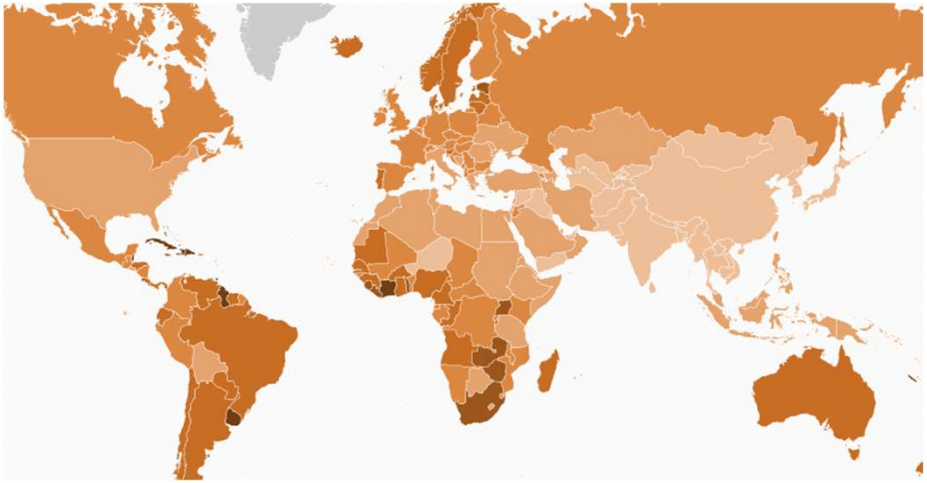
Blossoming cancer programs in LMICS began between 2010-2015

HIV testing/treatment tied to cervical cancer screening through PEPFAR funding

-Bush Institute received $90M from 2018 – 2020 to cervical cancer screening in HIV+ women in 10 countries

With the advent of COVID… all programs ceased to function





Global Cancer Burden

Incidence (above) and mortality (below) for all cancers:

-US and Australia – Skin Cancer and access to screening and diagnosis overestimate the impact of cancer relative to other countries

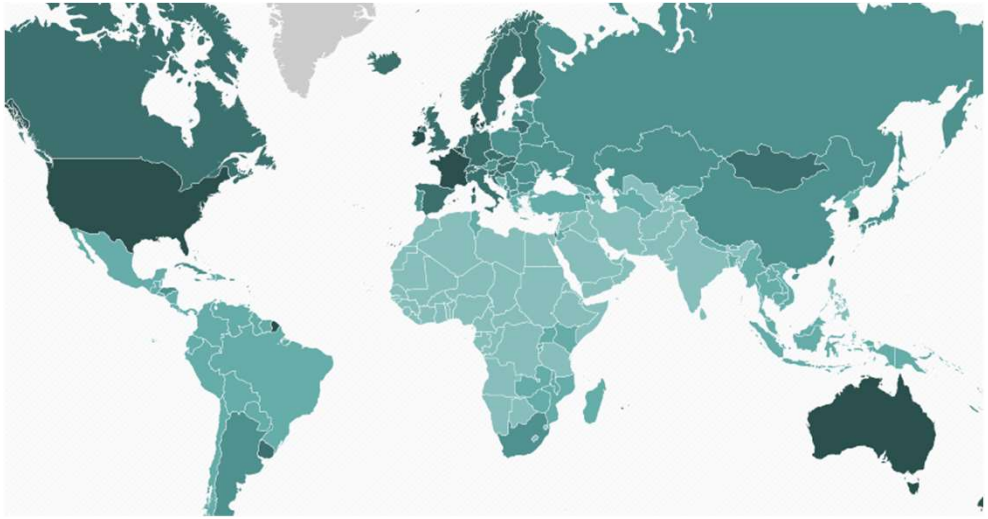
-A population of 1,000,000 people has, on average, 5,000 cancers per year (4500 to 5500)

-IF you are diagnosed with cancer in LMICs, you are much more likely to die (75%) than if you are in the US (35%).

-Lack of infrastructure for screening, diagnosis, and treatment underestimates the burden of cancer in LMICS

With the advent of COVID, what programs were functioning ceased as healthcare workers were task-shifted to COVID preparedness

-No biopsies, no treatments, no surgeries



Q&A session

Thank you

Union for International Cancer Control

31-33 Avenue Giuseppe Motta, 1202 Geneva, Switzerland

T. +41 (0)22 809 1811 F. +41 (0)22 809 1810
E. info@uicc.org www.uicc.org