Linking laboratory testing to clinical outcomes

February 8, 2024

Zhen Zhao, Weill Cornell Medicine, USA

QUALITY IN LABORATORY MEDICINE

The value of laboratory medicine to healthcare

- The single highest volume medical activity in healthcare (14 billion tests/year in the US)

Laboratory Medicine: A National Status Report, The Lewin Group, May 2008

Ducatman et al., *Acad Pathol*. 2022

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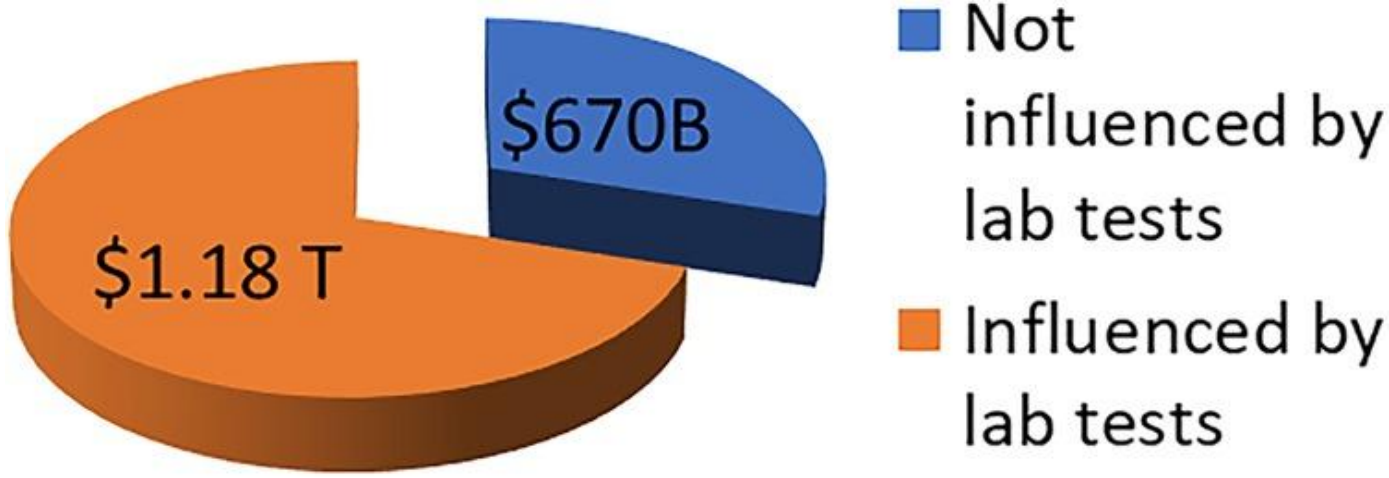
- Providing objective data about patient health

This recent report showed that 60% of the healthcare activities is influenced by the lab tests.

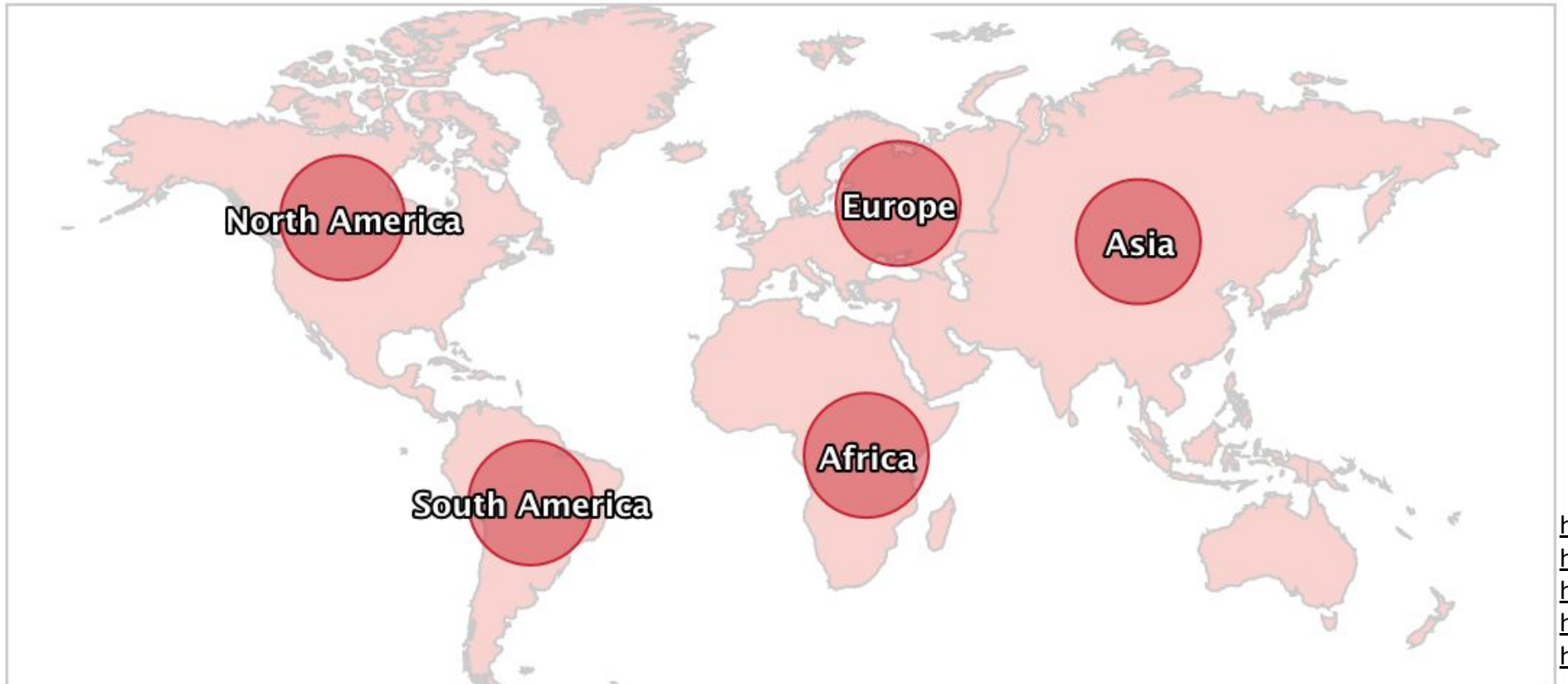


Laboratory Medicine: A National Status Report, The Lewin Group, May 2008

Ducatman et al., *Acad Pathol*. 2022

Clinical Laboratories Market Profile Overview

~ $200 billion	4.7%-5.8%	~ $300 billion
Market size 2021	growth rate	Revenue forecast 2028



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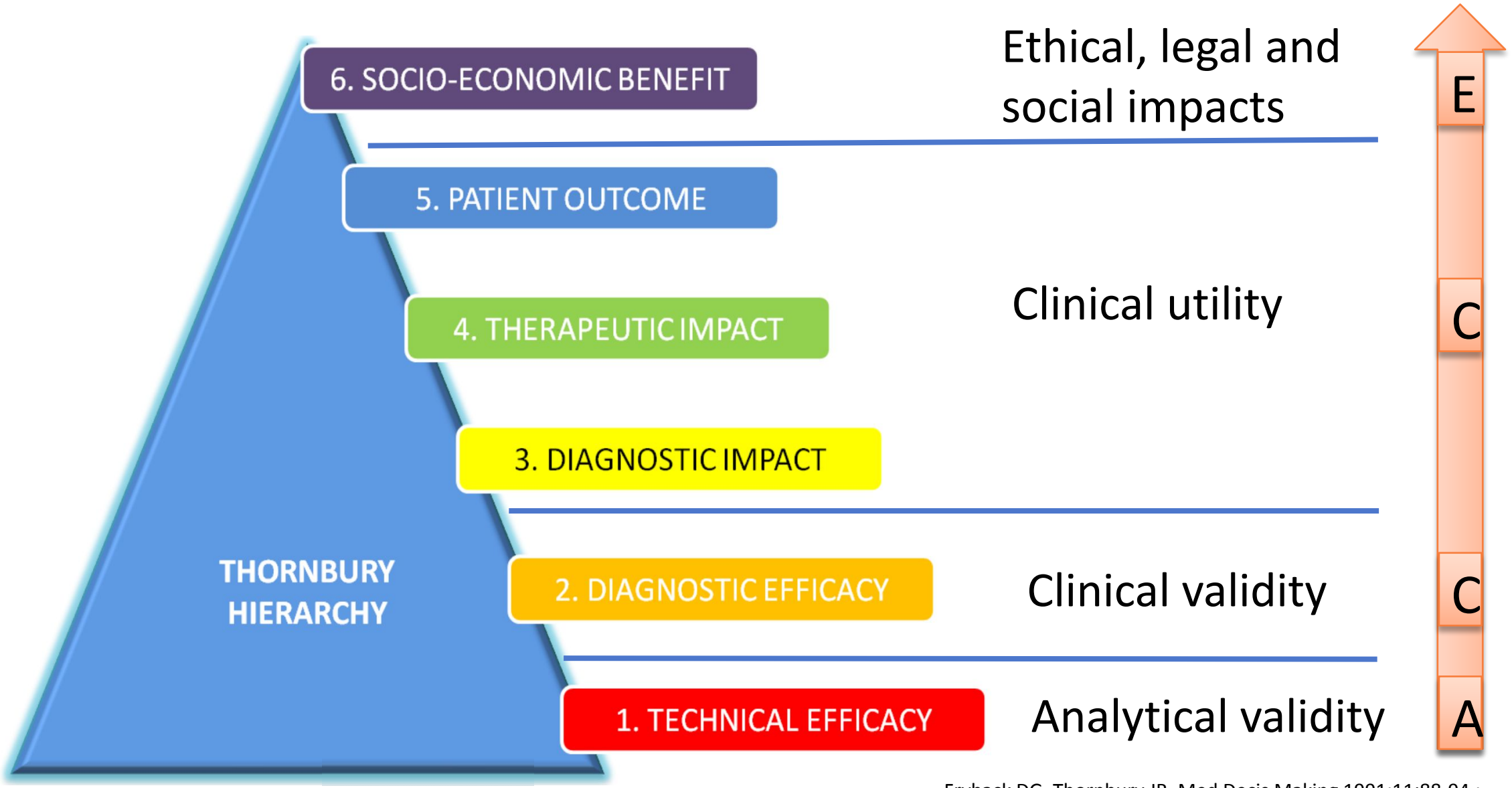
Two Major Frameworks to evaluate diagnostics tests



Fryback DG, Thornbury JR. Med Decis Making 1991;11:88-94.;
https://www.cdc.gov/genomics/gtesting/acce/index.htm

Two Major Frameworks to evaluate diagnostics tests

1. TECHNICAL EFFICACY

Analytical validity A

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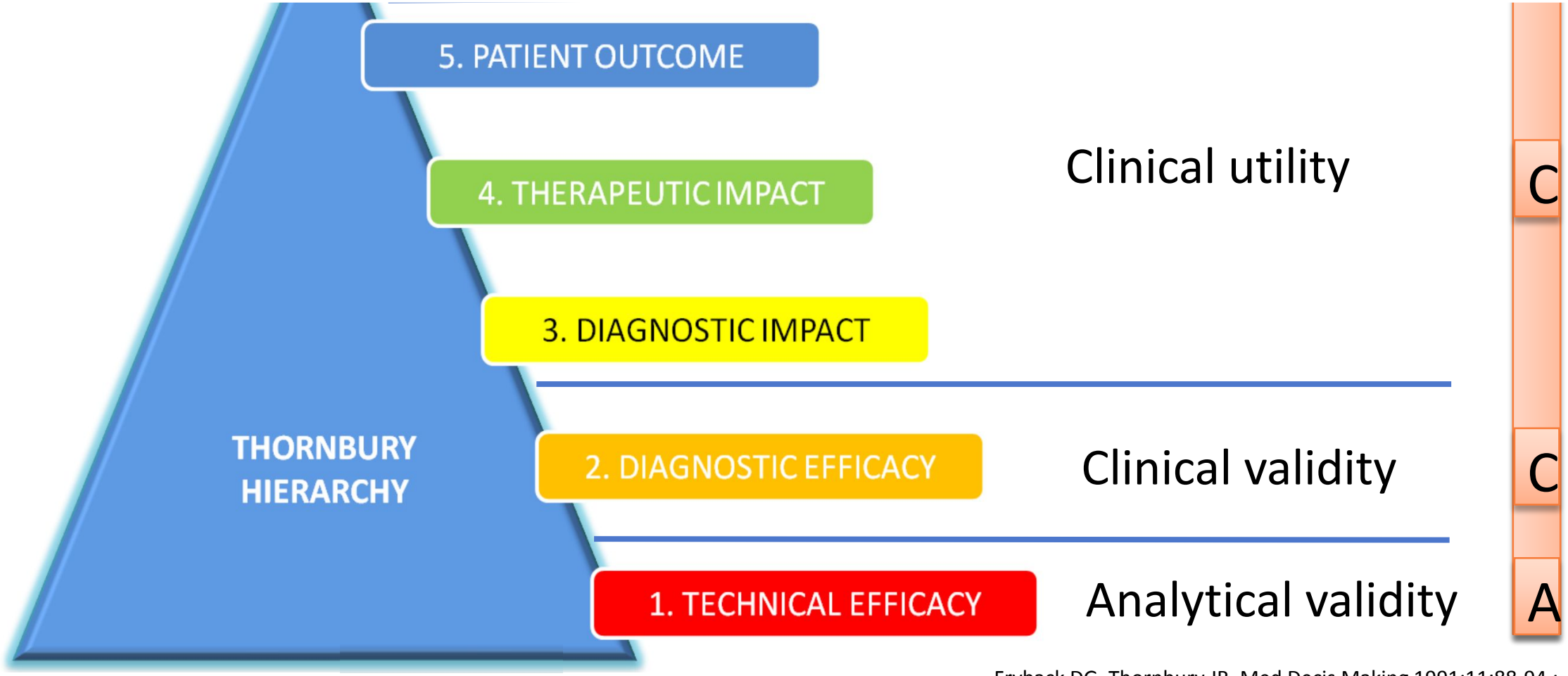

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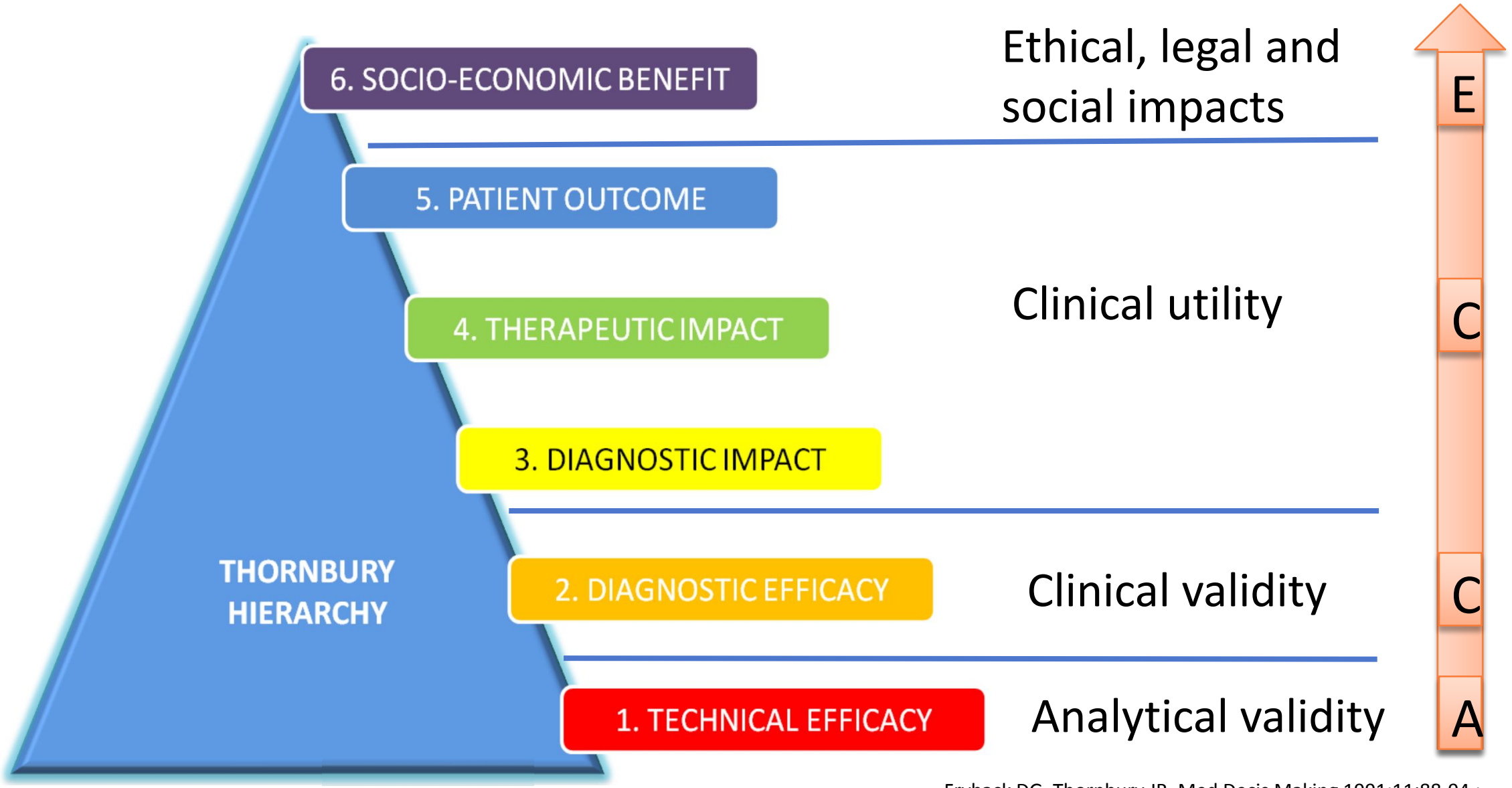
Two Major Frameworks to evaluate diagnostics tests



Fryback DG, Thornbury JR. Med Decis Making 1991;11:88-94.;
https://www.cdc.gov/genomics/gtesting/acce/index.htm

https://www.appliedpolicy.com/medicare-reimbursement-requirements-for-in-vitro-diagnostic-ivd-tests/

Providers, patients and payers' prospective

- Value: how it affects treatment decisions vs quantity of information provided.
- In the US , to be eligible for insurance coverage, a test must demonstrate clinical utility: the test's impact on clinical decision making.

A simplified equation to evaluate the value of laboratory testing

$$value = \frac{Outcome}{Cost}$$

Understand the impact of testing on management, care pathways and outcomes.

Outcome studies

Operational efficiency/
Clinical Workflow

Change patient
Management/
Clinical Decisions

Patient/clinical
Outcomes

Patient Centeredness

Cost-effectiveness/
Economics

Safety

TF-OSLM membership

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C. I. Suárez Sánchez	Member	CL	1st	2021 10 - 2024 12
V. Gounden	Member	SA	1st	2021 10 - 2024 12
E. M. Simbaqueba Sánchez	Corp. Rep./IL-Werfen	US	1st	2021 10 - 2024 12
J. A. Snyder	Corp. Rep./Siemens	US	1st	2021 10 - 2024 12
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M. Wakui	Japan Society of Clinical Chemistry (JSCC)
V. Pant	Nepalese Association for Clinical Chemistry (NACC)
E. Koldberg Amundsen	Norsk Selskap for Medisinsk Biokjemi (NSMB)
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TF-OSLM Scope and Mandate

IFCC Task Force on Outcome Studies in Laboratory Medicine (TF-OSLM)

- Identify existing evidence
- Create a repository/database
- Develop a funded research program
- Develop communication materials
- Collaboration

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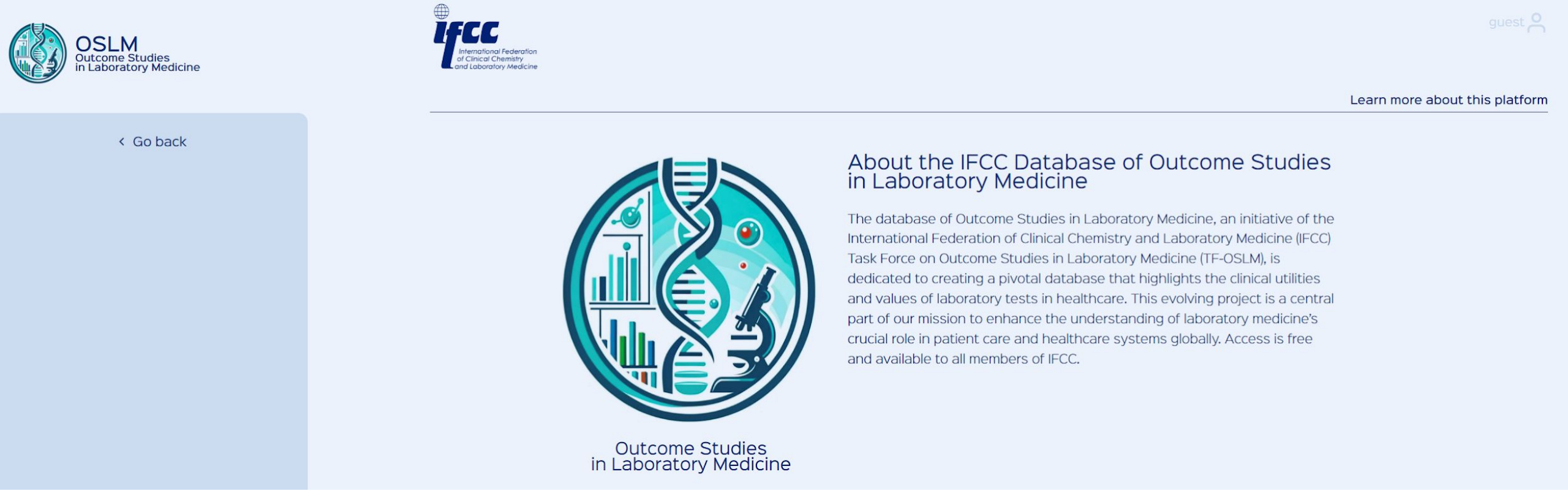
IFCC TF-OSLM officially launched the OSLM database

https://oslm.ifcc.org launched on Dec 1, 2023



A tool for supporting research, education, and policy development in healthcare.

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Database of Outcome Studies in Laboratory Medicine

Chemistry and Laboratory Medicine

Advancing excellence in laboratory medicine for better healthcare worldwide

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JAMA December 5, 2023

HIV POCT

Change patient management | Cluster RCT

Personalized acute kidney injury treatment.

Current opinion in critical care December 1, 2023

Kidney Disease

Review

Molecular-based targeted therapies in patients with hepatocellular carcinoma and hepato-cholangiocarcinoma refractory to atezolizumab/bevacizumab.

Journal of hepatology December 1, 2023

Cancer

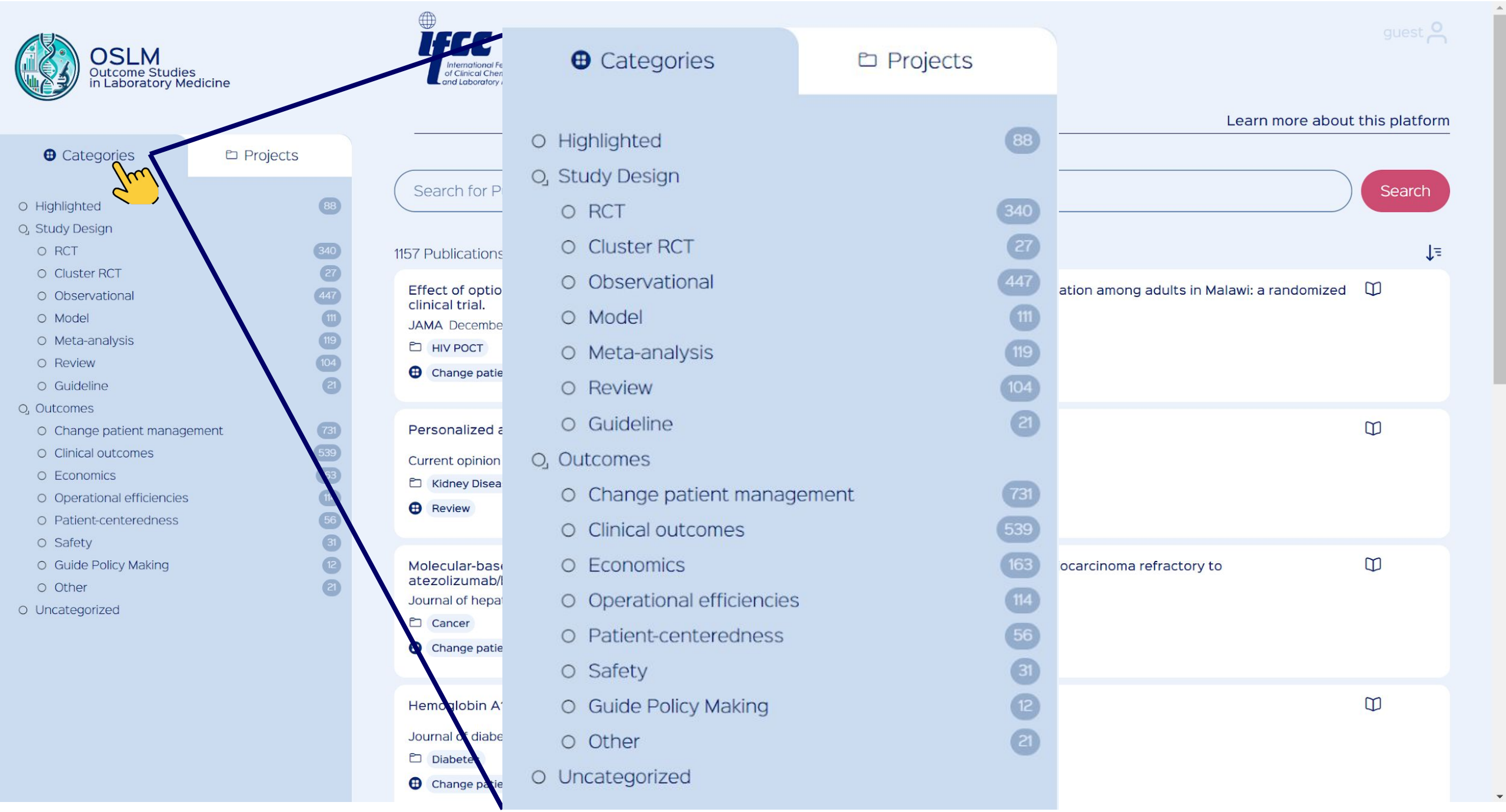
Change patient management | Clinical outcomes | Observational

Hemoglobin A1c Serum Level Predicts 5-year Mortality in Patients with Cognitive Impairment.

Journal of diabetes and metabolic disorders December 1, 2023

Diabetes

Change patient management | Clinical outcomes | Observational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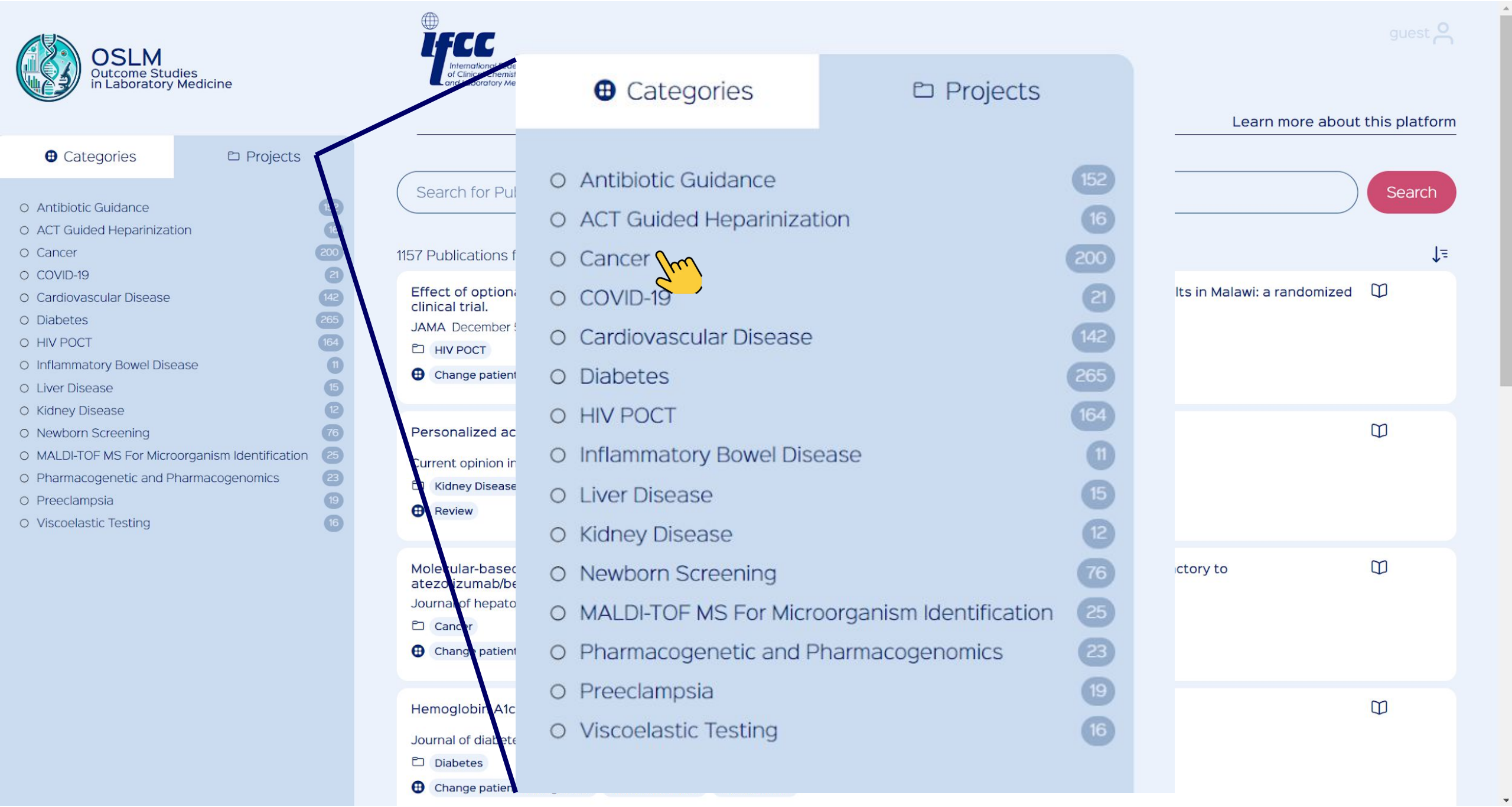
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Molecular-based targeted therapies in patients with hepatocellular carcinoma and hepato-cholangiocarcinoma refractory to atezolizumab/bevacizumab.

Journal of hepatology December 1, 2023

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Clinical availability and characteristics of multigene panel testing for recurrent/advanced gynecologic cancer.

International journal of clinical oncology November 1, 2023

Cancer

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A Retrospective Analysis of Biliary Tract Cancer Patients Presented to the Molecular Tumor Board at the Comprehensive Cancer Center Munich.

Targeted oncology September 1, 2023

Cancer

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Actionable molecular alterations in newly diagnosed and recurrent IDH1/2 wild-type glioblastoma patients and therapeutic implications:

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Osimertinib versus platinum-pemetrexed for patients with EGFR T790M advanced NSCLC and progression on a prior EGFR-tyrosine kinase inhibitor: AURA3 overall survival analysis.

Annals of oncology : official journal of the European Society for Medical Oncology November 1, 2020

Cancer

Change patient management | Clinical outcomes | RCT

Tepotinib plus gefitinib in patients with EGFR-mutant non-small-cell lung cancer with MET overexpression or MET amplification and acquired resistance to previous EGFR inhibitor (INSIGHT study): an open-label, phase 1b/2, multicentre, randomised trial.

The Lancet. Respiratory medicine November 1, 2020

Cancer

Change patient management | Clinical outcomes | RCT

Osimertinib for Japanese patients with T790M-positive advanced non-small-cell lung cancer: A pooled subgroup analysis.

Cancer science September 1, 2019

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Cancer science September 1, 2019

Cancer

Change patient management | Clinical outcomes | RCT

Outcome Evidence:
Shaping the healthcare decisions

Policy making:

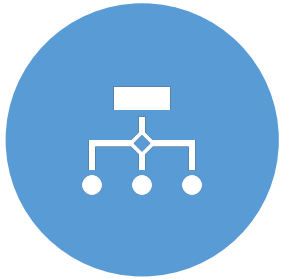
*Health coverage/reimbursement

*Health and public policies, regulations, strategies and guidelines

*Public funding

Clinical practice guideline development

Regulatory approval



Test adoption, implementation and utilization

HIV self-testing

An effective tool in overcoming barriers to traditional facility-based HIV testing services, such as stigma, distance, and a long waiting time for results

2016 SUPPLEMENT

GUIDELINES ON

HIV SELF-TESTING AND PARTNER NOTIFICATION

SUPPLEMENT TO CONSOLIDATED GUIDELINES ON HIV TESTING SERVICES

DECEMBER 2016

HIV TESTING SERVICES

World Health Organization

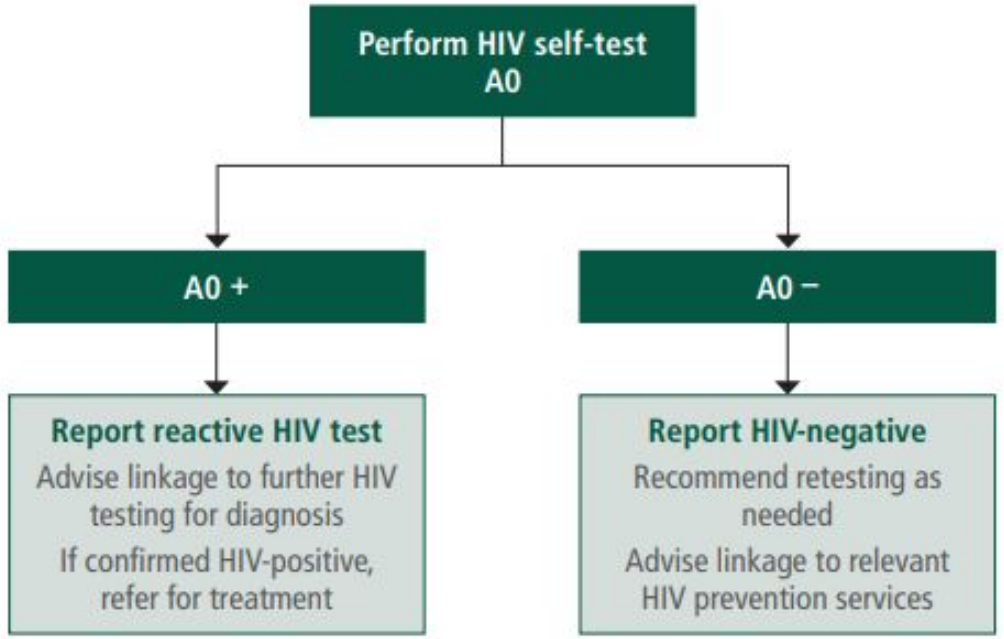
https://www.ncbi.nlm.nih.gov/books/NBK401684/pdf/Bookshelf_NBK401684.pdf

NEW

Recommendations

HIV self-testing should be offered as an additional approach to HIV testing services (*strong recommendation, moderate quality evidence*).

Fig. 2.1. HIVST testing strategy



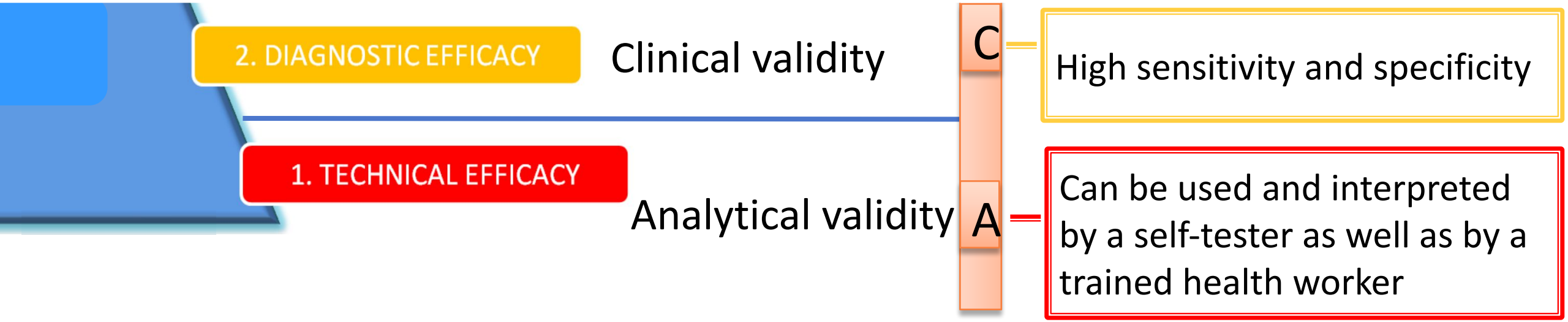
A0 = Assay 0 (test for triage).

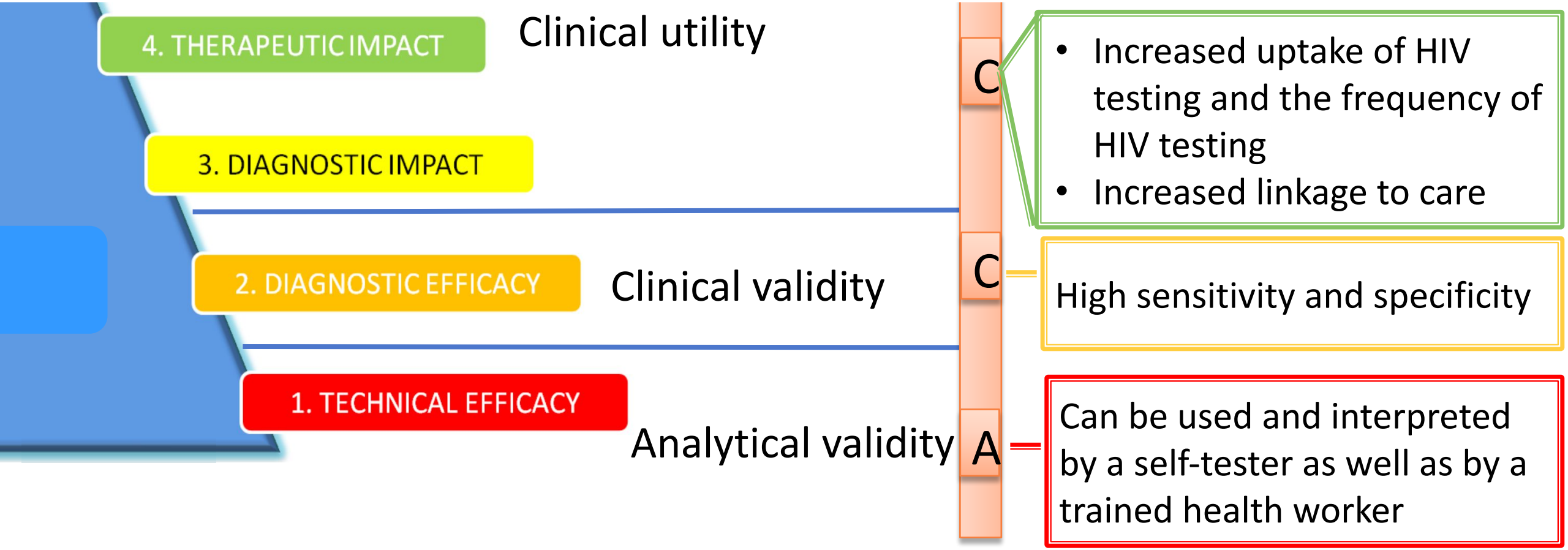
By the end of 2020, there were 88 countries that had implemented policies to support the sale of HIVSTs.

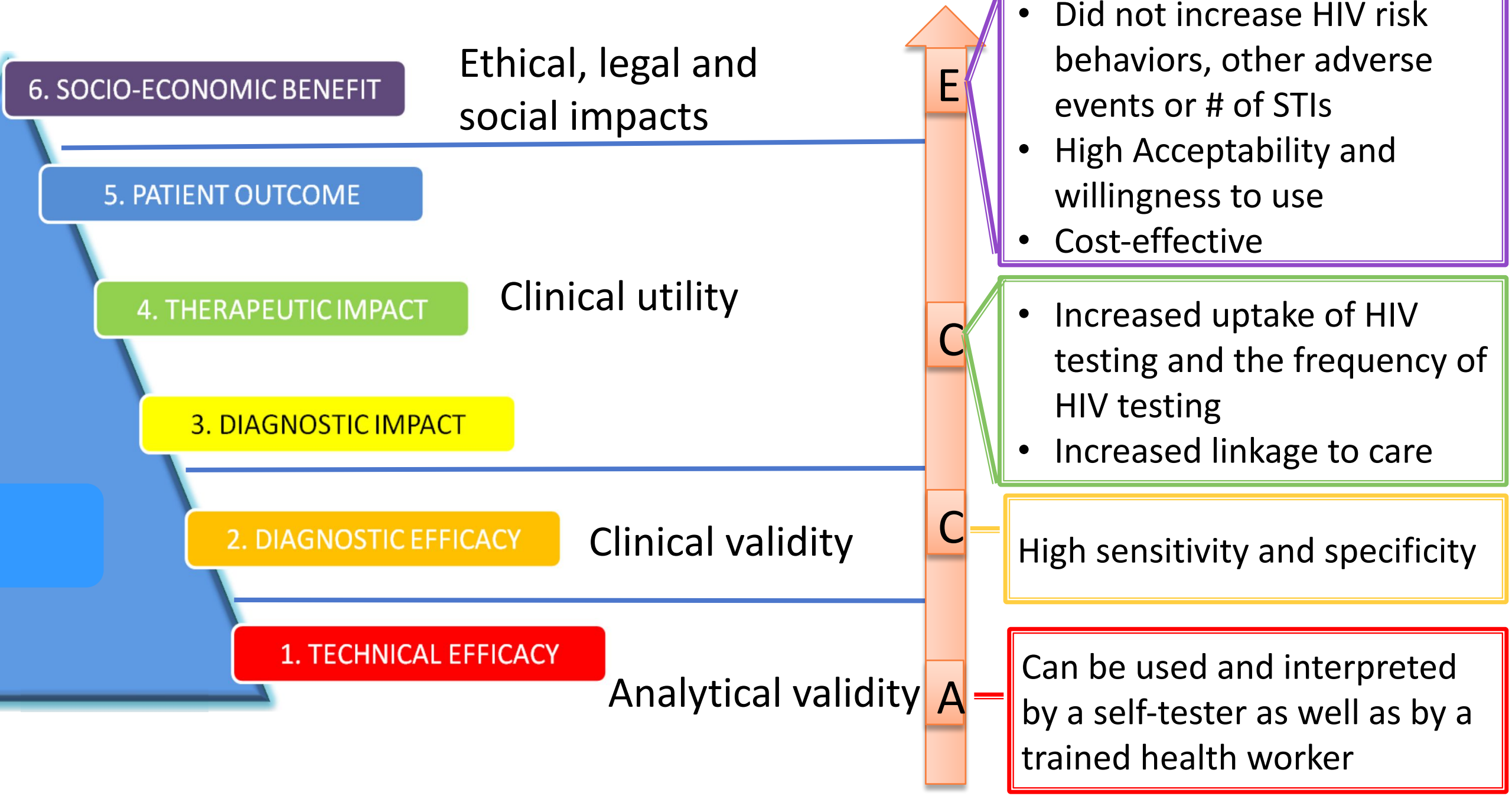
1. TECHNICAL EFFICACY

Analytical validity — A

Can be used and interpreted by a self-tester as well as by a trained health worker


2. DIAGNOSTIC EFFICACY
Clinical validity
C
High sensitivity and specificity
1. TECHNICAL EFFICACY
Analytical validity
A
Can be used and interpreted by a self-tester as well as by a trained health worker


4. THERAPEUTIC IMPACT
Clinical utility
3. DIAGNOSTIC IMPACT
2. DIAGNOSTIC EFFICACY
Clinical validity
1. TECHNICAL EFFICACY
Analytical validity
C
• Increased uptake of HIV testing and the frequency of HIV testing
• Increased linkage to care
C
High sensitivity and specificity
A
Can be used and interpreted by a self-tester as well as by a trained health worker


6. SOCIO-ECONOMIC BENEFIT
Ethical, legal and social impacts
5. PATIENT OUTCOME
4. THERAPEUTIC IMPACT
Clinical utility
3. DIAGNOSTIC IMPACT
2. DIAGNOSTIC EFFICACY
Clinical validity
1. TECHNICAL EFFICACY
Analytical validity
E
C
C
A
• Did not increase HIV risk behaviors, other adverse events or # of STIs
• High Acceptability and willingness to use
• Cost-effective
• Increased uptake of HIV testing and the frequency of HIV testing
• Increased linkage to care
High sensitivity and specificity
Can be used and interpreted by a self-tester as well as by a trained health worker

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HIV self testing

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JAMA December 5, 2023

HIV POCT

Change patient management | Cluster RCT

Acceptability, feasibility, and accuracy of blood-based HIV self-testing: A cross-sectional study in Ho Chi Minh City, Vietnam.

PLOS global public health January 1, 2023

HIV POCT

Observational | Patient-centeredness

Awareness, willingness and barriers to HIV Self-testing (HIVST) among Men who Have Sex with Men (MSM) in Brazil, Mexico, and Peru: A web-based cross-sectional study.

PLOS global public health January 1, 2022

HIV POCT

Observational | Patient-centeredness

Willingness of Chinese Men Who Have Sex With Men to Use Smartphone-Based Electronic Readers for HIV Self-testing: Web-Based Cross-sectional Study.

Journal of medical Internet research November 19, 2021

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JAMA July 30, 2014

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linkage to care

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Willingness of Chinese Men Who Have Sex With Men to Use Smartphone-Based Electronic Readers for HIV Self-testing: Web-Based Cross-sectional Study.

Journal of medical Internet research November 19, 2021

Original Investigation

FREE

July 23/30, 2014

Effect of Optional Home Initiation of HIV Care Following HIV Self-testing on Antiretroviral Therapy Initiation Among Adults in Malawi

A Randomized Clinical Trial

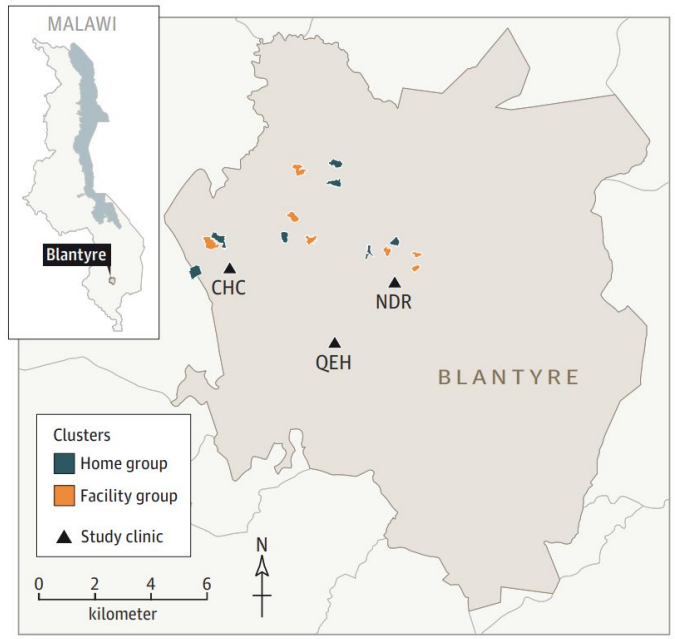
Peter MacPherson, PhD[1,2]; David G. Lalloo, MD[1]; Emily L. Webb, PhD[3]; et al

» Author Affiliations | Article Information

JAMA. 2014;312(4):372-379. doi:10.1001/jama.2014.6493

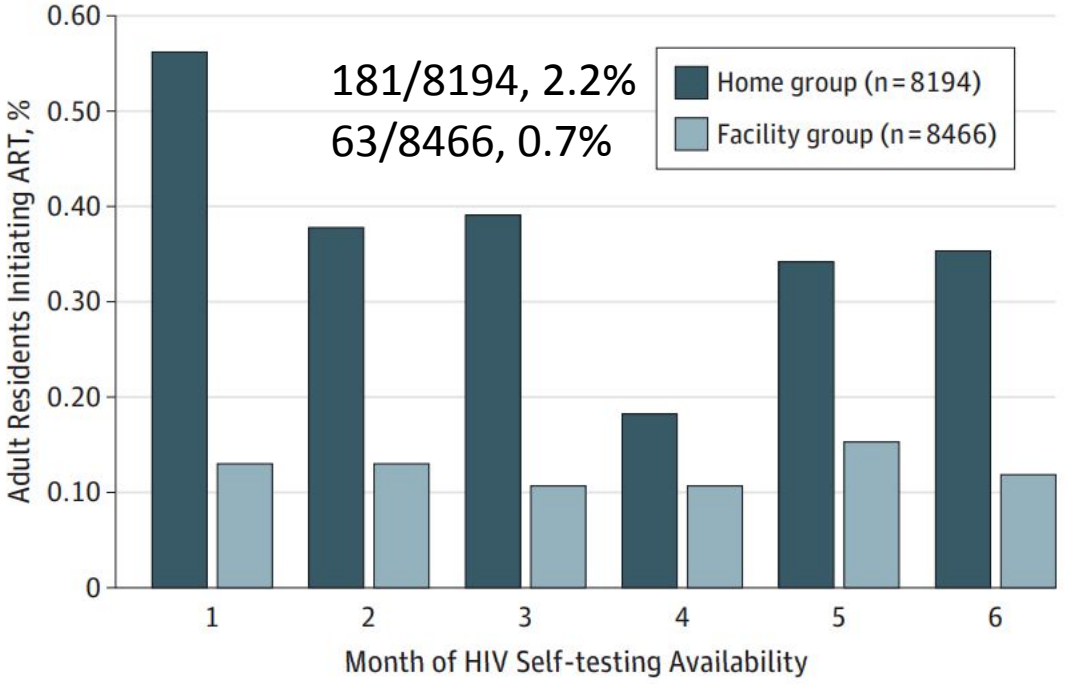
A significantly greater proportion of adults in the home group initiated ART compared with the facility group

Figure 1. Location of Study Clusters and Allocation



Lake Malawi is shown in light blue. CHC indicates Chilomoni Health Center; NDR, Ndirande Health Center; QEH, Queen Elizabeth Central Hospital.

Figure 3. Cluster Resident ART Initiations During 6 Months of HIV Self-testing Availability



ART indicates antiretroviral therapy.

Test-Treatment (Patient management) RCTs

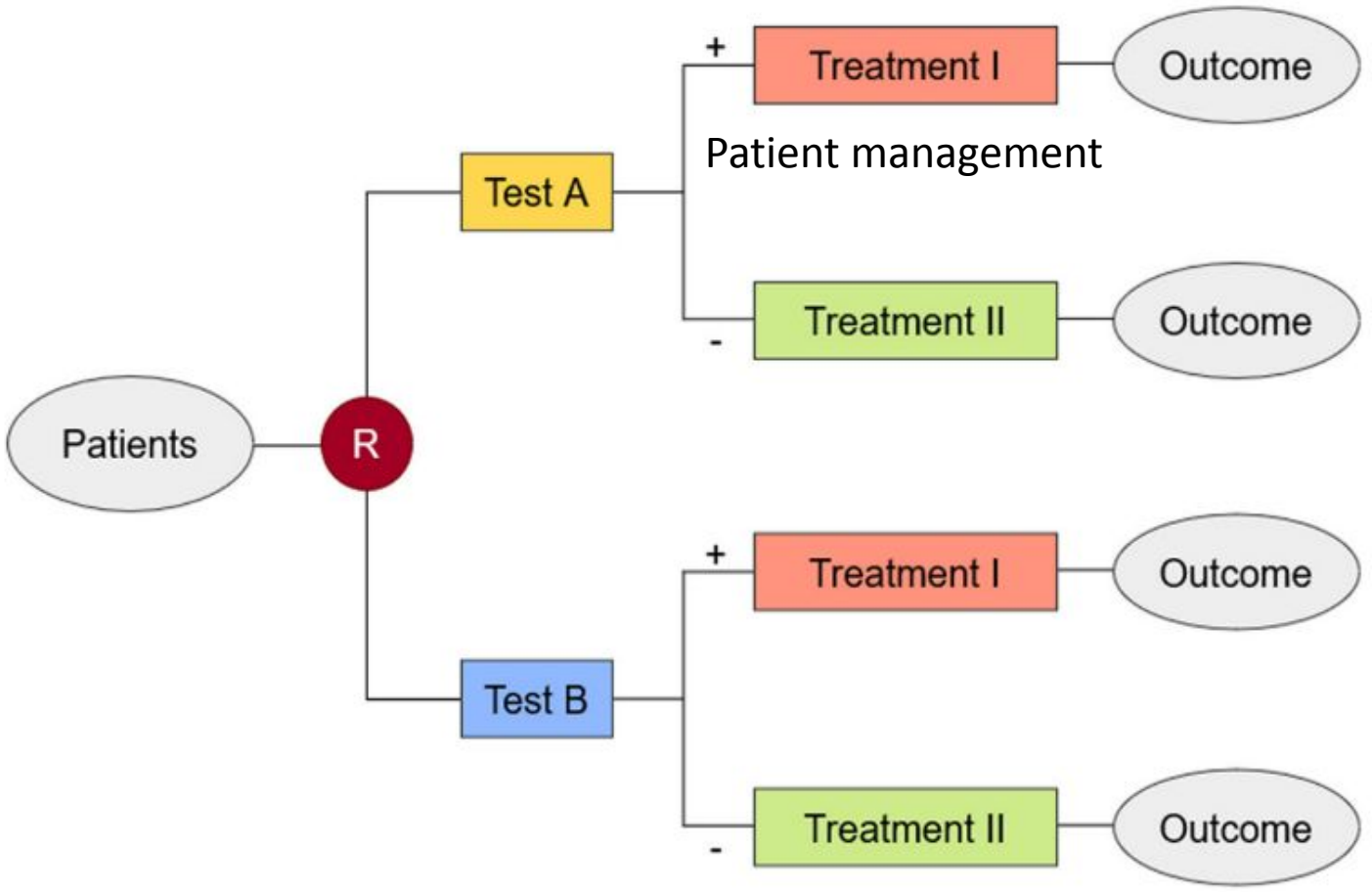


Fig. 1 A schematic representation of a classical test-treatment RCT [9]

Figure from: Hot, A., et al. (2021). "Randomized test-treatment studies with an outlook on adaptive designs." BMC Med Res Methodol **21**(1): 110.

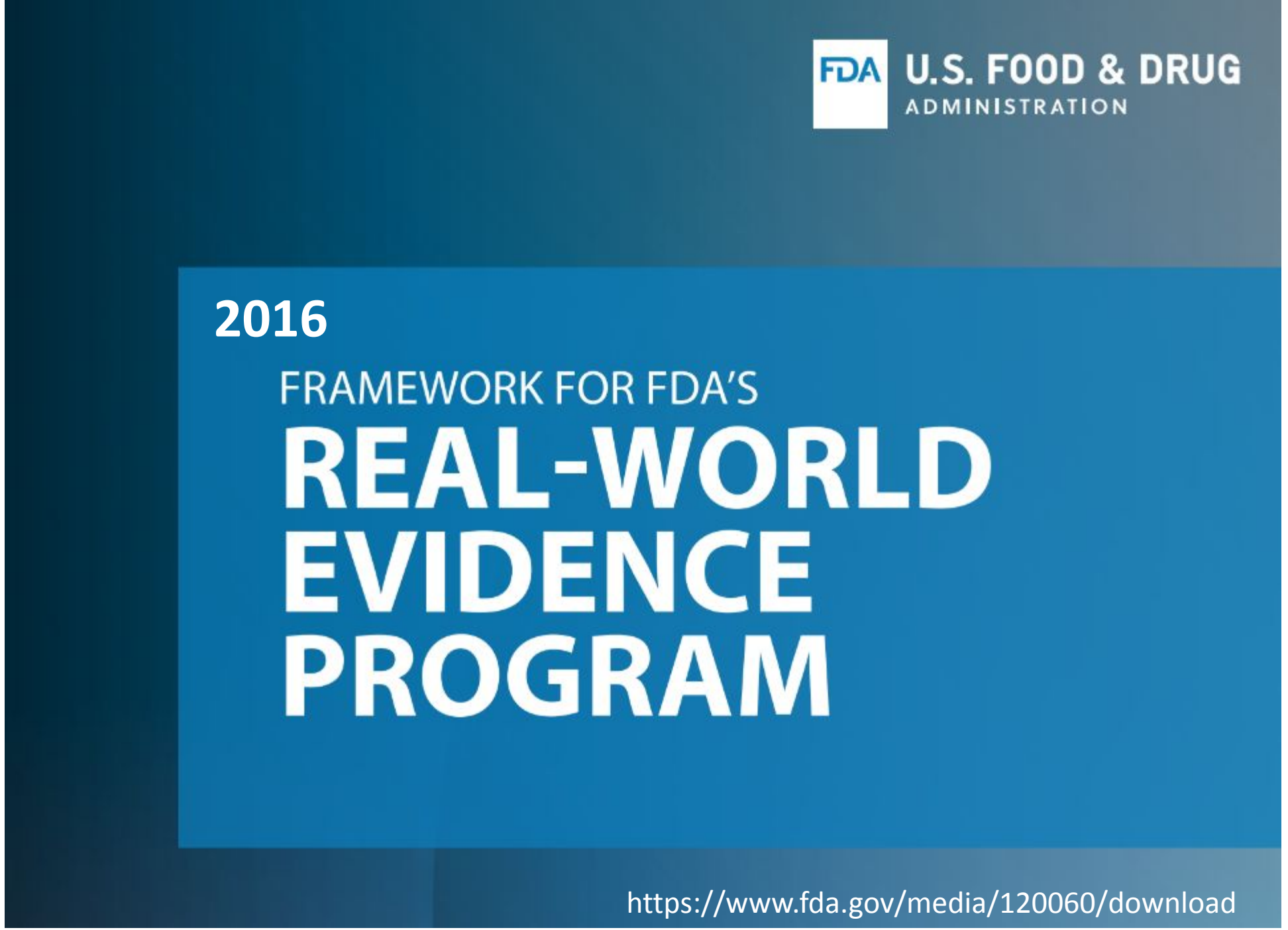
Benefits and limitations of traditional clinical trials

- Traditional clinical trials – Evaluate test performance in controlled setting

- Benefits include:
  - Control over the study design and protocol
  - Control for confounding

- Limitations
  - Usually expensive and time-consuming
  - May be difficult to collect rare outcomes
  - How generalizable are results?

https://www.cdc.gov/cliac/docs/november-2021/13_Rubinstein-CLIAC-RWE.pdf


FDA
U.S. FOOD & DRUG
ADMINISTRATION
2016
FRAMEWORK FOR FDA'S
REAL-WORLD
EVIDENCE
PROGRAM
https://www.fda.gov/media/120060/download

FDA definition of real world data and real world evidence

Real World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources

- electronic health records (EHRs)
- medical claims data
- product and disease registries
- patient-generated data, including in-home settings
- data gathered from other sources, such as mobile devices, that can inform on health status

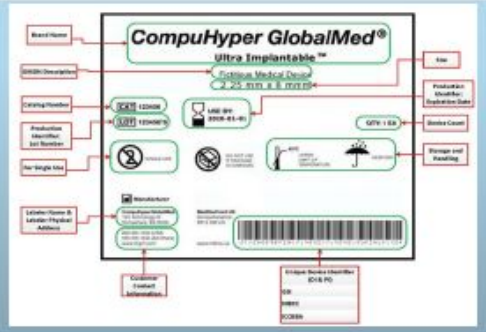
Real World Evidence (RWE) is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD

Generated using different study designs, including but not limited to randomized trials (e.g., large simple trials, pragmatic trials), externally controlled trials, and observational studies

Real world data sources

Diagnostic Laboratory and Imaging

Device/Patient Registries



Device-Generated Data

Patient-Generated Data

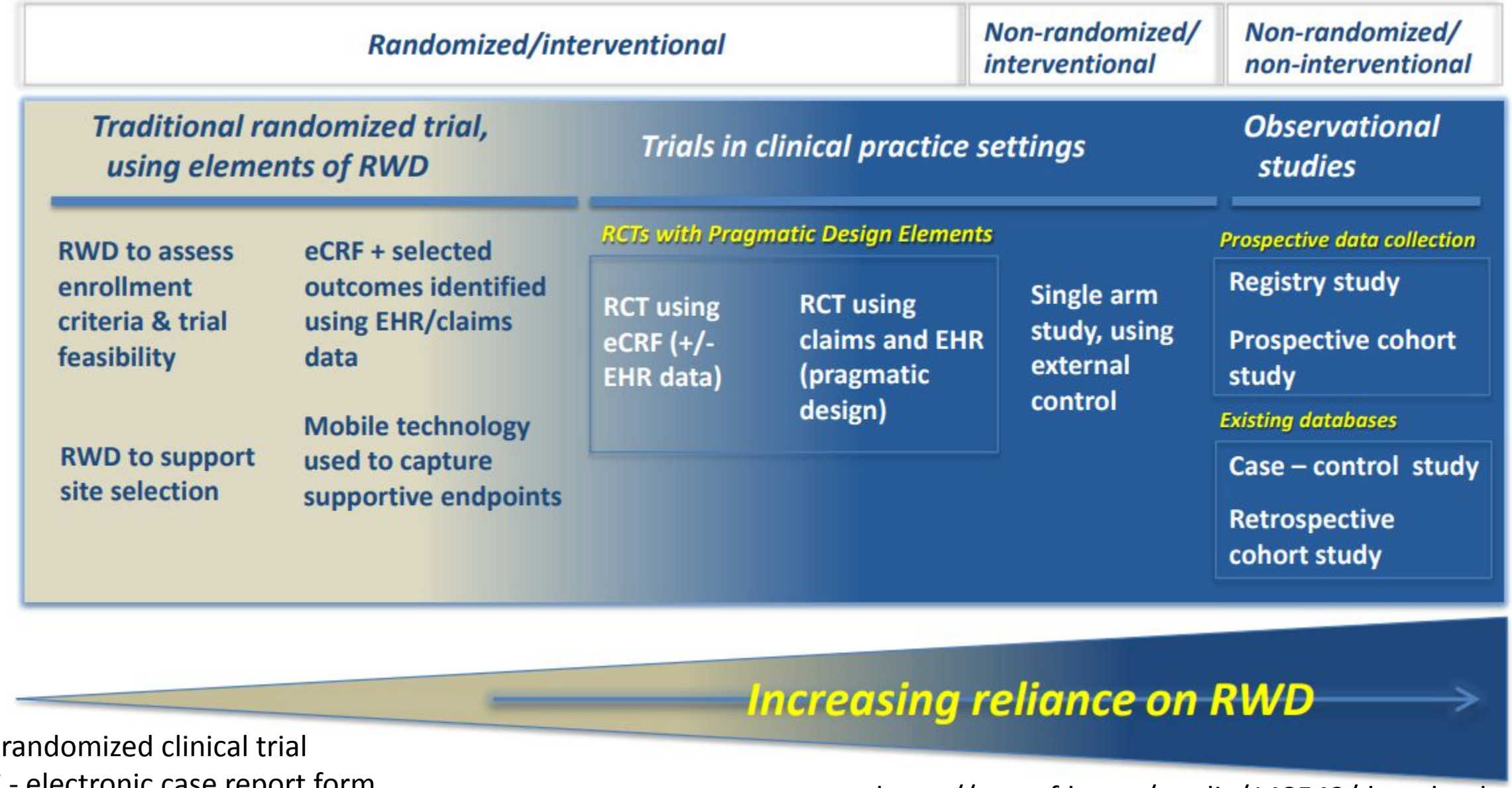
Electronic Health Records

Medical Billing Claims

https://www.cdc.gov/cliac/docs/november-2021/13_Rubinstein-CLIAC-RWE.pdf


Collection
Use
Analysis
RWD
RWE

Study Design and Real-World Data



RCT- randomized clinical trial
eCRF - electronic case report form

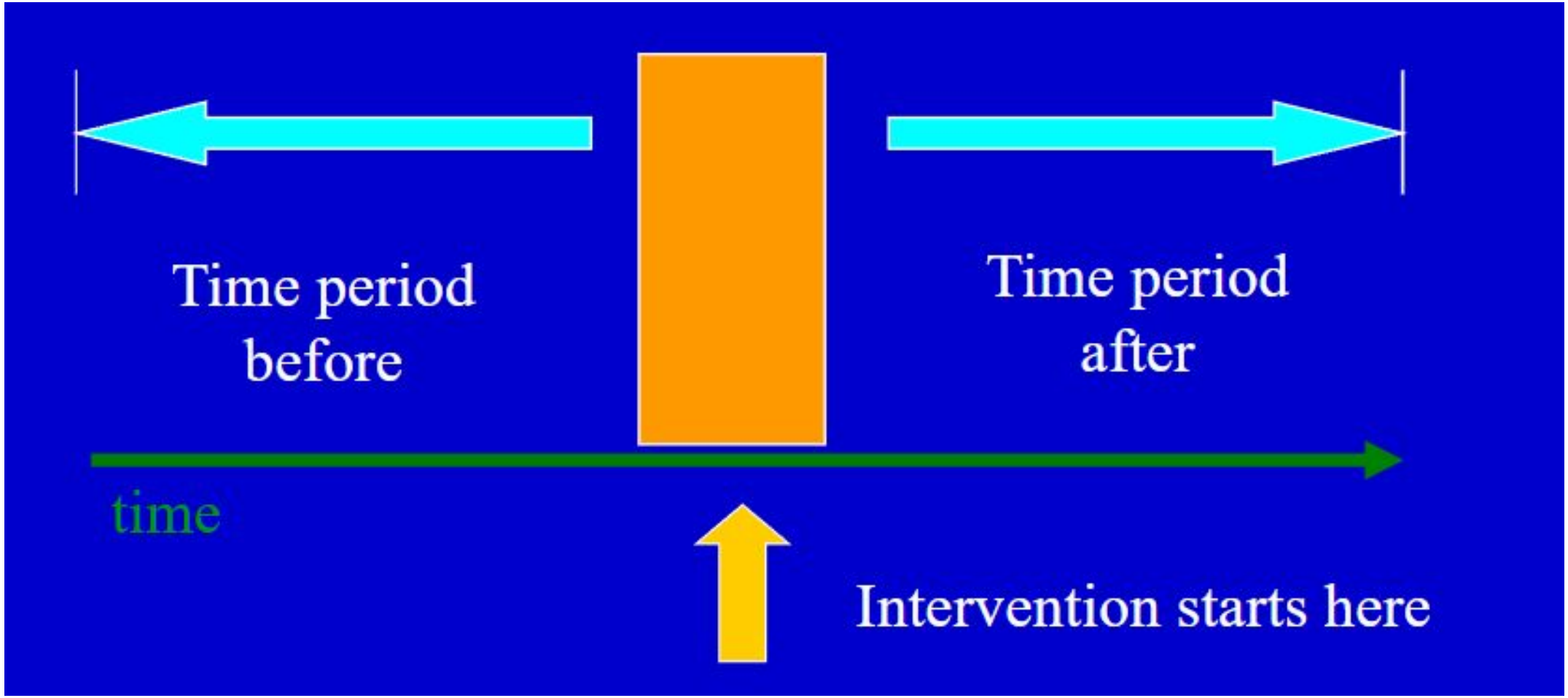
https://www.fda.gov/media/148543/download

Potential benefits of real-world data sources

- Understand device performance in real-world environment to inform benefit-risk
- Collect outcomes not always feasible in traditional trials
- Opportunities to partner w/patients in new ways
- Reduced time/cost to answer important questions
- Inform future device modifications and new technology development
- Better align evidence generation with innovation cycles

https://www.cdc.gov/cliac/docs/november-2021/13_Rubinstein-CLIAC-RWE.pdf

Before-and-After study



Outcome Evidence:
Shaping the healthcare decisions

Policy making:

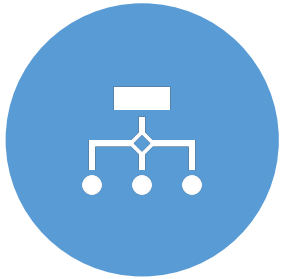
*Health coverage/reimbursement

*Health and public policies, regulations, strategies and guidelines

*Public funding

Clinical practice guideline development

Regulatory approval



Test adoption, implementation and utilization

OSLM
Outcome Studies
in Laboratory Medicine

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

manager

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Categories | Projects

edit

- Highlighted 89
- Study Design
  - RCT 341
  - Cluster RCT 28
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  - Model 113
  - Meta-analysis 119
  - Review 105
  - Guideline 21
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  - Clinical outcomes 548
  - Economics 166
  - Operational efficiencies 120
  - Patient-centeredness 56
  - Safety 32
  - Guide Policy Making 12
  - Other 21
- Uncategorized

troponin, implementation

Search

7 Publications found

Implementation of the European Society of Cardiology 0/3-hour accelerated diagnostic protocol, using high sensitive troponin T: a clinical practice evaluation of safety and effectiveness involving 3003 patients with suspected acute coronary syndrome.

Open heart December 26, 2023

Cardiovascular Disease

Change patient management | Clinical outcomes | Observational | Operational efficiencies | Safety

Improved Utilization of Serial Testing Without Increased Admissions after Implementation of High-Sensitivity Troponin I: a Controlled Retrospective Cohort Study.

Journal of general internal medicine November 22, 2023

Cardiovascular Disease

Change patient management | Observational | Operational efficiencies

Frequency, compliance, and yield of cardiac testing after high-sensitivity troponin accelerated diagnostic protocol implementation.

The American journal of emergency medicine October 1, 2023

Cardiovascular Disease

Change patient management | Observational

Implementation of High-Sensitivity Cardiac Troponin Assays in the United States.

Journal of the American College of Cardiology January 24, 2023

Cardiovascular Disease

Change patient management | Observational | Operational efficiencies

Home › Journal of General Internal Medicine › Article

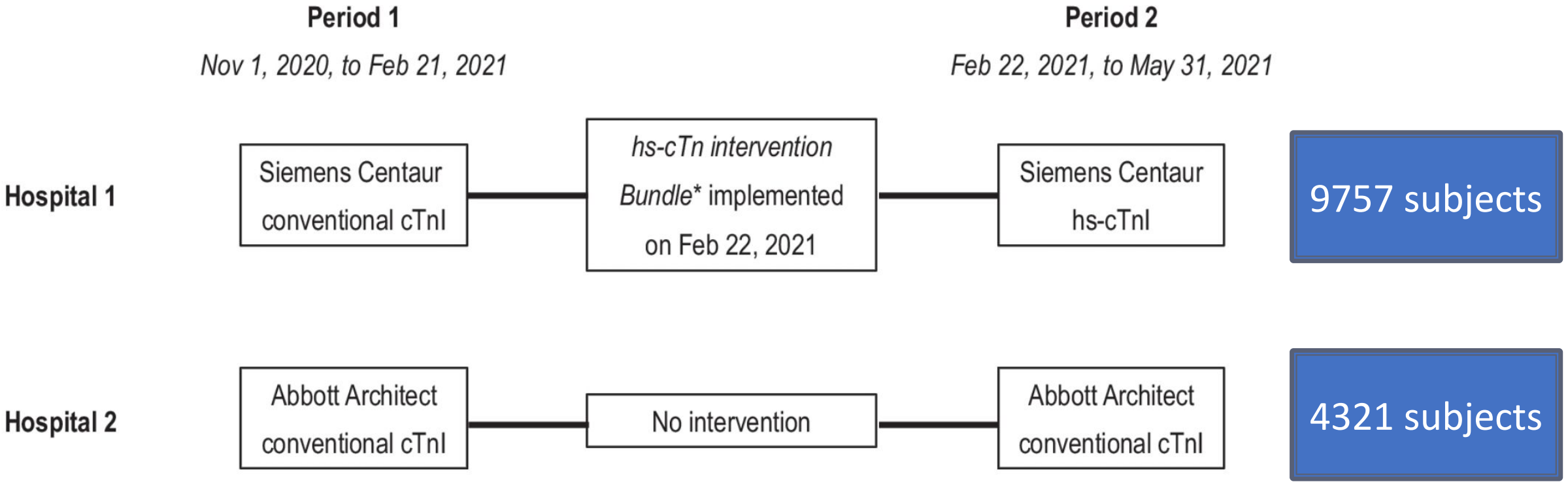
Improved Utilization of Serial Testing Without Increased Admissions after Implementation of High-Sensitivity Troponin I: a Controlled Retrospective Cohort Study

Original Research | Published: 22 November 2023

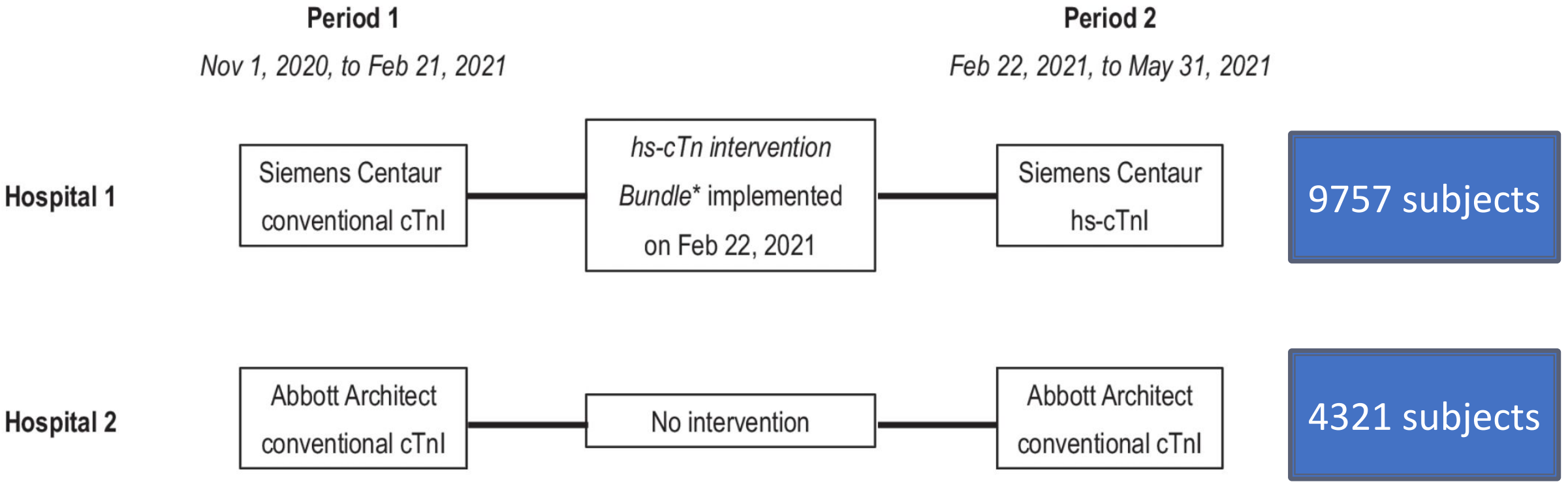
Journal of General Internal Medicine

Objective: To evaluate the impact of transitioning from conventional cardiac troponin (cTn) to hs-cTn on test and resource utilization, operational efficiency, and patient safety.

Design: Retrospective cohort before and after study

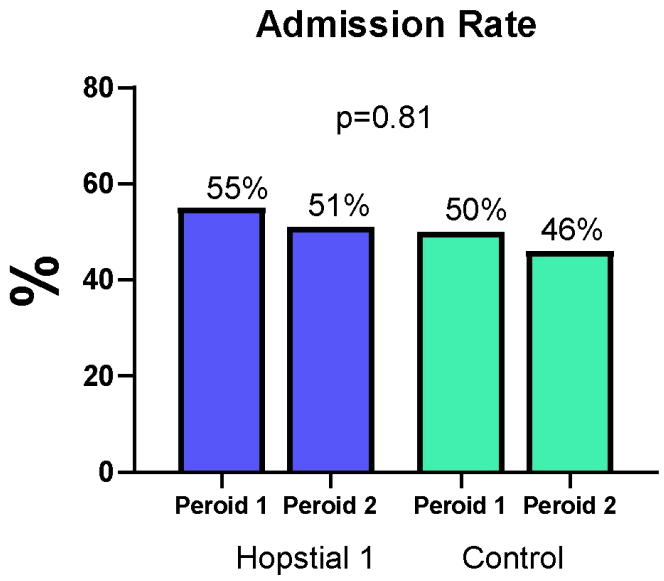


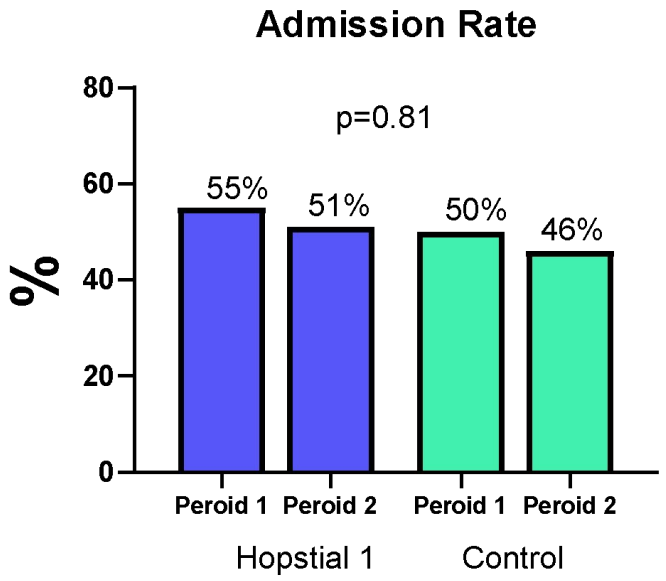
Design: Retrospective cohort before and after study



Participants: Consecutive emergency department (ED) patients with at least one cTn test resulted.

Intervention: a 0/2-h diagnostic algorithm for non-ST-elevation myocardial infarction


Admission Rate
p=0.81
%
80
60
40
20
0
55%
51%
50%
46%
Peroid 1
Peroid 2
Peroid 1
Peroid 2
Hopstial 1
Control


Admission Rate
p=0.81
%
80
60
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Peroid 1
Peroid 2
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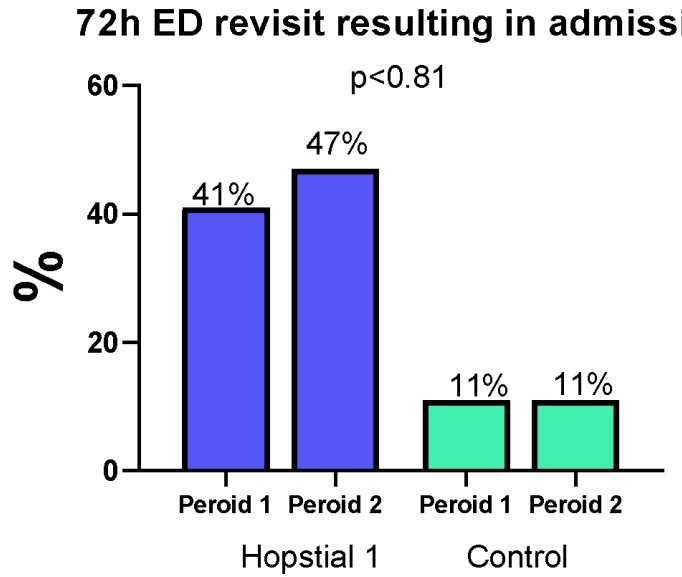
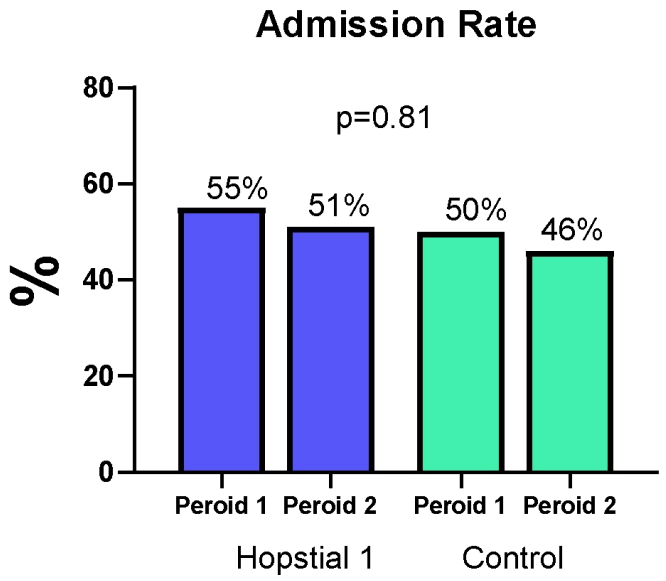
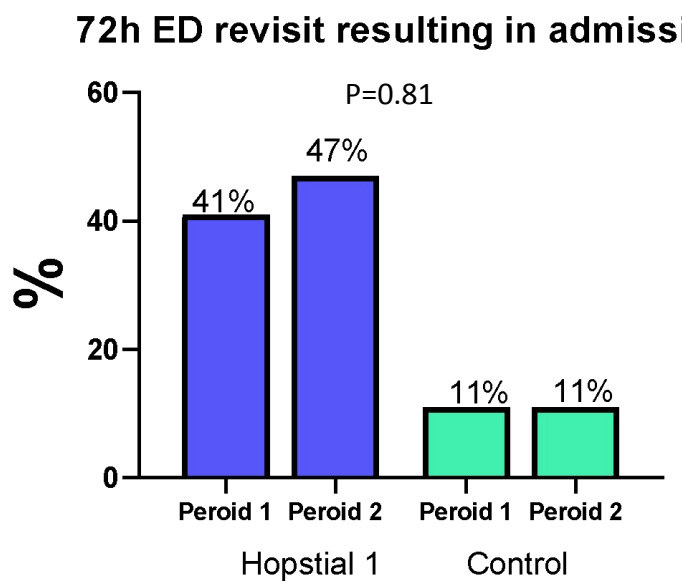
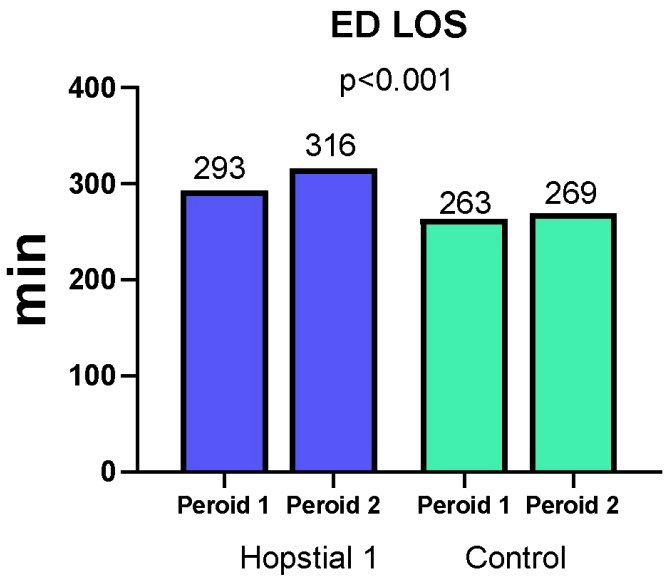
Peroid 2
Hopstial 1
Control

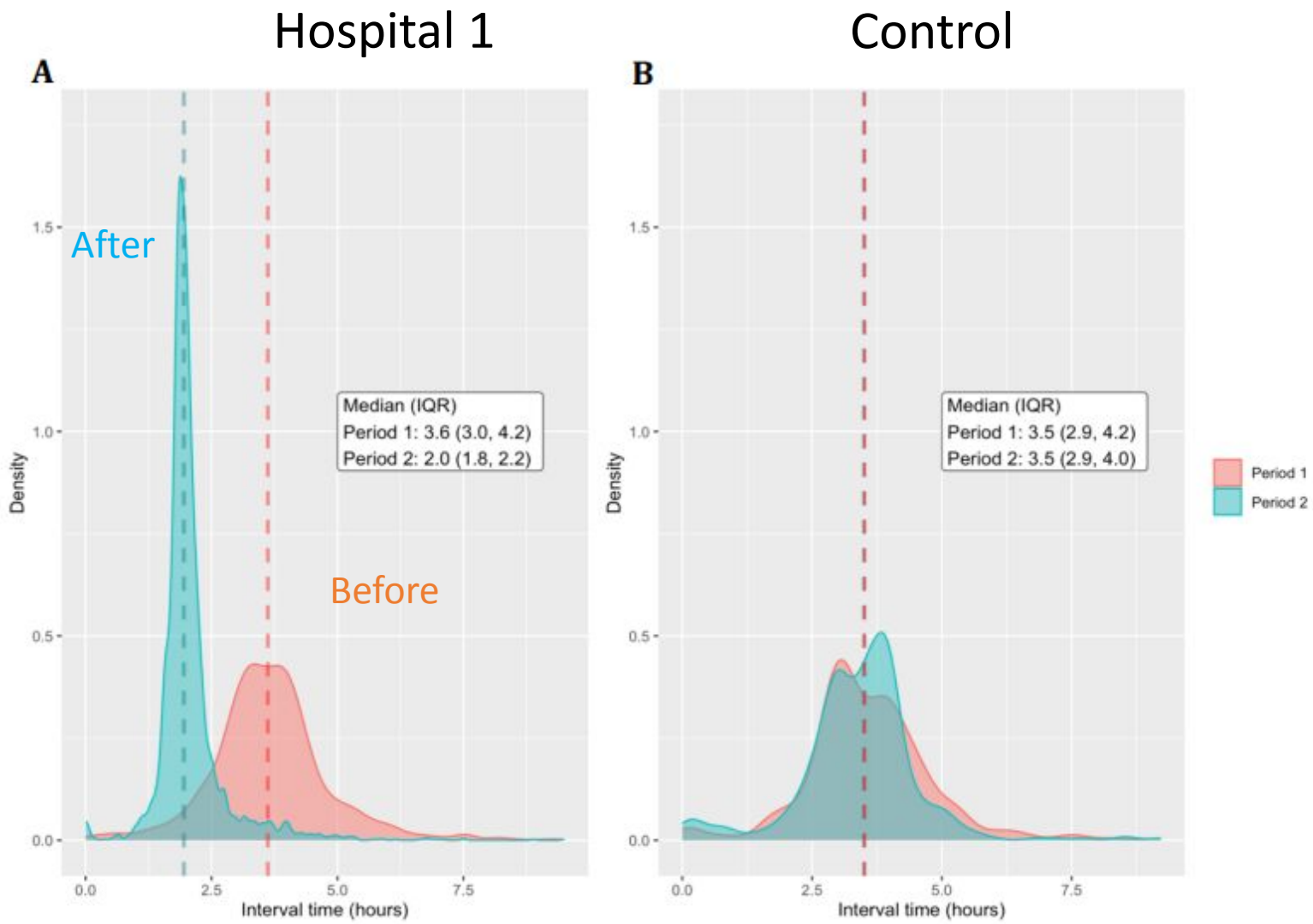

72h ED revisit resulting in admission
p<0.81
%
60
40
20
0
41%
47%
11%
11%
Peroid 1
Peroid 2
Peroid 1
Peroid 2
Hopstial 1
Control


Admission Rate
p=0.81
%
80
60
40
20
0
55%
51%
50%
46%
Peroid 1
Peroid 2
Peroid 1
Peroid 2
Hopstial 1
Control

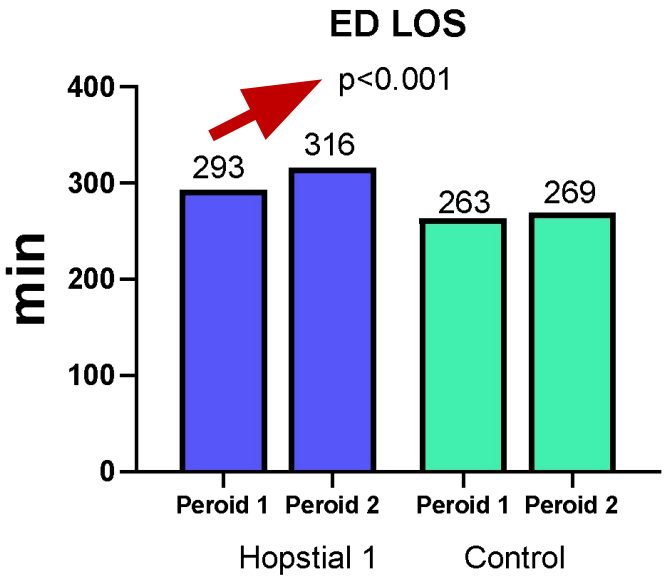

72h ED revisit resulting in admission
P=0.81
%
60
40
20
0
41%
47%
11%
11%
Peroid 1
Peroid 2
Peroid 1
Peroid 2
Hopstial 1
Control

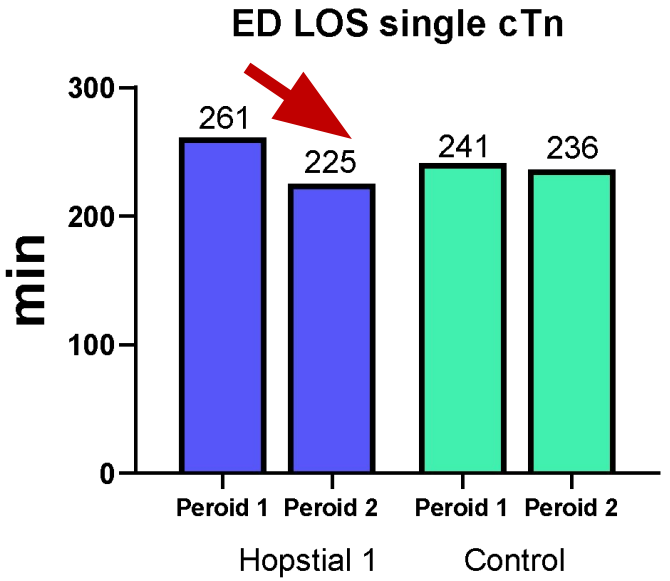

ED LOS
p<0.001
min
400
300
200
100
0
293
316
263
269
Peroid 1
Peroid 2
Peroid 1
Peroid 2
Hopstial 1
Control

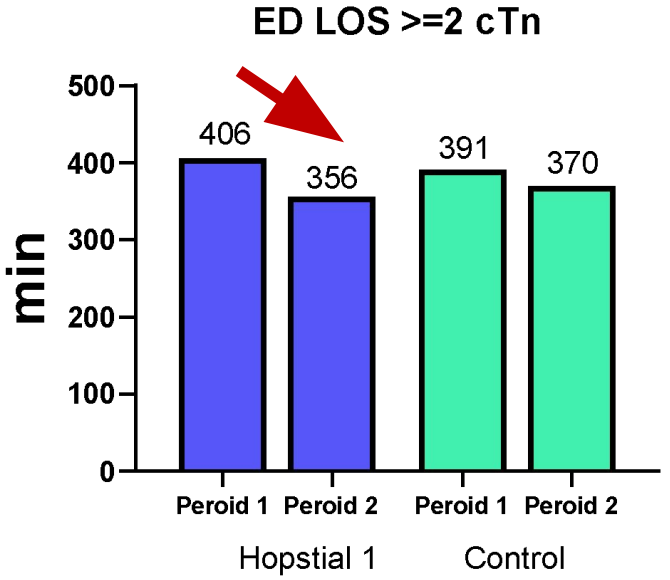
Time interval between first and second troponin test collection among those with serial testing



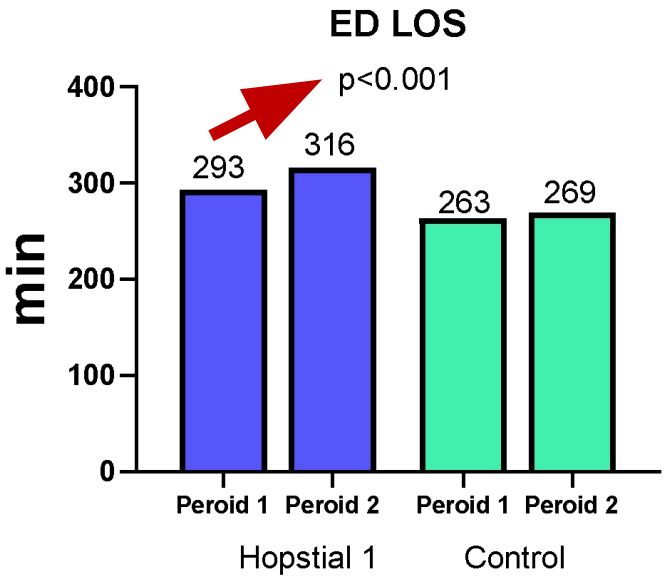
A closer look at ED LOS

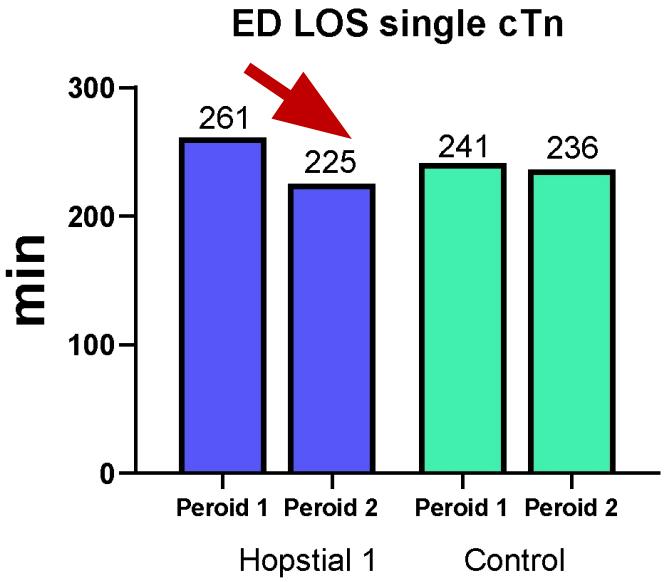


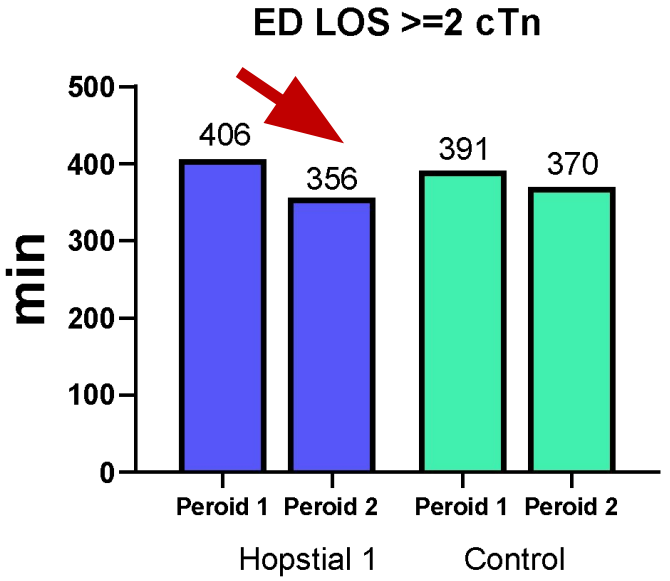


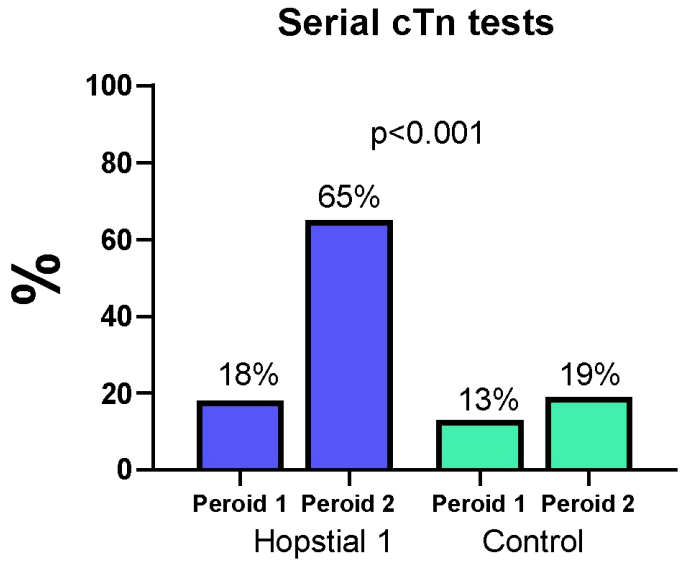


A closer look at ED LOS









Improvement in care consistent with national guidelines

- **Conclusions:** Implementation of a hs-cTn was associated with an improvement in serial cTn testing, a neutral effect on probability of hospital admission, and a modest increase in ED LOS.

- Recent cardiology and emergency medicine society guidelines recommend use of serial cTn testing in patients presenting with symptoms suspicious for NSTEMI. Thus, implementation of the hs-cTn was associated with an improvement in care consistent with national guidelines.

“Control” for before and after study design

- A major strength of this study is the comparison to a control hospital where the intervention was not undertaken. This has significant advantages over single-arm before-and-after studies, most notably in controlling for potential temporal trends unrelated to the intervention.

- To the best of our knowledge, this is the first study to employ this design to evaluate the effect of implementation of hs-cTn on these outcomes.

TF-OSLM Scope and Mandate

IFCC Task Force on Outcome Studies in Laboratory Medicine (TF-OSLM)

- Identify existing evidence
- Create a repository/database
- Develop a funded research program
- Develop communication materials
- Collaboration

Research Funding Available

International Federation of Clinical Chemistry and Laboratory Medicine

Call For Study Proposals

IFCC's Task Force on Outcome Studies in Laboratory Medicine (TF-OSLM) is seeking research proposals for studies evaluating the **impact of laboratory testing on health outcomes.**

Strategic Objectives

1. To promote directed research evaluating the role of laboratory medicine on clinical outcomes

2. To build awareness and understanding with regards to the critical role of laboratory medicine plays in healthcare outcomes

What will be funded?

Patient Outcomes

? Implemented in clinical practice?

?Influence decision making?

?Change patient management?

?Contribute to healthcare process?

IFCC Call For Outcome Studies Application Form

Form description

Applicant (Principal investigator name) *

Long answer text

Principal investigator's Email *

Long answer text

*

Principal investigator Title

Long answer text

*

Applicant organization/institution

Long answer text

Title of project *

Long answer text

*

Abstract (< 500 words)

Justification of the project as an outcome study (It is crucial to demonstrate that the study links the laboratory testing to patient management, and improvements/changes in clinical outcomes.) *

Long answer text

*

Proposal

The following need to be incorporated into **a single PDF file** of the proposal submission (6 page limit; Key references and Research team sections are not included in the page limit). **Please use the PI's name as the file name.**

***Title:** The title should be concise

***Scope of project**

***Statement of research problem**

***Brief Background to the clinical problem:** Explain the area of concern, or what needs justify the research (this could be a sub-heading). Any information that helps the evaluator to understand the clinical problem you are aiming to solve should be included. Indicate why you believe that it is, in fact, a researchable problem. This section could be combined with the literature review, or form a sub-section of it.

***Significance of the research**

***Objectives of the research:** Clarify the aims and objectives of the research. Where feasible, objectives should be divided into main and secondary objectives.

***Research strategy, design and methodology**

***Project duration and timeline:** details should be included with regard to timelines for completion and deliverables. For projects where the proposed timeline exceeds the maximum time duration of 1 year, consideration will only be given if there is evidence of other funding resources that will allow for successful completion of the project (to be submitted with grant proposal).

***Expected outcomes, results and contributions of the research**

***Previous research activities related to the proposed study:** applicant's involvement with management of projects before; previous publications relevant to the proposed project; previous publications/activities relative to outcome studies

***Ethical considerations: Ethics Committee approval should be obtained either at the time of grant request, or before the funding is provided.**

***Budget** (CHF 5000 to 10000 over a period of 1 year duration and any non-study related cost are not eligible)**:** Provide an itemized budget describing both use of the IFCC grant and if applicable funds from other sources

***Conflict of interest (COI):** any COI related to the proposed study

***Key References (5-10 key references to be stated)**

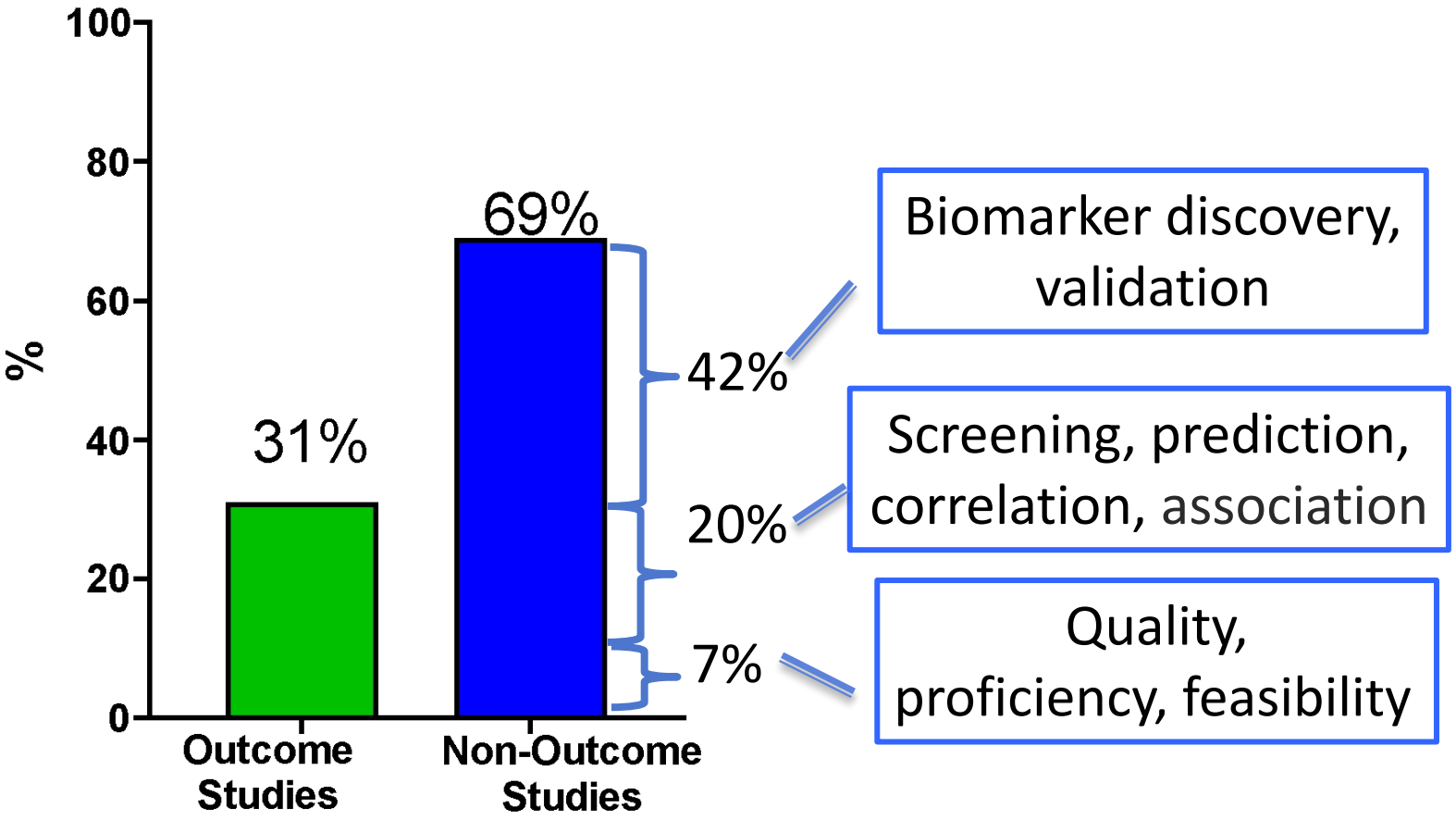
***Research team**: Principal Investigator and any other project team member's strengths along with their roles and responsibilities should be clearly described. CV (maximum 5 pages) of the principle investigator and supporting letters from co-investigators

***Optional**: A figure/flow chart could be used to describe the use of the test in the clinical pathway and the outcomes

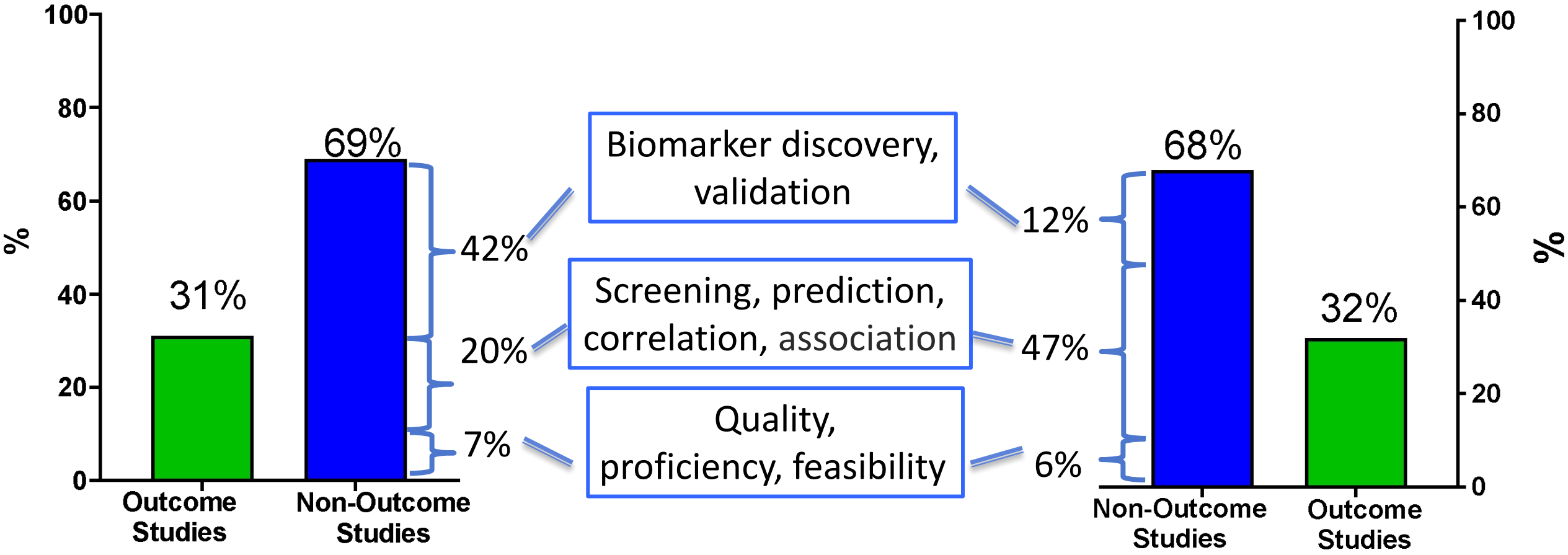
55 submissions in 2022 and 34 submissions in 2023
6 selected

Year	Country	Title of project
2022	Canada	Defining the importance and impact of clinical laboratory testing practices and result return on Covid-19 patients: A GENCOV study
2022	Australia	The '70%' claim: finding the evidence base through big data analysis
2022	Georgia	The research implementation of the clinical model for evaluation CYP2C19 alleles genotype guided clopidogrel treatment
2022	Zambia	Impact of clinical laboratory test profile on the clinical management and outcome of Acute Kidney injury at Livingstone University Teaching Hospital: The ICLaTA study
2022	Nigeria	Impact of NT-proBNP Guided Management of Chronic Heart Failure on patient outcome in a Nigerian tertiary Hospital.
2023	Canada	Impact of sFlt-1 and PlGF testing on the management of women with suspected preeclampsia in a high-risk obstetrics unit

Lessons learned from “Call for proposals”

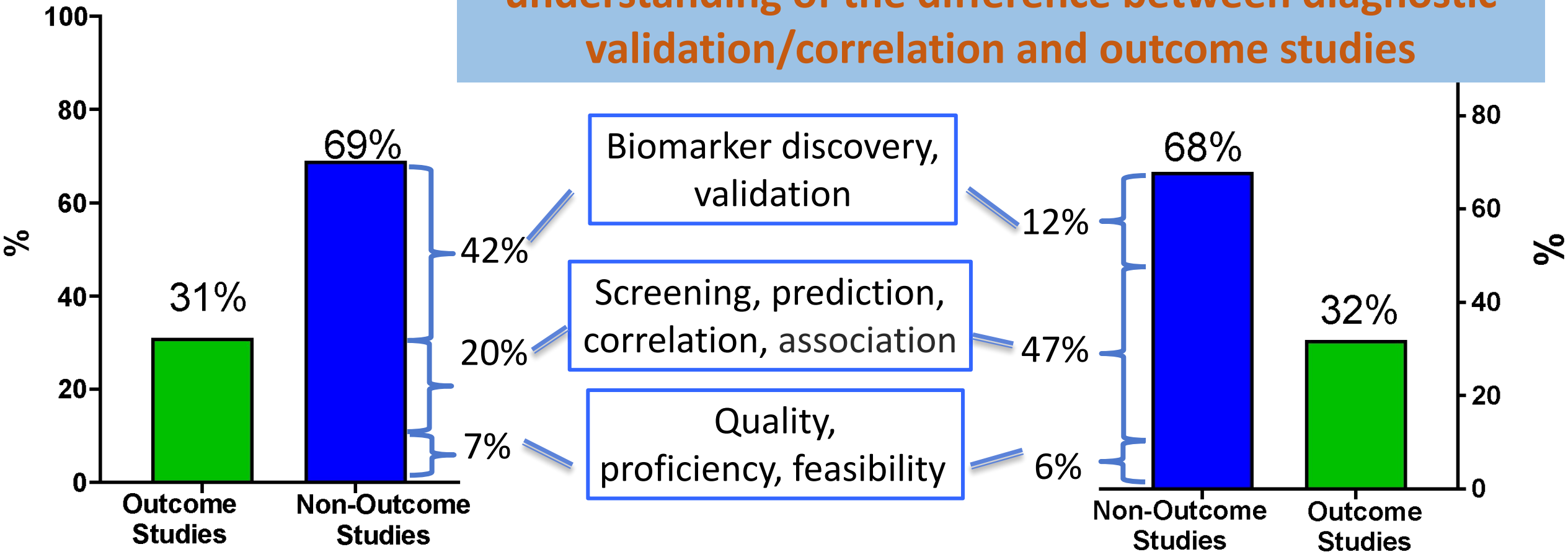


Lessons learned from “Call for proposals”



Lessons learned from “Call for proposals”

The gap and need for better awareness and understanding of the difference between diagnostic validation/correlation and outcome studies



TF-OSLM Scope and Mandate

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- Identify existing evidence
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Volume 69, Issue 11
November 2023

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JOURNAL ARTICLE

Linking Laboratory Testing to Clinical Outcomes: Bridging the Gap through Outcome-Based Studies in Laboratory Medicine

Verena Gounden, Mithu Banerjee, Erik Koldberg Amundsen, Muhittin A Serdar, Claudio Iván Suárez Sánchez, Colleen Strain, David Kinniburgh, Zhen Zhao ✉ on behalf of the IFCC Task Force on Outcome Studies in Laboratory Medicine

Clinical Chemistry, Volume 69, Issue 11, November 2023, Pages 1317–1321,
https://doi.org/10.1093/clinchem/hvad132
Published: 09 September 2023 **Article history** ▾

https://academic.oup.com/clinchem/article/69/11/1317/7265356?guestAccessKey=ab434da2-9f2f-4124-a84c-fe1e39d7b40e&utm_source=authortollfreelink&utm_campaign=clinchem&utm_medium=email

IFCC TF-OSLM call for actions

- Further stimulate the development of high-quality outcome studies by calling on multidisciplinary collaboration.
- Clinical effectiveness trials and studies should become a standard component of diagnostic test evaluation.
- Funding must also be emphasized and allocated appropriately to ensure the successful implementation of outcome studies.

2024 TF-OSLM - Call for study proposals

https://ifcc.org/executive-board-and-council/eb-task-forces/task-force-on-outcome-studies-in-laboratory-medicine-tf-oslm/

Acknowledgement

- TF-OSLM members and corresponding members
- IFCC EB: Dr. David Kinniburgh and Dr. Khosrow Adeli
- IFCC office: Ms. Smerada Skenderaj
- IFCC Value Proposition for Laboratory Medicine Committee: Dr. Andrew St John and Dr. Chris Price
- IFCC Task Force on Ethics: Dr. Nilda Fink
- IFCC Evidence-based Laboratory medicine Committee: Dr. Annalise Zemlin and Dr. Andrew Don-Wauchope
- ADLM (formerly AACC) Academy: Dr. Hong Kee Lee
- ADLM Value of Laboratory Medicine Steering committee
- ADLM volunteers
- Weill Cornell Library: Kevin Pain

Thank you!

Please contact me for any suggestions and comments:

zhz9010@med.cornell.edu