

Sixth Annual World Health
Continuing Medical Education Conference

Health Disparities Impacting Global and Local Caribbean Populations

June 16–17, 2023

Hyatt Centric Arlington
1325 Wilson Blvd.
Arlington, VA

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Obstetrical Ultrasound Impact in HIC vs LMIC:

Published Evidence vs Field Experiences in Haiti
Promoting 'Precision Charity'

Berndt P Schmit, MD MBOE

Associate Professor of Radiology
George Washington University

Unite Por Lutte De Sante
Cap Haitien, Haiti
Hand-held Ultrasound
November 2022

Disclosures

- Consultant with Radiology Business Solutions
- Founder of Humanitarian Radiology Development Corps, 501c3 charity
- Unpaid Advisor for Emagine Solutions Technology
  - VistaScan – handheld ultrasound
  - The Journey – pregnancy monitoring app
- No Financial Conflict

Personal Bias:
I'm a Data Skeptic

Nothing is more dangerous than
a smart, well-intentioned person
with a spreadsheet

Data Infatuation

Data Envy

Garbage in = Garbage out

Content

- Obstetrical care background
- Outcomes Data for Obstetrical Ultrasound in HIC vs LMIC
  - Value Stream Map
  - Broken & Weak Systems
- Big Aid
  - Fallibility
  - Data Colonialism
- 'Precision Charity'
- Examples from Haiti

Learning Objectives

- Understanding the potential pitfalls of the published literature about impact of Obstetrical Ultrasound
- Understanding the importance of building complete processes as revealed by careful Value Stream Mapping
- Raise awareness of current state of obstetrical ultrasound in Haiti and other LMIC
- Importance of real world experience & direct engagement

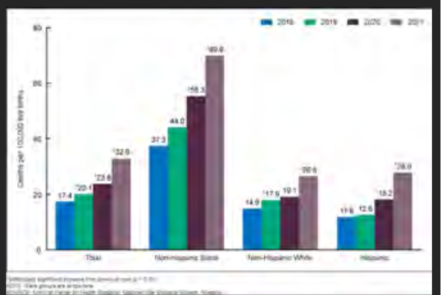
Obstetrical Care: HIC vs LMIC

Outcomes

Maternal Mortality Rate /100,000

USA (2021)	32.9
Malawi (2017)	349
Haiti (2015)	488

USA



CDC March 2023

Neonatal Mortality Rate /1000

USA (2021)	3.5
Malawi (2020)	19
Haiti (2020)	25

‘Neonatal Mortality’ <28days

CDC
World Bank

OB Standard of Care: HIC

Cost

Average childbirth costs

	Average cost of childbirth	Average out-of-pocket cost for health insurance plan members
Childbirth	$18,865	$2,854
Vaginal delivery	$14,768	$2,655
Cesarean	$26,280	$3,214

Source: Peterson-KFF Health System Tracker, 2022. Costs are based on large group health insurance plans.

OB Standard of Care: HIC vs LMIC

Cesarean Section Rate

USA Overall C/S: 32.1%
USA Primary C/S: 22.3%

Primary C/S Sub-Saharan Africa: 5%
Primary C/S Latin America & Caribbean: 42.8%

March of Dimes, 2021
BMJ Global Health, 2021

OB Standard of Care: HIC
Ultrasound

ACOG Recommendation:
- One ultrasound: Usually at 18-22 weeks
- May also get first trimester US
  - Dates, location, number, anomalies

Typical HIC Ultrasound exams:
- 8-14wk: gestational age
  - 11-14wk: fetal anomaly, nuchal fold
- 18-20 weeks: Anatomy
- 36wk: Position check

World Health Organization

Recommend OB ultrasound < 24 weeks to:
- Gestation age
- Detect fetal anomalies
- Detect multiple pregnancy
- Reduce induction of labor
- ‘Improve woman’s pregnancy experience’

World Health Organization, 2016

Does OB Ultrasound Work in HIC?

OB Ultrasound: HIC

- Routine *Late* OB Ultrasound (2015)
  >24 weeks
- Cochrane Review
  - 13 trials
  - 35,000 women
  - 1980 - 2013

Routine Ultrasound in Late Pregnancy after 24 weeks' Gestation (Review)
The Cochrane Collaboration. 2015

OB Ultrasound: HIC

- Routine *Late* OB Ultrasound (2015)
  >24 weeks

No association between late US and:

• Perinatal mortality	(RR 1.01, 95% CI 0.67-1.54)
• Pre-term birth	(RR 0.96, 95% CI 0.85-1.08)
• Induction of Labor	(RR 0.93, 95% CI 0.81-1.07)
• Cesarean Section	(RR 1.03, 95% CI 0.92-1.15)

Routine Ultrasound in Late Pregnancy after 24 weeks' Gestation (Review)
The Cochrane Collaboration. 2015

OB Ultrasound: HIC

- Routine *Early* OB Ultrasound Cochrane (2021)
  <24 weeks
- Cochrane Review
  - 13 Randomized Controlled Trials
  - Papers from 1982 - 2018
  - 85,000 women

Routine Ultrasound for Fetal Assessment before 24 weeks' Gestation
Cochrane Database Syst Rev. Aug 2021

OB Ultrasound: HIC

- Routine *Early* OB Ultrasound Cochrane (2021)
  <24 weeks

- Little difference for perinatal loss (RR 0.98, 95% 0.81-1.20)
- Little difference intrauterine fetal death (RR 0.97, 95% 0.66-1.42)
- May reduce induction of labor (better dates) (RR 0.48, 95% 0.31-0.73)
- May improve detection of multiple pregnancy (RR 0.05, 95% 0.02-0.16)
- May increase detection of major fetal abnormality (RR 3.45, 95% 1.67-7.12)
- Probably increase termination for major anomaly (RR 2.36, 95% 1.13-4.93)

Routine Ultrasound for Fetal Assessment before 24 weeks' Gestation
Cochrane Database Syst Rev. Aug 2021

Cochrane OB Ultrasound Review:
Issues They Cited

- Late OB Ultrasound (2015):
  - None of papers had treatment algorithms
    - No standard management
  - Most from 1984 – 1996

- Early OB Ultrasound (2021):
  - May underestimate effect of US because
    - Ultrasound technology evolution in 1980 – 1990's
    - Control arm also got US

Can't withhold ultrasound from control patients!

Data Support of OB Ultrasound in HIC is Complicated

???

Does OB Ultrasound Work in LMIC?

Global Network for Women's & Children's Health Research (GNWCHR), Nov 2018

- 5 Rural LMIC
  - Guatemala, Pakistan, DRC, Kenya, Zambia
  - 500 care centers
- Ultrasound Training
  - 2 wks Hand-on training
  - 12 wks pilot & supervision
  - No prior US experience
  - Midwife, X-ray Tech, RN, Medical Officer
- 24,263 Intervention
  - US at 16-22wk and 32-36wk
- 23,160 Control

RL Goldenberg,,, EM McClure
Routine Antenatal Ultrasound in Low- and Middle-income countries: first look – a cluster randomized trial
BJOG, Nov 2018

Global Network for Women's & Children's Health Research (2018)

Conclusion

No increase:

ANC visits or Hospital delivery

No decrease:

Maternal Mortality
Maternal Near-miss Mortality
Neonatal Death or Stillbirth

"…without improvement in the quality of care at health facilities in LMIC, there appears to be limited impact of routine ANC use of US alone."

Global Network for Women's & Children's Health Research (2018)

Results

Multiple Gestation	1.3%
Growth Restriction	5.0%
Oligohydramnios	0.9%
Polyhydramnios	1.1%
Placenta Previa (>28wks)	0.3%
Abnormal Lie	5.6%

9.3% referred for further care

Only 71.1% attended the referral appointment

Global Network for Women's & Children's Health Research (2018)

Issues They Cited:
Why no benefit shown?

- Control group: 43% got ultrasound
- Intervention group: 22% didn't get ultrasound
- 28.9% didn't go to referral appointment

Huge Drop-in!

Large Drop-out!

Evidence for OB Ultrasound in LMIC

Global Network for Women's & Children's Health Research (Nov 2018)

TBA Traditional Birth Attendant

Rural Areas of:

McClure *et al. BMC Pregnancy and Childbirth* 2014, **14**:73
http://www.biomedcentral.com/1471-2393/14/73

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Table 3 Ultrasound trial sites

	Chimaltenango Guatemala	Lusaka Zambia	Western Provence Kenya	Thatta Pakistan	DRC
Study Clusters* (N)	18	10	12	10	8
Births 2009-2010 (N)**	10,706	14,154	17,541	25,909	NA
Birth attendant (%)					
Physician	27.9	2.7	1.6	22.7	0.1
Nurse/midwife	1.5	43.9	34.8	25.1	21.3
TBA	70.4	32.2	51.1	49.7	77.5
Family/unattended	0.2	21.2	12.5	2.5	12.1
Birth location (%)					
Hospital	26.0	5.7	9.5	24.3	0.1
Health clinic	3.1	42.0	25.6	23.3	25.4
Home	70.9	52.2	64.9	52.3	74.5
C-section rate (%)	11.4	1.0	1.1	6.6	0.1
Mortality rates/1000					
Neonatal (28 day) **	27	22	16	45	27
Stillbirth	22	27	20	54	23
Maternal mortality ratio/ 100,000, Mean	95	211	88	239	540

*Study clusters for the Ultrasound Trial.
**DRC birth rates based on 2006–2007 and 7-day neonatal mortality rate [38].

USA

NMR 3.5

MMR 23.8

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Highest Physician Attendance

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Highest Home Birth Rate

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Highest Hospital Rate

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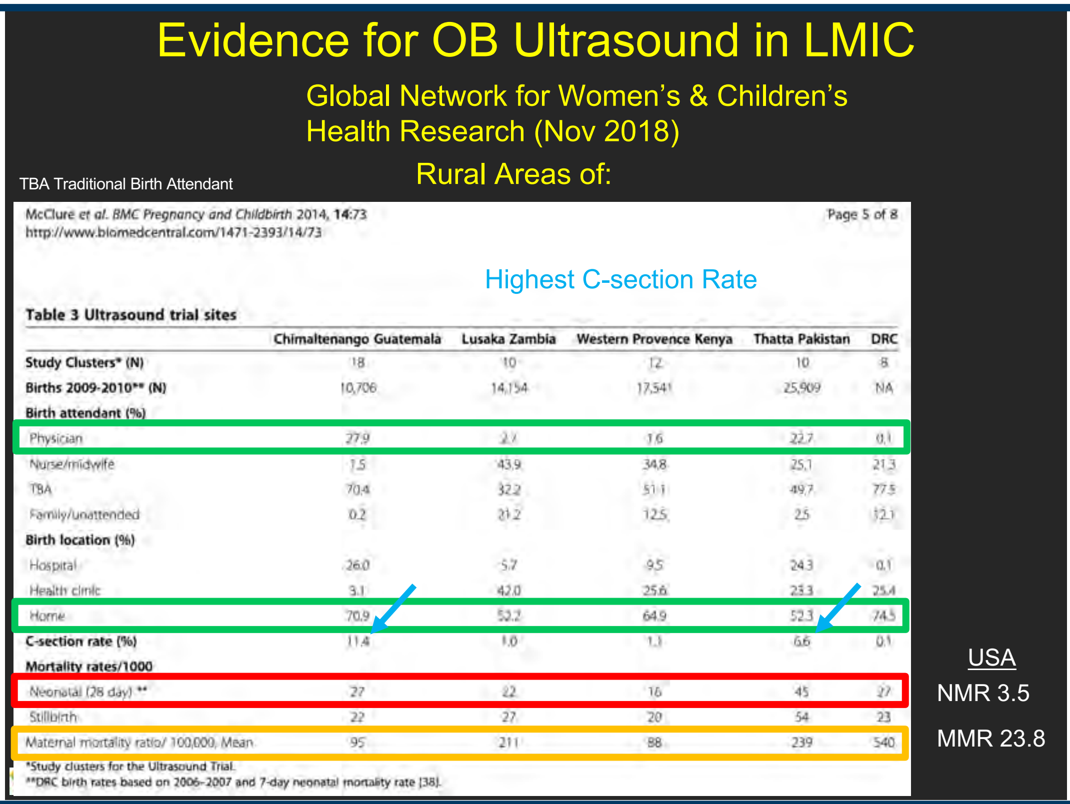

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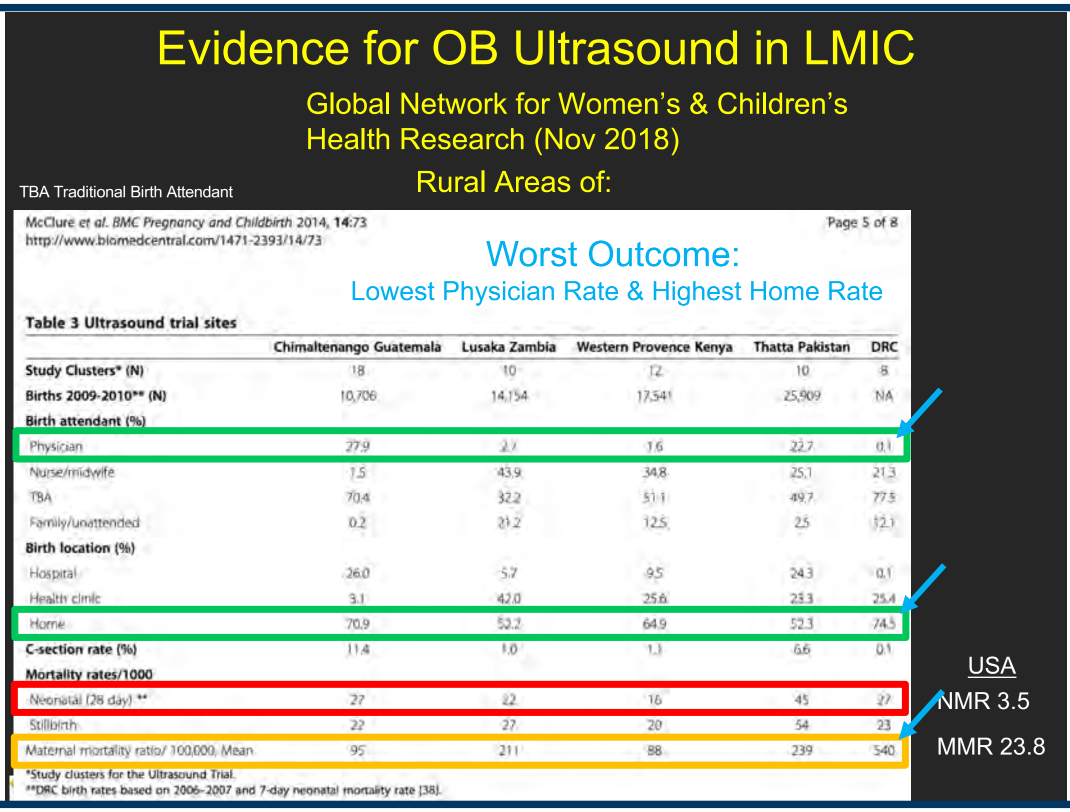

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Data Support of OB Ultrasound in LMIC is Complicated

???

What's going on?

Possibilities:

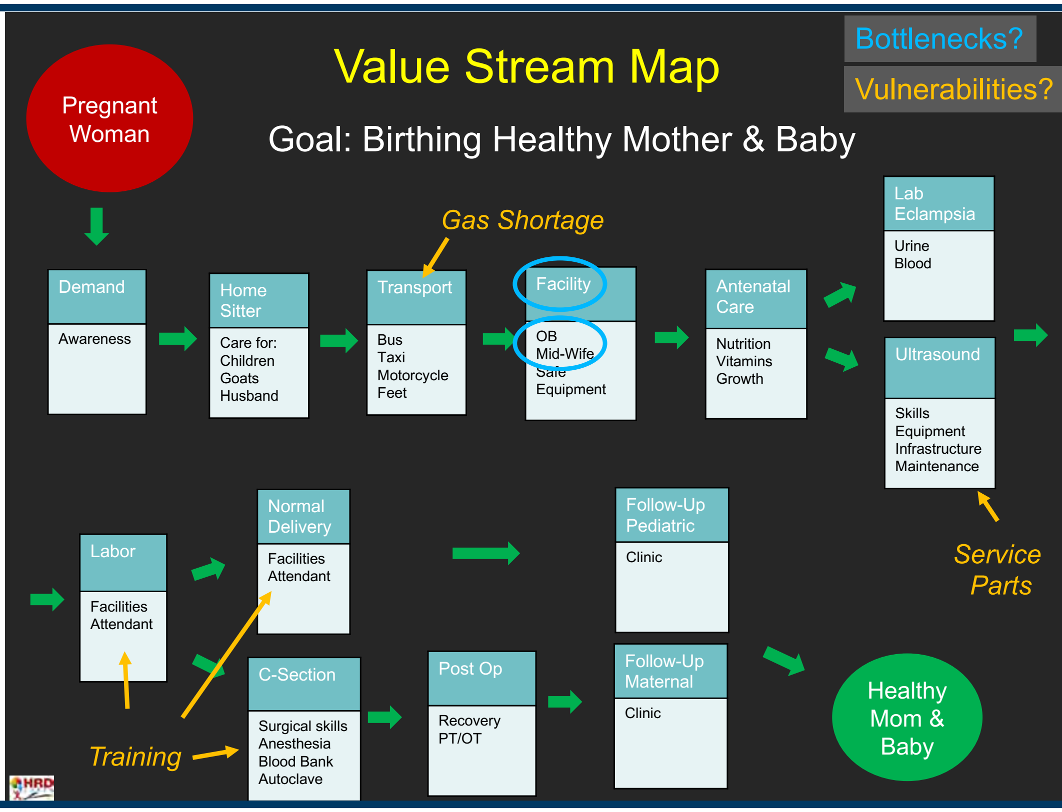
- Large Scale Project
- 'Weak Health Care Systems'
- Broken Value Stream Map

GNWCHR, BJOG, Nov 2018

Value Stream Map

- VSM: Diagram detailing all process steps
  - Box: describes a single process step
  - Arrows: show relationships & flow
  - Details for each step
    - Time duration
    - Staffing needs
    - Equipment needs
    - Cost
    - Vulnerabilities

Learning to See: Value Stream Mapping to Add Value and Decrease Muda
Mike Rother & John Shook
Lean Enterprise Institute. 2009



Recap of the "Data"

OB Ultrasound apparently may not have much impact in HIC or LMIC

Issues with OB Ultrasound "Data"

- Old papers
- Can't withhold Ultrasound
  - Drop-in & Drop-out
- "Weak healthcare systems"
- Broken Value Streams

Let's Charge Forward *Anyways!*

Improve Obstetrical Care in LMIC by Adding Ultrasound

Major Charity Foundation Press Release

Investing in Handheld Ultrasound Company

SHARE THIS PAGE:

[redacted]

[redacted]

[redacted] has created the world's first handheld whole body ultrasound system to democratize healthcare and provide global access to medical imaging. The device is critical to the foundation's vision of an ecosystem where hardware, software, data and expertise come together to improve maternal health. With the foundation's investment, the company is partnering with third parties to build key obstetric algorithms that will enable high quality pregnancy management in places where it is most in need in the developing world.

Investment Date: August 2018

Press Release

News Story

Major Charity Foundation

Grant

Purpose

To support product development for an AI-enabled, obstetric ultrasound device for LMICs

Division Gender Equality	Date MARCH 2022
Region served GLOBAL, AFRICA	Committed amount $5,915,885
Grant topic MNCH Discovery and Tools	Duration (months) 22
Grantee location [redacted], United States	

AI: Artificial Intelligence

Major Charity Foundation & Handheld Ultrasound Company

500 Ultrasounds for Kenya
500 Ultrasounds for S. Africa
3-months training

[redacted]

View All News

03/09/2022

[redacted] $5M Grant to Advance Maternal and Fetal Health

[redacted] to provide 1,000 healthcare workers in Sub-Saharan Africa with technology and training to empower better clinical decision-making through point-of-care ultrasound

GUILFORD, Conn. & NEW YORK--(BUSINESS WIRE)--[redacted], a digital health company transforming care with handheld, whole-body ultrasound, today announced it received a grant in the amount of $5 million from the [redacted] improve maternal and fetal health. Through this grant [redacted] will provide 1,000 healthcare workers in Sub-Saharan Africa with [redacted] the world's only handheld, whole-body point-of-care ultrasound probe.

Complications of pregnancy represent some of the largest contributors of morbidity and mortality in resource constrained care settings. [redacted] will bring 1,000 [redacted] probes to Sub-Saharan Africa to improve community access to medical imaging. As part of this initiative, 500 probes will be given to mid-level practitioners in Kenya and 500 will be distributed to healthcare workers in South Africa; both distributions will focus on improving maternal and fetal health.

"Many places in the world, especially low- and middle-income countries, are diagnostic deserts, leaving practitioners with virtually no imaging modalities to aid in the diagnosis and subsequent treatment of patients," said Dr. [redacted], President and CEO [redacted]. "At [redacted] we've long envisioned and innovated for the next generation of point-of-care. With this grant, we take another important step toward improving worldwide access to medical imaging and will also demonstrate how mid-level practitioners can meaningfully enhance care for pregnant women and their unborn infants."

"For years, the [redacted] Foundation has supported [redacted] efforts to improve healthcare in the places where it's most needed," said Darius Shahida, Chief Strategy and Business Development Officer a [redacted]. "This new grant represents an important step toward that goal in its potential to signal the transformational impact of [redacted] technology in some of the most remote settings."

Major Charity Foundation & Handheld Ultrasound Company

[redacted] Overview News Events & Presentati

1 month post training survey: 90% of respondents have identified a high-risk condition

View All News

12/19/2022

[redacted] Completes Successful Deployment ... Workers Acros

Three-month training program resulted in impressive ultrasound adoption rates and broad identification of high-risk conditions, with hundreds of mid-level practitioners enhancing maternal-fetal care through handheld ultrasound

Successful deployment and trainings complete phase one of a historic two-part deployment, under a $5 million grant from the [redacted] Foundation, to expand access to medical imaging across Sub-Saharan Africa

BURLINGTON, Mass. & NAIROBI, Kenya--(BUSINESS WIRE)-- [redacted]), a digital health company transforming care through the power of handheld, whole-body ultrasound, today announced the completion of phase one of its deployment and training program in Kenya. The program brought 500 [redacted] devices and ultrasound training to local mid-level healthcare practitioners and was part of a larger effort — supported by a $5 million grant from the [redacted] Foundation — to equip 1,000 healthcare workers in Sub-Saharan Africa with [redacted] the world's only handheld, whole-body ultrasound probe to advance maternal and fetal health.

... and now have the skills and equipment to bring [redacted] back to across Kenya. (Photo: Business Wire)

The first-of-its-kind program in Kenya, previously announced and launched in September 2022, represents an important step toward improving worldwide access to essential medical imaging. Designed as an exemplary global health delivery intervention, the program meaningfully measured the impact that mid-level practitioners can have on maternal-fetal care when provided the right digital health tools, paired with scalable in-person training.

10 cohorts, comprising 514 practitioners in total, have completed training and now have the skills and equipment to bring free point-of-care ultrasound assessment back to 224 public health facilities across eight Kenyan counties, as well as two Urban facilities and three training institutions in Nairobi. These facilities, predominantly in rural settings and without access to broadband, are the safety net for hundreds of thousands of patients in the community, the majority of whom never before received ultrasound during their pregnancy. Initial data signify an impressive adoption rate, as demonstrated by tens of thousands of scans completed since the program launch, and a one-month post-training survey finding that over 90% of respondents have identified a high-risk condition using the [redacted]

Major Charity Foundation & Handheld Ultrasound Company

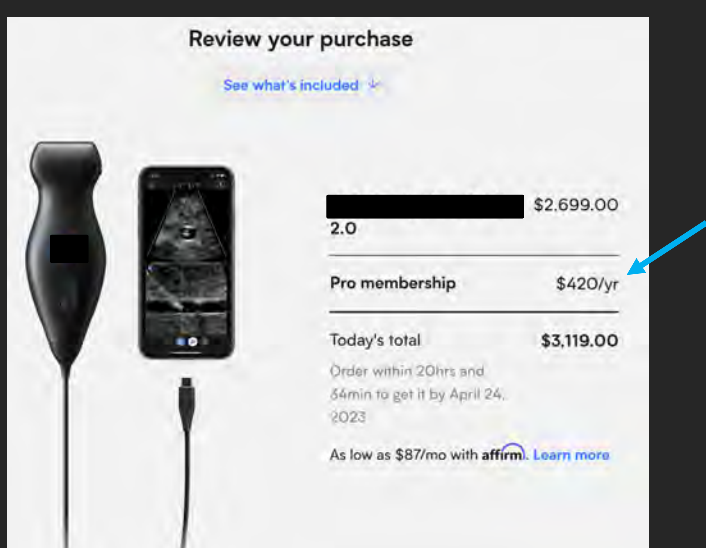
Questions we should ask:

- What happened to the Value Stream?
- Where are referrals going?
- What are outcomes?
- GNWCHR OB ultrasound project didn't have impact, will this large-scale project work?

General Question:
Does Big Aid Work?

These authors say ‘No’!

Handheld Ultrasound Company



April 2023

Handheld Ultrasound Company

Annual 'Membership' Fee

Is a membership required?

Purchase of a new [redacted] requires the purchase of a [redacted] membership. After the first year, if Pro members choose not to renew their membership, they would lose access to member-only features, such as Power Doppler, study sharing, and the education portal. They would continue to have access to the studies they've already saved, but would no longer be able to save new studies. The [redacted] would only operate in a live view mode with access to B-mode and Color Doppler.

Major Charity Foundation & Handheld Ultrasound Company

Questions we should ask:

- Who owns the images?
- What's being done with the saved images?
- Will the 'AI product development' help the people of Africa?

Purpose

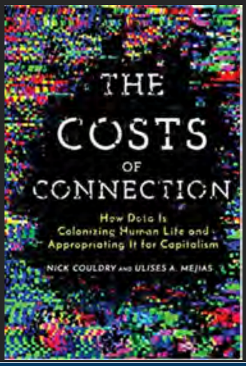
To support product development for an AI-enabled, obstetric ultrasound device for LMICs

Division Gender Equality	Date MARCH 2022
Region served GLOBAL, AFRICA	Committed amount $5,915,885
Grant topic MNCH Discovery and Tools	Duration (months) 22

Data Colonialism

Colonialism
- Extractive
- Asymmetric

Will Africans get the Artificial Intelligence capability even if they don't pay for the membership?



The Costs of Connection:
How Data Is Colonizing Human Life & Appropriating It for Capitalism.
Nick Couldry & Ulises Mejias. 2019

Recap

Unclear data support for OB ultrasound benefit in HIC & LMIC

Big Aid may not work either…

Precision Charity

Approach is scaled smaller to foster customization, transparency, nimbleness & accountability

Precision Charity

Making a Project 'Right'

- Right Size
- Right Tools
- Right People
- Right Training
- Right Ownership
- Right Setting
- Right Timeframe

Key Features of Precision Charity

- Requires hands-on detailed knowledge
  - Boots in the mud approach
    - Go to 'Gemba'
  - Direct line of sight
  - Client focused & lead
- Requires personal relationships
- Hard to scale-up

Applying 'Precision Charity' Approach to LMIC Obstetrical Ultrasound

- POCUS
  - Point of Care Ultrasound (Hand-held)
- Personally selected clinicians
- Tailored training
- Long-term support
- Build & integrate into existing clinical landscape

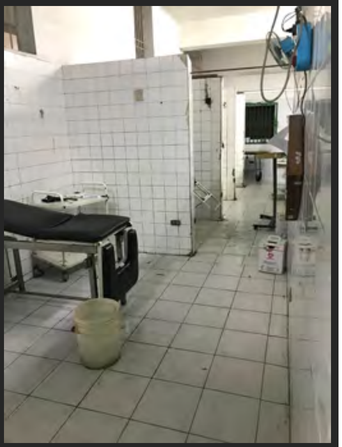
Haiti Examples

Two HRD Corps Ultrasound Projects

Precision Charity

Full Size Ultrasound - Chancerelles

- Invited by Haitian residents to help Chancerelles Hospital
  - Only OB hospital for Port au Prince, Haiti
  - Chancerelles Hospital had *zero* functioning Ultrasound



Precision Charity

Full Size Ultrasound - Chancerelles

- Donated Sequoia Ultrasounds to Chancerelles
  - One in Mar 2018
  - Two in Dec 2019
- Immediately Operational
  - OB attendings and residents already new how to scan
- Closed for 1 year due to security risks
  - Re-opened Feb 2022

Precision Charity

Full Size Ultrasound - Chancerelles

Chancerelles Dec 2019

Logbook of Patient Exams
Chancerelles Oct 2020

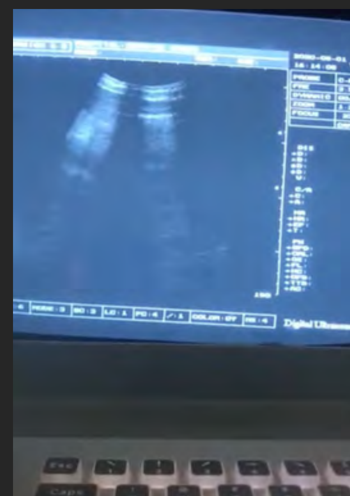
N+1 rule
Donate an extra for backup capacity

Precision Charity

POCUS – Serving Sante

Serving Sante: OB Charity

- Cap Haitien, Haiti
- Dr. Nelly Osias: Haitian Obstetrician
- Broken Ultrasound



Original Full-size Ultrasound
Poor Image & Cracked Crystal
Aug 2020

Precision Charity

POCUS – Serving Sante

Donated 2 VistaScans

Dr. Osias
Hand-held Ultrasound
March 2021

N+1 rule
Donate an extra for backup capacity

Precision Charity
POCUS – Serving Sante

Full Value Stream present
- Facility: Serving Sante charity
- Staff: Dr. Osias
- Available Skillsets:
  - Prenatal care
  - Ultrasound
  - Labor management
  - Cesarian Section
  - Postop & Post labor care

Precision Charity Outcomes?

Need proof?
- Academics vs Real world

Collecting exam data

Feedback from Dr. Osias
- She finds critical diagnoses she can act on
- Often electric power is out at Justinien Hospital, and VistaScan is the only functioning Ultrasound
- The portability is great

Serving Sante
Hand-held Ultrasound
Aug 2021

Summary

- Papers on OB ultrasound impact in HIC & LMIC
  - Data skepticism
  - Why studies didn't show impact
  - Value Stream Mapping
  - Potential fallibility of Big Aid
- 'Precision Charity'
  - Making a project 'right'
  - Custom tailored engagement
- HRD Corps OB ultrasound projects in Haiti

Let's be:

Data Skeptics

Data Savvy

Thank You!

HRD CORPS

bpschmit12@gmail.com

Disclosures

- Consultant with Radiology Business Solutions
- Founder of Humanitarian Radiology Development Corps, 501c3 charity
- Unpaid Advisor for Emagine Solutions Technology
  - VistaScan – handheld ultrasound
  - The Journey – pregnancy monitoring app
- No Financial Conflict

Applications of Artificial Intelligence in Oncology

June 16, 2023

AHMED ALI MD,
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Speaker Disclosure

- I have NO financial disclosure or conflicts of interest with the presented material in this presentation.

Objectives

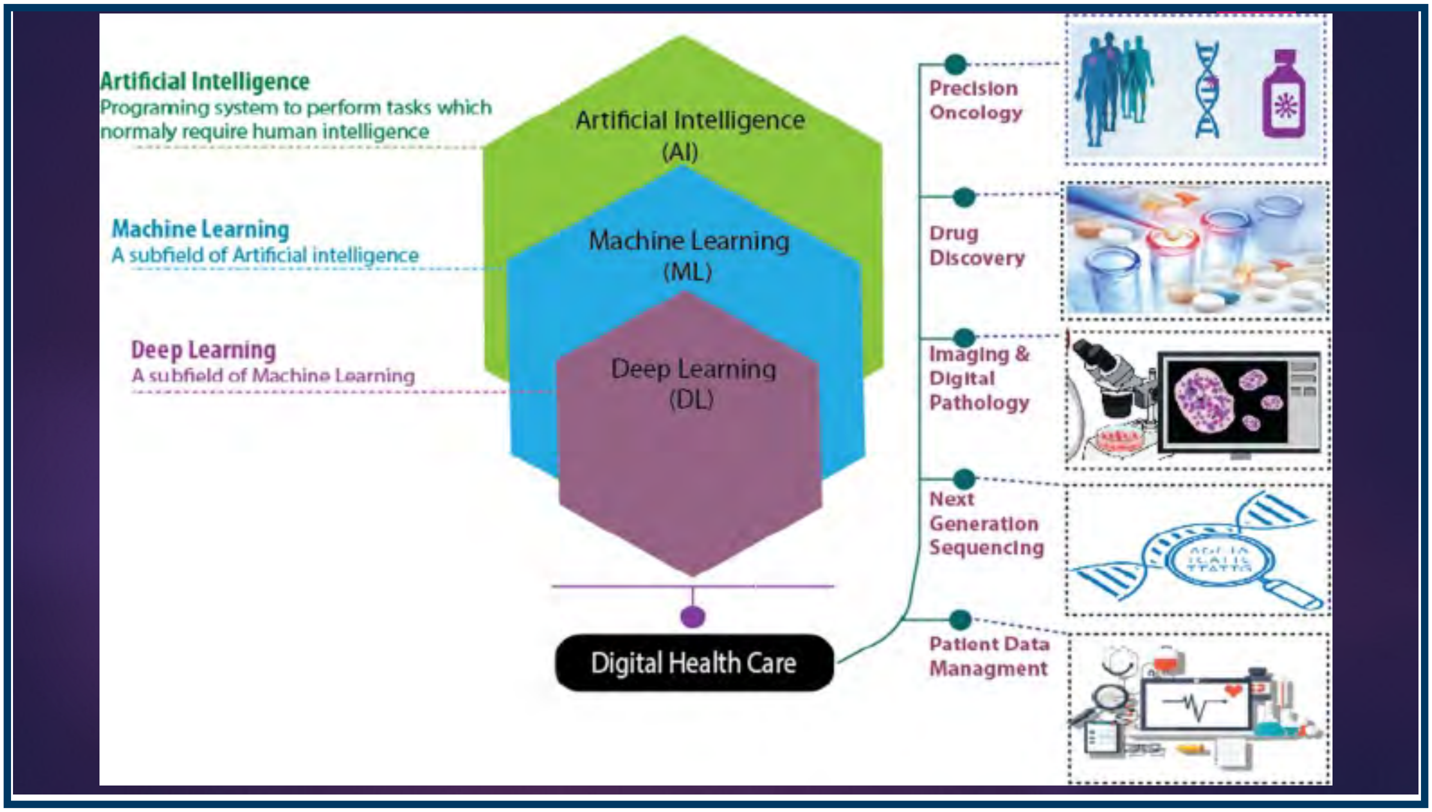
- Overview of Artificial intelligence (AI)
- Different layers of AI
- AI model formation
- Applications of AI in Oncology

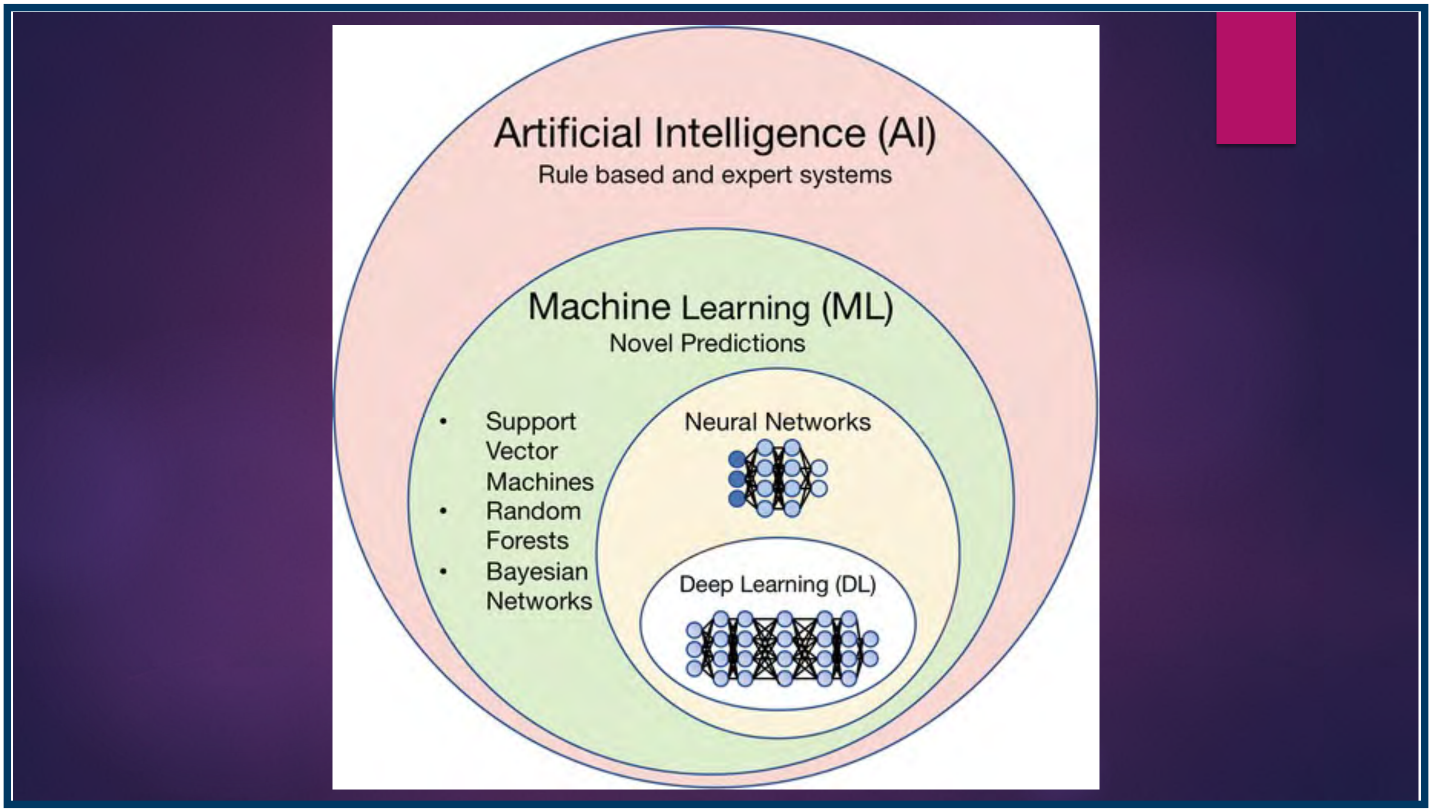
Overview of AI

- The Artificial intelligence can be described as a branch of computer science dealing with the simulation of intelligent behavior in computers.
- It relies on computers following algorithms established by humans or learned by computer method to support decisions or execute certain tasks .
- The broad field of computer science in which machines or algorithms are programmed to simulate human intelligence is encompassed by the term AI.

- Artificial intelligence (AI) in oncology is no longer hypothetical, and its U.S. Food and Drug Administration–approved use is expanding in several clinical scenarios, most prominently involving cancer diagnostics and computer vision.
- There are unique ethical and legal considerations associated with artificial intelligence models that limit their broad application and reproducibility, including their inherent bias when trained with data sets that disproportionately exclude underrepresented persons.

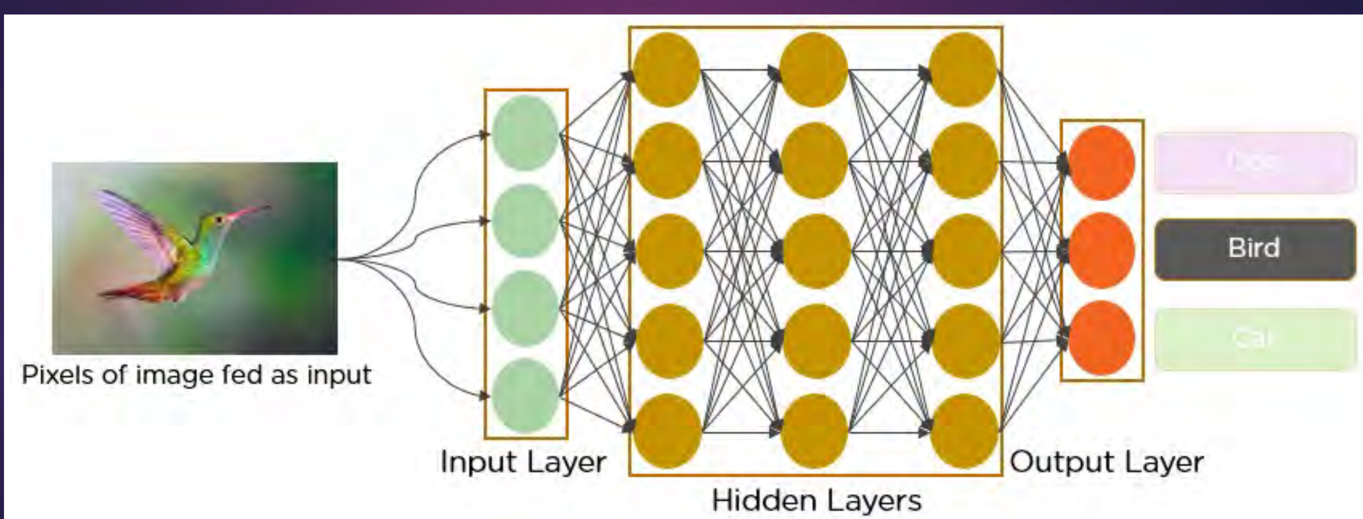
- Machine learning (ML) is a branch of AI in which computers perform defined tasks and apply statistical methods to detect hidden patterns in the data and to improve model performance.
- The ML subfield of Deep Learning (DL), unlike classic ML, does not require human-defined heuristics to find a solution for a task. Rather, DL operates by the power of multilayered neural networks, thereby enabling self-discovery of features unknown or unanticipated by humans and eliminating manual human effort for feature extraction.


Artificial Intelligence
Programing system to perform tasks which normaly require human intelligence
Machine Learning
A subfield of Artificial intelligence
Deep Learning
A subfield of Machine Learning
Artificial Intelligence (AI)
Machine Learning (ML)
Deep Learning (DL)
Digital Health Care
Precision Oncology
Drug Discovery
Imaging & Digital Pathology
Next Generation Sequencing
Patient Data Managment

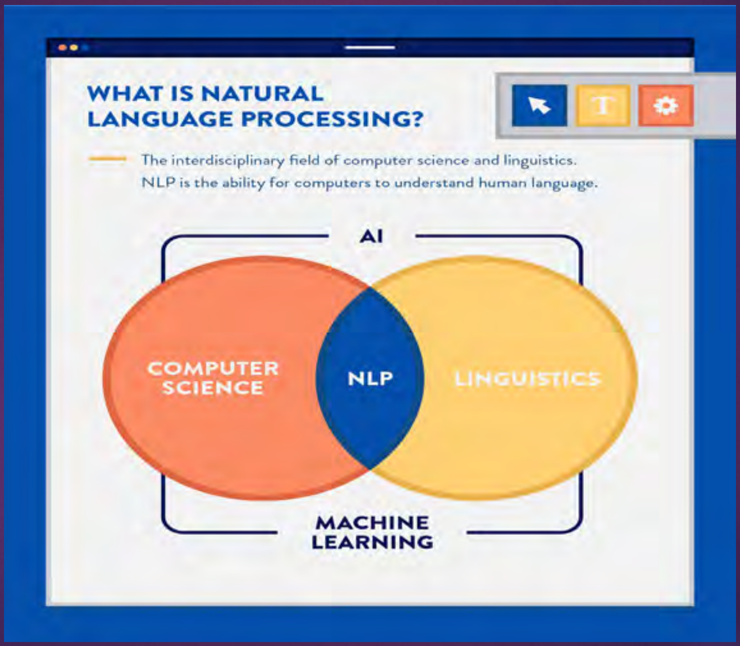

Artificial Intelligence (AI)
Rule based and expert systems
Machine Learning (ML)
Novel Predictions
• Support Vector Machines
• Random Forests
• Bayesian Networks
Neural Networks
Deep Learning (DL)

- Convolutional neural networks (CNNs), a type of DL, along with tremendously growing computing power have led to accelerated development of AI-based applications, particularly in medical imaging.
- Natural language processing (NLP) is an adjacent specialty within AI that attempts to interface human language with machine interpretation; it is used to transform unstructured data—from EHR clinical notes and diagnostic or procedural reports—into discrete data elements.

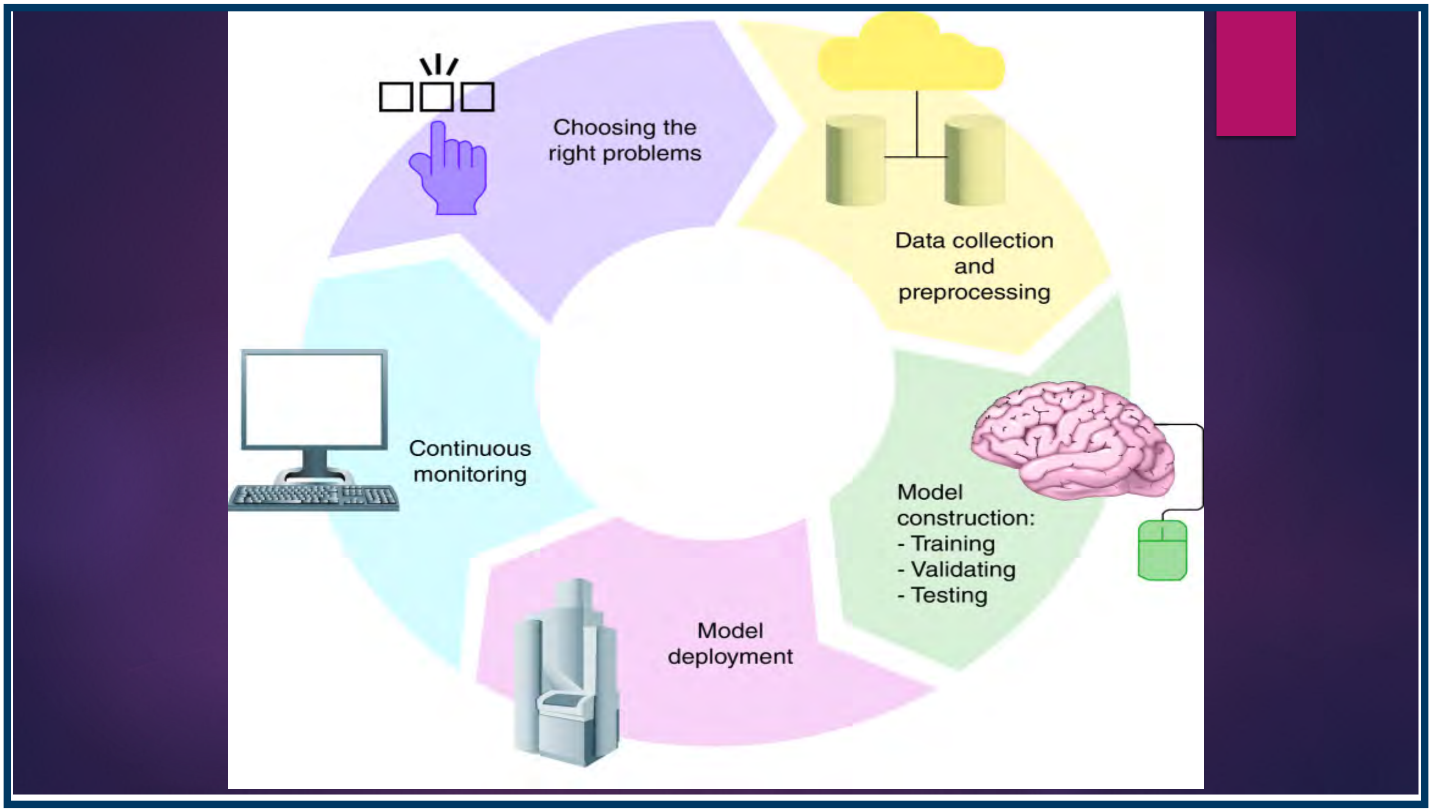
CNN

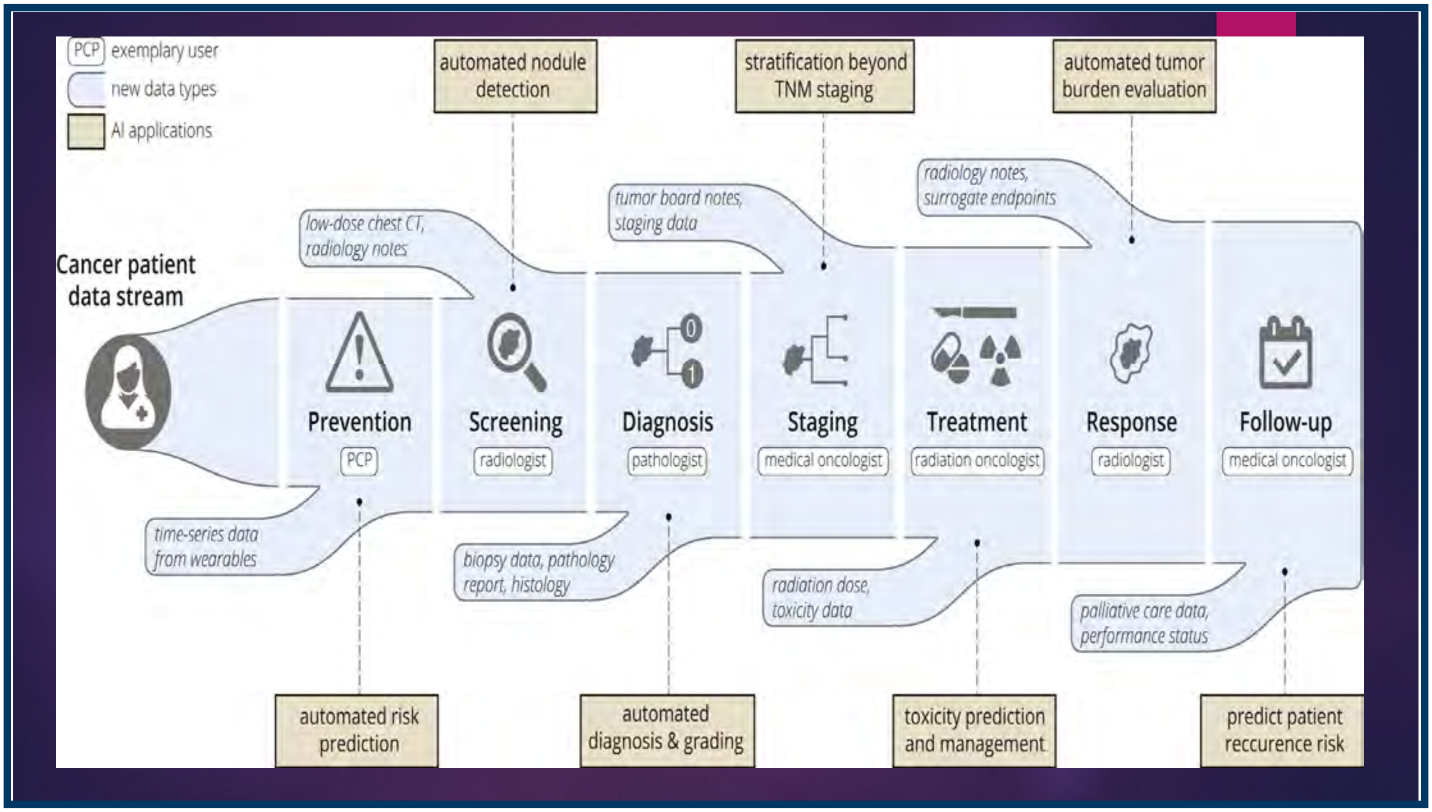


NLP



- The development and validation of ML models include
  - The correct problem
  - Data collection
  - Processing
  - Internal validation
  - Optimization
  - Evaluation
  - External validation


Choosing the right problems
Data collection and preprocessing
Model construction:
- Training
- Validating
- Testing
Model deployment
Continuous monitoring

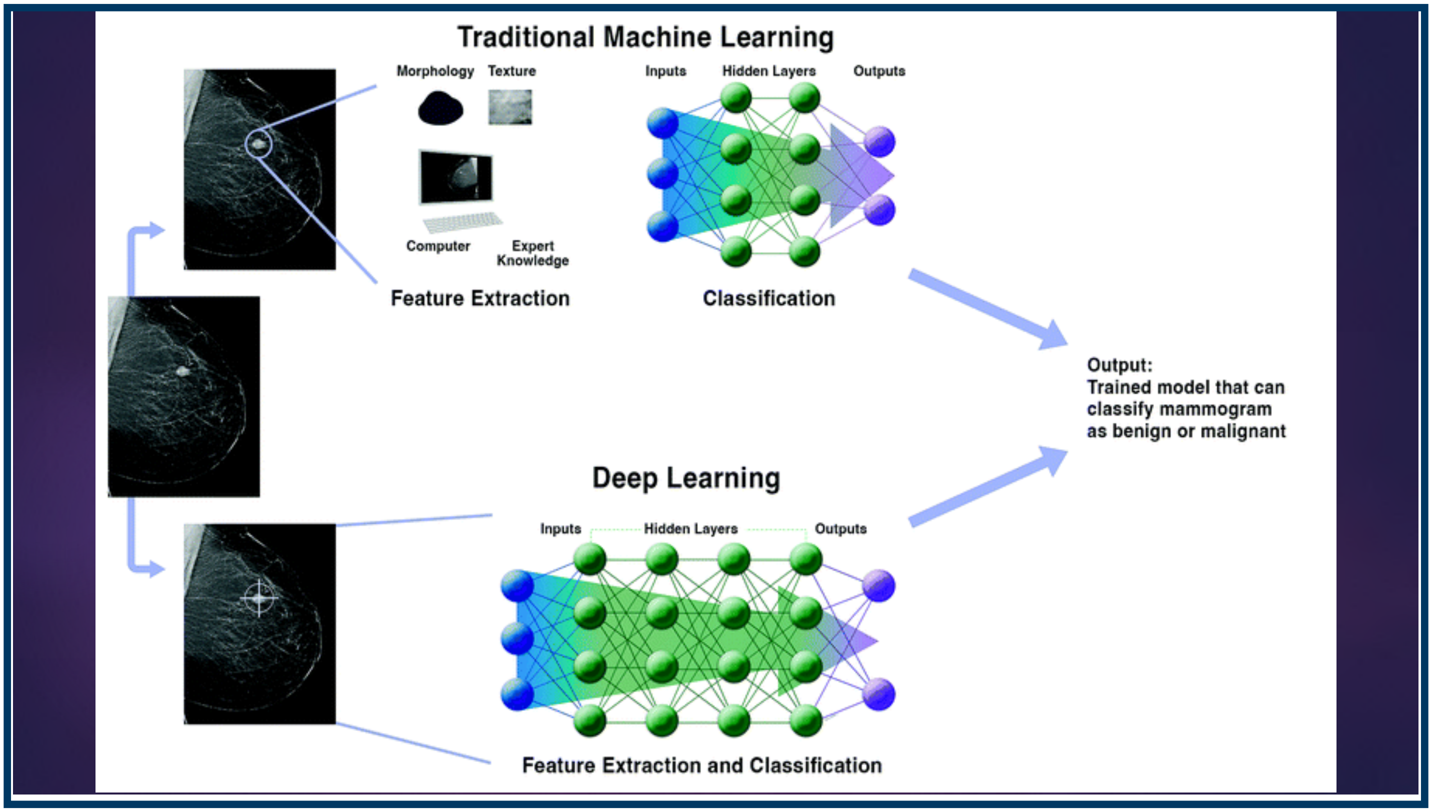

PCP exemplary user
new data types
AI applications
Cancer patient data stream
automated nodule detection
stratification beyond TNM staging
automated tumor burden evaluation
low-dose chest CT, radiology notes
tumor board notes, staging data
radiology notes, surrogate endpoints
Prevention
PCP
Screening
radiologist
Diagnosis
pathologist
Staging
medical oncologist
Treatment
radiation oncologist
Response
radiologist
Follow-up
medical oncologist
time-series data from wearables
biopsy data, pathology report, histology
radiation dose, toxicity data
palliative care data, performance status
automated risk prediction
automated diagnosis & grading
toxicity prediction and management
predict patient reccurence risk

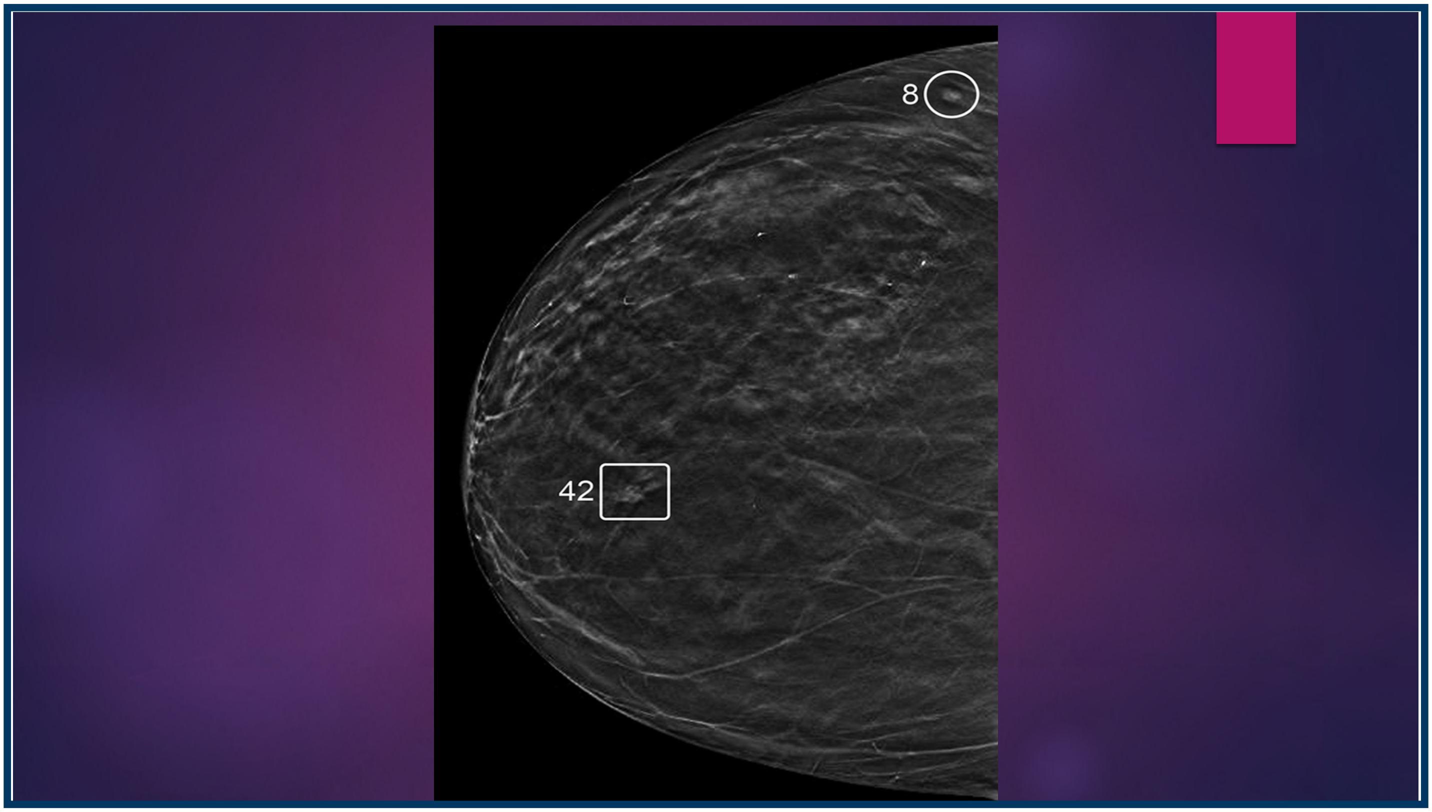
AI in Oncology

- Artificial intelligence for cancer imaging
- Personalized medicine
- Cancer research
- Cancer screening
- Therapy response
- Treatment complications
- Survival & disease recurrence

Cancer Imaging

- In the field of oncologic radiographic imaging, AI is being used for detection and diagnosis.
- Computer-aided detection has been used historically for breast cancer imaging, but it did not demonstrate high clinical value. Hence, breast cancer imaging has been a prime target for AI-based cancer detection.
- For example, AI-based models are now routinely a part of breast imaging and are being used clinically in many practices. There are at least five U.S. Food and Drug Administration–approved breast-imaging detection and diagnosis algorithms.


Traditional Machine Learning
Morphology
Texture
Computer
Expert Knowledge
Feature Extraction
Inputs
Hidden Layers
Outputs
Classification
Output:
Trained model that can classify mammogram as benign or malignant
Deep Learning
Inputs
Hidden Layers
Outputs
Feature Extraction and Classification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42

TABLE 1: Examples of FDA-Approved Lesion Detection and Diagnosis Applications for Screening Mammography[a]

Tool (Company)	No. of Cases	No. of Radiologists in Reader Study	Reported AUCs: Radiologists Aided Versus Radiologists Unaided	FDA Class	Type of Mammogram	Vendor
MammoScreen 2.0 (Therapixel)[b] [25, 26]	240 for DM 240 for DBT	14 for DM 20 for DBT	0.80 vs 0.77 for DM 0.83 vs 0.79 for DBT	II	DM and DBT	GE Healthcare (DM) Hologic (DM and DBT)
Genius AI Detection (Hologic) [27]	390	17	0.83 vs 0.79	II	DBT	Hologic
ProFound AI Software 3.0 (iCAD)[c] [28, 29]	260	24	0.85 vs 0.80	II	DBT	GE Healthcare, Hologic, Siemens Healthineers
Transpara 1.7.0 (ScreenPoint Medical)[d] [30, 33, 100]	240 for DM 240 for DBT	14 for DM 18 for DBT	0.89 vs 0.87 for DM 0.86 vs 0.83 for DBT	II	DM and DBT	GE Healthcare (DM), Philips Healthcare (DM), Fujifilm (DM and DBT), Hologic (DM and DBT), Siemens Healthineers (DM and DBT)
Lunit INSIGHT MMG (Lunit) [31]	240	12	0.81 vs 0.75	II	DM	GE Healthcare, Hologic, Siemens Healthineers

Note—DM = digital 2D mammography, DBT = digital breast tomosynthesis.
[a]The information in this table is based on the referenced FDA documentation and, where indicated, verification by company representatives.
[b]De Snoeck Q, Therapixel representative, written communication, 2021.
[c]Hawkins R, iCAD representative, written and oral communications, 2021.
[d]Karssemeijer N, ScreenPoint Medical representative, written communication, 2021.

Personalized Medicine

- Cancer is a disease of the genome, so it's no wonder that oncology has particularly benefited from AI innovations.
- For instance, DNA methylation assessment in cancers has been proven to be useful for classification and prognostication.
- The machine-determined DNA methylation approach can lead to the recategorization of more than 70% of human-labeled tumors, which could lead to significantly different prognostication and treatment decisions.

- Assistant-decision systems, such as Watson for Oncology, have shown acceptable concordance with the decisions made by multidisciplinary teams. This can aid in patient-level decision making in a fast and less resource-intensive manner.
- AI models also promise to be valuable in complex cases such as in those patients who present as cancer of unknown primary, which still represents 1–2% of newly diagnosed cancers.
- A deep learning model based on H&E-stained whole-slide imaging was able to classify the site of origin of metastatic tumor with 83% accuracy.

- An emerging cancer screening strategy is the development of whole blood pan-cancer detection from deep sequencing.
- Whole blood is attractive for analysis given its ready accessibility and the fact that all cells in the body, either directly or indirectly, have access to the circulatory system.
- Substantial progress has been made in identifying circulating tumor cell-free DNA for cancer prognostication, which subsequently has led to its evaluation for cancer screening and detection, as well as for cancer-recurrence surveillance.

Cancer Research

- AI is also applicable in preclinical settings such as basic / translational research and cancer drugs development.
- AI identifies potential new drugs within a short time period at an affordable cost.
- Drug testing can simulate and predict the effectiveness of cancer therapies leading to better results in *in vivo* experiments, which in turn would accelerate clinical research.

- Clinical trials can also become more efficient with the use of AI. Study outcomes can be predicted using AI models which could significantly lower costs of drug development.
- AI has been used to identify patients for clinical trials by incorporating inclusion and exclusion criteria to search EHR and identify eligible patients, hence facilitating participant accrual.
- Data suggested that a higher rate of clinical trial enrollment not only leads to faster advances in cancer treatment but is also related to better cancer population survival outcomes.

Cancer Screening

- AI-algorithms have proven to be able to assess unstructured data and accurately estimate the probability of patients developing various diseases including cancer.
- AI models can refine risk-stratification definitions and impact decisions on cancer screening recommendations with satisfactory accuracy.
- For example, For tumors with no established screening approach which are mainly asymptomatic at initial stages, personalized risk-prediction could facilitate early diagnosis and potentially lead to higher cure rates.

- A well-known application of EHR data is disease risk stratification. Calculating risk stratification was limited by the quantity of data that could be retrospectively reviewed, and analyzed using traditional statistical methods.
- Artificial intelligence-based algorithms have proven to be able to assess unstructured data and accurately estimate the probability of patients developing various diseases including cancer

Therapy Response

- AI can help predicting treatment response using tumor characteristics obtained from radiologic images. Individual patient responses to high-cost treatments such as immunotherapy can be predicted and may help in-patient care decision-making, and facilitate efficient use of healthcare resources.
- Prediction of complete pathological response after neoadjuvant treatments could reduce treatment intensity since it allows identification of patients who would be candidates for a conservative approach rather than radical interventions.

- In one study, A correlation between immune microenvironment and pathologic complete response (pCR) in Breast cancer (BC) patients receiving neoadjuvant treatment (NAT) in an RNA-seq dataset.
- Then, Machine learning models to predict pCR with NAT for BC patients using immunological gene expression measured by the RNA-seq platform and validated the predictive power and robustness of the models in independent external datasets.
- It was proven that the model was related to the immune microenvironment and genomic mutations.

Treatment complications

- AI has the potential to predict treatment-related toxicity related to radiation and chemotherapy.
- This has the potential to guide the discussion of risks and benefits associated with different treatment modalities and support personalized RT dose-delivery.
- ML models have been able to predict visit to emergency rooms and hospital admissions due to cancer therapy-related symptoms.
- Using those predictions in clinical practice can help with the provision of a preventive supportive approach to high-risk patients.
- This would not only improve patient care but also relieve healthcare systems with the burden of preventable hospital encounters.

Survival & disease recurrence

- Algorithms for survival prediction have been developed for many cancer types, including breast, prostate and lung cancers.
- AI-based algorithms have shown better accuracy for predicting survival than conventional analytic approaches.
- In addition, the risk of disease recurrence after curative treatment can been predicted using AI models. The use of AI for recurrence prediction has showed increased accuracy compared with conventional statistical models, which will further support clinical follow-up plan optimization.

Summary

- The promise of highly personalized oncology care using AI technologies has been forecasted since the emergence of the field.
- Examples of successful clinical applications of AI can be found throughout the cancer continuum and in multidisciplinary practice.
- The future of precision oncology, in which living databases of multimodal datatypes are recursively used to improve clinical models, may yield unprecedented patient outcomes.
- There are unique ethical and legal considerations associated with artificial intelligence models that limit their broad application and reproducibility, including their inherent bias when trained with data sets that disproportionately exclude underrepresented persons.

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Legal Issues in Psychiatry and Medicine

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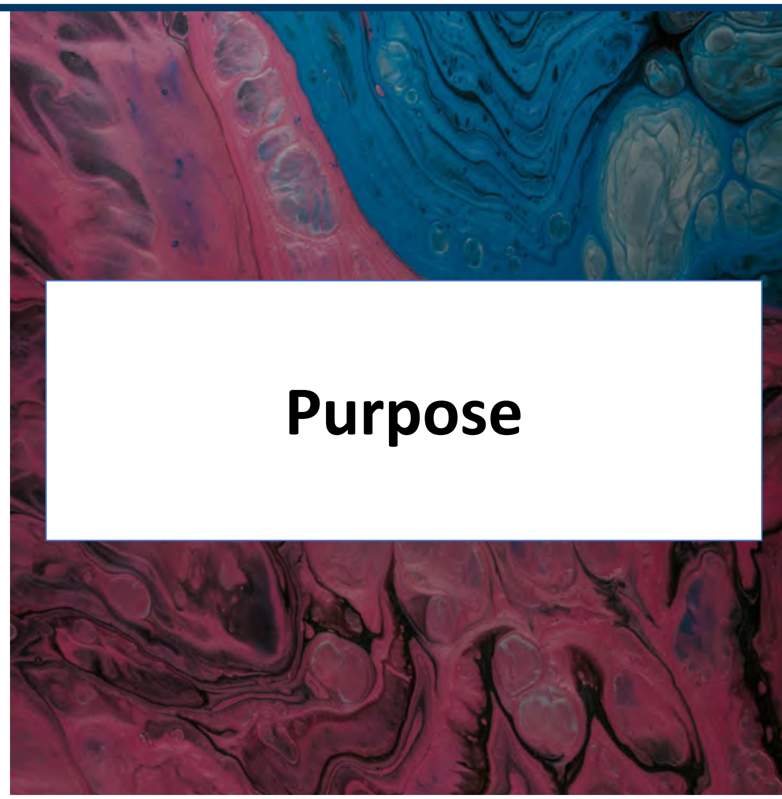
Disclosures

- None

Purpose:

-To update and optimize the knowledge base of attendees in some concepts of forensic medicine



Objectives:

-To identify, update the basic legal principles underpinning the process of psychiatric admission and hospitalizations.

-To review some of the legal issues common to the fields of both medicine and psychiatry.

-To clarify the penumbrae of the notions of competence, and decisional capacity as they apply to decision-making during and at the end of life.

- Legal principles: police powers and parens patriae
- Concepts of Dangerousness
  - Severe mental illness
  - Dangerousness to self and/or others as a result of mental illness
- Mental hygiene laws from legislatures
  - 939 and 937 sections
- Patient's rights vs. society protections
- Voluntary vs. involuntary hospitalizations

Legal Criteria for Evaluations and Admissions

- Concepts of proof
  - Preponderance of the evidence (P 51%)
  - Clear and convincing evidence (CC 75%)
  - Beyond a reasonable doubt (BRD 99%)
- Capacity to stand trial. Necessary elements.
- Guilt and insanity
  - Not guilty because of insanity
  - Guilty, but insane
- Death sentence and insanity

Mental Illness and Criminal Justice

Competence vs. Decisional Capacity

- Legal vs. medical concepts
- Capacity is always assumed to be present unless…
- Related concepts: Confidentiality and privilege
  - Clinician’s obligations vs. patient’s rights

Competence vs. Decisional Capacity

- Capacity can be global, but almost always specific
- Capacity is flexible, fluid, may be transient and reversible
- Capacity is not diagnosis dependent

Decisional Capacity and Informed Consent

- Patient autonomy and informed consent
- Elements of informed consent
  - Voluntariness
  - Information
  - Capacity/Competence

Information Standards

- Dx and nature of the condition
- Nature and purpose of proposed treatment
- Risks and consequences
- Expected benefits and likelihood of success
- Available alternatives and their benefits and risks
- No treatment as an alternative

Capacity/Competency Standards (ERA)

- Evidence of a choice
- Logical Reasoning about the risk and benefits of the choice
- Appreciation of the consequences of the choice

Cultural/Ethnic Considerations of Informed Consent

Exceptions to Informed Consent

- Emergency situations
- Waiver (expressed instead of implied)
- Therapeutic privilege

Surrogate Decision-Making

- Before incapacity
  - Advance directives
  - Instructional directives
  - Proxy directives
  - Joint ownership and trusts
  - Wills

Surrogate Decision-Making

- After incapacity
  - Guardianship
  - Guardianship process
  - Guardianship termination
  - Representative payee

Other Specific Capacities

- Testamentary capacity
- Contractual capacity
- Driving capacity
- Capacity to work
- Testimonial capacity (Fact vs. Expert)

Testamentary Capacity

- Knowledge and understanding of a will
- Extent of their bounty
- Natural objects of their bounty
- Need for psychiatric evaluation or videotape
- Contestation of a will
- Posthumous assessment of the Testator

Questions, Comments, Concerns?

Thank You

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