La salute digitale tra deontologia medica e biodiritto

Guido Cavagnoli

Carlo Casonato

Responsabilità e deontologia

Giuramento di Ippocrate di Cos

1897 regolamento Ordine di Trento

1912 Codice dell'Ordine di Torino

1948 Referendum Federazione sul codice di Torino

1954 Pubblicazione del testo

1978 approvazione del testo dal Consiglio Nazionale

1989 Nuova edizione del codice di deontologia medica

1995 Nuova edizione del codice di deontologia medica

1998 Nuova edizione del codice di deontologia medica

2006 Nuova edizione del codice di deontologia medica

2014 Nuova edizione del codice di deontologia medica (con modifiche 2016, 2017, 2019)

73

REGOLAMENTO INTERNO

PER LA CAMERA DEI MEDICI

IN TRENTO

TRENTO
STAB. LIT. TIP. SCOTONI E VITTI, ED.
—
1897.

Codice di deontologia medica

Art. 1 *Definizione*

… Il Codice regola anche i comportamenti assunti al di fuori dell'esercizio professionale quando ritenuti rilevanti e incidenti sul decoro della professione…

Codice di deontologia medica

Art. 3 *Doveri generali e competenze del medico*

Doveri del medico sono **la tutela della vita**, **della salute psico-fisica**, **il trattamento del dolore e il sollievo della sofferenza**, nel rispetto della **libertà** e della **dignità** della **persona**, senza discriminazione alcuna, quali che siano le condizioni istituzionali o sociali nelle quali opera.

Al fine di tutelare la salute individuale e collettiva, il medico esercita attività basate sulle competenze, specifiche ed esclusive, previste negli obiettivi formativi degli Ordinamenti didattici dei Corsi di Laurea in Medicina e Chirurgia e Odontoiatria e Protesi dentaria, integrate e ampliate dallo sviluppo delle conoscenze in medicina, delle abilità tecniche e non tecniche connesse alla pratica professionale, delle innovazioni organizzative e gestionali in sanità, dell'insegnamento e della ricerca.

La **diagnosi** a fini preventivi, terapeutici e riabilitativi è una diretta, esclusiva e non delegabile competenza del medico e impegna la sua autonomia e responsabilità.

Tali attività, legittimate dall'abilitazione dello Stato e dall'iscrizione agli Ordini professionali nei rispettivi Albi, sono altresì definite dal Codice.

Codice di deontologia medica

Art. 10 *Segreto professionale*

Il medico deve mantenere il segreto su tutto ciò di cui è a conoscenza in ragione della propria attività professionale.

La morte della persona assistita non esime il medico dall'obbligo del segreto professionale. Il medico informa i collaboratori e discenti dell'obbligo del segreto professionale sollecitandone il rispetto.

La violazione del segreto professionale assume maggiore gravità quando ne possa derivare profitto proprio o altrui, ovvero nocumento per la persona assistita o per altri.

La rivelazione è ammessa esclusivamente se motivata da una giusta causa prevista dall'ordinamento o dall'adempimento di un obbligo di legge.

Il medico non deve rendere all'Autorità competente in materia di giustizia e di sicurezza testimonianze su fatti e circostanze inerenti al segreto professionale.

La sospensione o l'interdizione dall'esercizio professionale e la cancellazione dagli Albi non dispensano dall'osservanza del segreto professionale.

Codice di deontologia medica

Art. 20 *Relazione di cura*

La relazione tra medico e paziente è costituita sulla libertà di scelta e sull'individuazione e condivisione delle rispettive autonomie e responsabilità.

Il medico nella relazione persegue l'alleanza di cura fondata sulla reciproca fiducia e sul mutuo rispetto dei valori e dei diritti e su un'informazione comprensibile e completa, considerando il tempo della comunicazione quale tempo di cura.

Codice di deontologia medica

Art. 35 *Consenso e dissenso informato*

L'acquisizione del consenso o del dissenso è un atto di specifica ed esclusiva competenza del medico, non delegabile.

Il medico non intraprende né prosegue in procedure diagnostiche e/o interventi terapeutici senza la preliminare acquisizione del consenso informato o in presenza di dissenso informato.

Il medico acquisisce, in forma scritta e sottoscritta o con altre modalità di pari efficacia documentale, il consenso o il dissenso del paziente, nei casi previsti dall'ordinamento e dal Codice e in quelli prevedibilmente gravati da elevato rischio di mortalità o da esiti che incidano in modo rilevante sull'integrità psico-fisica.

Il medico tiene in adeguata considerazione le opinioni espresse dal minore in tutti i processi decisionali che lo riguardano.

Codice di deontologia medica

Art. 78 *Tecnologie informatiche*

Il medico, nell'uso degli strumenti informatici, garantisce l'acquisizione del consenso, la tutela della riservatezza, la pertinenza dei dati raccolti e, per quanto di propria competenza, la sicurezza delle tecniche.

Il medico, nell'uso di tecnologie di informazione e comunicazione di dati clinici, persegue l'appropriatezza clinica e adotta le proprie decisioni nel rispetto degli eventuali contributi multidisciplinari, garantendo la consapevole partecipazione della persona assistita.

Il medico, nell'utilizzo delle tecnologie di informazione e comunicazione a fini di prevenzione, diagnosi, cura o sorveglianza clinica, o tali da influire sulle prestazioni dell'uomo, si attiene ai criteri di proporzionalità, appropriatezza, efficacia e sicurezza, nel rispetto dei diritti della persona e degli indirizzi applicativi allegati

Problema medico legale

Vuoti di responsabilità

- **Colpevolezza:** ad es., un incidente stradale evitabile che coinvolge un sistema di sistema di guida automatizzato che nessuno potrebbe individualmente prevedere o prevenire.
- **Rendicontabilità morale** (obbligo di spiegare le proprie ragioni e azioni agli altri): ad es., un medico che utilizza sistemi di IA e che non è in grado di spiegare le ragioni della sua diagnosi a un paziente.
- **Rendicontazione pubblica** (obbligo per gli agenti pubblici di spiegare le loro azioni): IA che sposta i poteri discrezionali verso esperti analisti di dati (spesso esternalizzati a società private) il cui lavoro è più difficile da controllare pubblicamente.

Alcune avvertenze

- Gli sconvolgimenti [dell'intelligenza artificiale] possono intensificarsi rapidamente e diventare più spaventosi e persino cataclismici. Immagina come un robot medico, originariamente programmato per liberare il cancro, potrebbe concludere che il modo migliore per cancellare il cancro è quello di sterminare gli esseri umani che sono geneticamente predisposti alla malattia.

  (Nick Bilton, editorialista tecnologico su NYT)

- Se il governo regola l'uso di droni o cellule staminali o l'intelligenza artificiale, tutto ciò significa che il lavoro e la ricerca lasciano i confini di quel paese e vanno da qualche altra parte.

  (Peter Diamandis ingegnere, medico e imprenditore)

Un consiglio

- «Cos'è, dunque, la Saggezza Pratica?
- È l'abilità morale unita alla volontà morale necessaria per compiere le scelte giuste. Le persone sagge sanno come e quando fare eccezioni alle regole; come e quando improvvisare; come fare la cosa giusta, non solo quando farla; come scegliere tra regole e virtù quando queste sono in conflitto. Il messaggio dietro questa affermazione è molto importante. Tutti, chi più chi meno, sappiamo distinguere tra il Bene e il Male; è una cosa estremamente facile. Le decisioni difficili sono quelle tra una cosa giusta e un'altra cosa giusta. Inoltre, le persone sagge sanno essere empatiche nei confronti degli altri e utilizzano tutte queste abilità per raggiungere gli obiettivi giusti, cioè per servire gli altri, non per manipolarli».

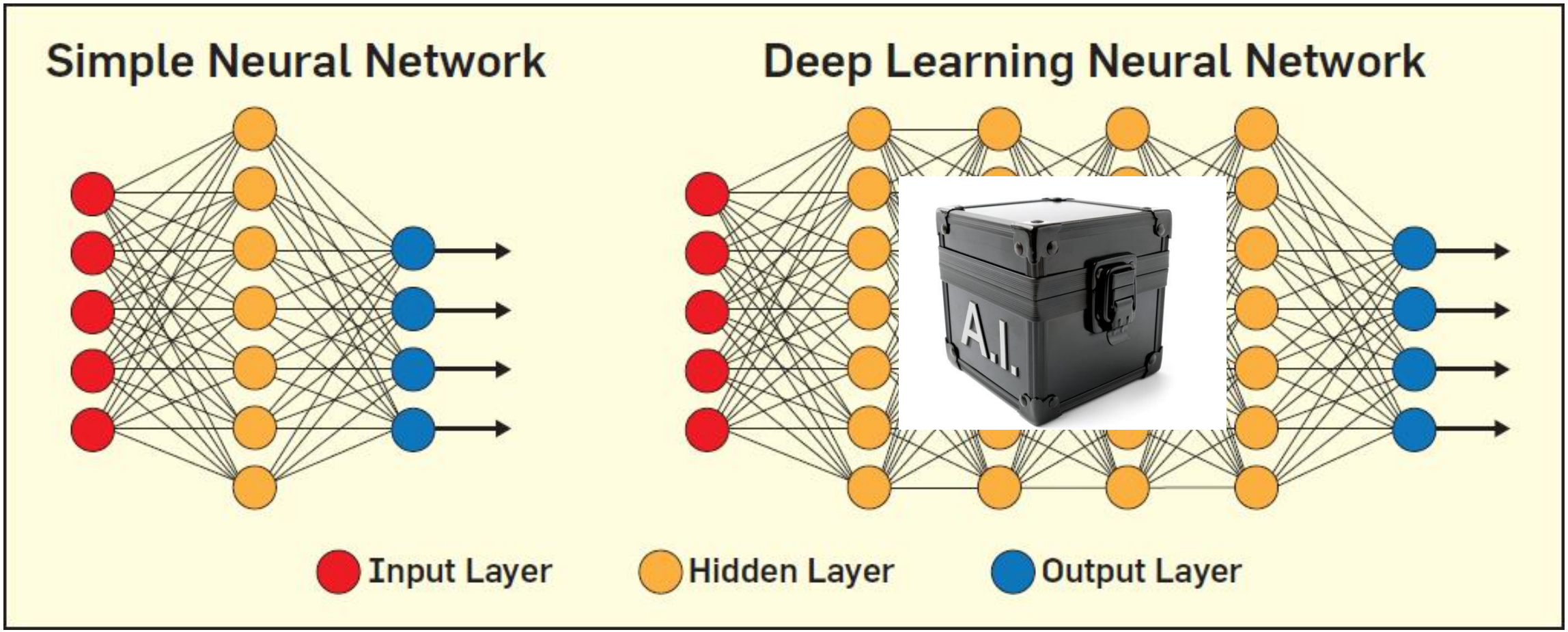
(B. Schwartz. Psicologo e professore in Pennsylvania: The paradox of choice)

CDM nuovo 78: # 1

Il medico:

- Verifica di qualità, affidabilità, trasparenza, efficacia, sicurezza del sistema
- Responsabilità
- Collaborare a governance, controllo e segnalazione di malfunzionamenti
- Formazione e aggiornamento (+/–)

The black box



New from Hastings Bioethics Forum

May 10, 2023

For Ethical Use of AI in Medicine, Don't Overlook Maintenance and Repair

By Kellie Owens

Published on May 9, 2023

CDM nuovo 78: # 2

Il medico e il paziente

- Beneficenza e non maleficenza
- Privacy
- Non discriminazione

Bias

Attempts to use data from the Framingham Heart Study to predict the risk of cardiovascular events in non-white populations have led to biased results, with both overestimations and underestimations of risk (NEJM, 2018)

RESEARCH ARTICLE

Dissecting racial bias in an algorithm used to manage the health of populations

ZIAD OBERMEYER, BRIAN POWERS, CHRISTINE VOGELI, AND SENDHIL MULLAINATHAN Authors Info & Affiliations

SCIENCE • 25 Oct 2019 • Vol 366, Issue 6464 • pp. 447-453 • DOI: 10.1126/science.aax2342

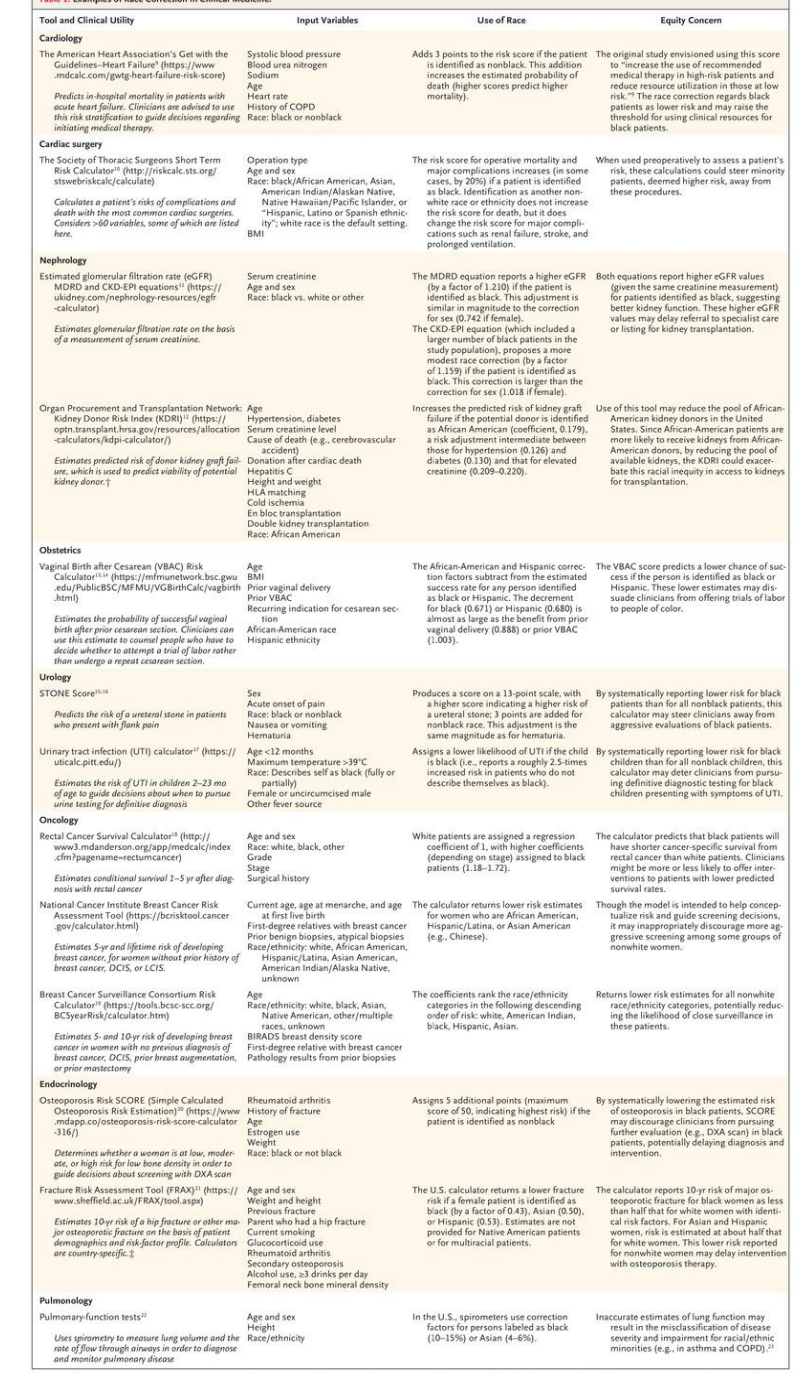
Racial bias in health algorithms

Bias

‘Physicians use these algorithms to individualize risk assessment and guide clinical decisions.
By embedding race …, these algorithms propagate
race-based medicine.’

Results: ‘more attention or resources to white patients than to members of racial and ethnic minorities’

(NEJM, 2020)



Tool and Clinical Utility	Input Variables	Use of Race	Equity Concern
Cardiology			
The American Heart Association's Get with the Guidelines–Heart Failure[9] (https://www.mdcalc.com/gwtg-heart-failure-risk-score) *Predicts in-hospital mortality in patients with acute heart failure. Clinicians are advised to use this risk stratification to guide decisions regarding initiating medical therapy.*	Systolic blood pressure Blood urea nitrogen Sodium Age Heart rate History of COPD Race: black or nonblack	Adds 3 points to the risk score if the patient is identified as nonblack. This addition increases the estimated probability of death (higher scores predict higher mortality).	The original study envisioned using this score to "increase the use of recommended medical therapy in high-risk patients and reduce resource utilization in those at low risk."[9] The race correction regards black patients as lower risk and may raise the threshold for using clinical resources for black patients.
Cardiac surgery			
The Society of Thoracic Surgeons Short Term Risk Calculator[10] (http://riskcalc.sts.org/stswebriskcalc/calculate) *Calculates a patient's risks of complications and death with the most common cardiac surgeries. Considers >60 variables, some of which are listed here.*	Operation type Age and sex Race: black/African American, Asian, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, or "Hispanic, Latino or Spanish ethnicity"; white race is the default setting. BMI	The risk score for operative mortality and major complications increases (in some cases, by 20%) if a patient is identified as black. Identification as another nonwhite race or ethnicity does not increase the risk score for death, but it does change the risk score for major complications such as renal failure, stroke, and prolonged ventilation.	When used preoperatively to assess a patient's risk, these calculations could steer minority patients, deemed higher risk, away from these procedures.
Nephrology			
Estimated glomerular filtration rate (eGFR) MDRD and CKD-EPI equations[11] (https://ukidney.com/nephrology-resources/egfr-calculator) *Estimates glomerular filtration rate on the basis of a measurement of serum creatinine.*	Serum creatinine Age and sex Race: black vs. white or other	The MDRD equation reports a higher eGFR (by a factor of 1.210) if the patient is identified as black. This adjustment is similar in magnitude to the correction for sex (0.742 if female). The CKD-EPI equation (which included a larger number of black patients in the study population), proposes a more modest race correction (by a factor of 1.159) if the patient is identified as black. This correction is larger than the correction for sex (1.018 if female).	Both equations report higher eGFR values (given the same creatinine measurement) for patients identified as black, suggesting better kidney function. These higher eGFR values may delay referral to specialist care or listing for kidney transplantation.
Organ Procurement and Transplantation Network: Kidney Donor Risk Index (KDRI)[12] (https://optn.transplant.hrsa.gov/resources/allocation-calculators/kdpi-calculator/) *Estimates predicted risk of donor kidney graft failure, which is used to predict viability of potential kidney donor.†*	Age Hypertension, diabetes Serum creatinine level Cause of death (e.g., cerebrovascular accident) Donation after cardiac death Hepatitis C Height and weight HLA matching Cold ischemia En bloc transplantation Double kidney transplantation Race: African American	Increases the predicted risk of kidney graft failure if the potential donor is identified as African American (coefficient, 0.179), a risk adjustment intermediate between those for hypertension (0.126) and diabetes (0.130) and that for elevated creatinine (0.209–0.220).	Use of this tool may reduce the pool of African-American kidney donors in the United States. Since African-American patients are more likely to receive kidneys from African-American donors, by reducing the pool of available kidneys, the KDRI could exacerbate this racial inequity in access to kidneys for transplantation.
Obstetrics			
Vaginal Birth after Cesarean (VBAC) Risk Calculator[13,14] (https://mfmunetwork.bsc.gwu.edu/PublicBSC/MFMU/VGBirthCalc/vagbirth.html) *Estimates the probability of successful vaginal birth after prior cesarean section. Clinicians can use this estimate to counsel people who have to decide whether to attempt a trial of labor rather than undergo a repeat cesarean section.*	Age BMI Prior vaginal delivery Prior VBAC Recurring indication for cesarean section African-American race Hispanic ethnicity	The African-American and Hispanic correction factors subtract from the estimated success rate for any person identified as black or Hispanic. The decrement for black (0.671) or Hispanic (0.680) is almost as large as the benefit from prior vaginal delivery (0.888) or prior VBAC (1.003).	The VBAC score predicts a lower chance of success if the person is identified as black or Hispanic. These lower estimates may dissuade clinicians from offering trials of labor to people of color.
Urology			
STONE Score[15,16] *Predicts the risk of a ureteral stone in patients who present with flank pain*	Sex Acute onset of pain Race: black or nonblack Nausea or vomiting Hematuria	Produces a score on a 13-point scale, with a higher score indicating a higher risk of a ureteral stone; 3 points are added for nonblack race. This adjustment is the same magnitude as for hematuria.	By systematically reporting lower risk for black patients than for all nonblack patients, this calculator may steer clinicians away from aggressive evaluations of black patients.
Urinary tract infection (UTI) calculator[17] (https://uticalc.pitt.edu/) *Estimates the risk of UTI in children 2–23 mo of age to guide decisions about when to pursue urine testing for definitive diagnosis*	Age <12 months Maximum temperature >39°C Race: Describes self as black (fully or partially) Female or uncircumcised male Other fever source	Assigns a lower likelihood of UTI if the child is black (i.e., reports a roughly 2.5-times increased risk in patients who do not describe themselves as black).	By systematically reporting lower risk for black children than for all nonblack children, this calculator may deter clinicians from pursuing definitive diagnostic testing for black children presenting with symptoms of UTI.
Oncology			
Rectal Cancer Survival Calculator[18] (http://www3.mdanderson.org/app/medcalc/index.cfm?pagename=rectumcancer) *Estimates conditional survival 1–5 yr after diagnosis with rectal cancer*	Age and sex Race: white, black, other Grade Stage Surgical history	White patients are assigned a regression coefficient of 1, with higher coefficients (depending on stage) assigned to black patients (1.18–1.72).	The calculator predicts that black patients will have shorter cancer-specific survival from rectal cancer than white patients. Clinicians might be more or less likely to offer interventions to patients with lower predicted survival rates.
National Cancer Institute Breast Cancer Risk Assessment Tool (https://bcrisktool.cancer.gov/calculator.html) *Estimates 5-yr and lifetime risk of developing breast cancer, for women without prior history of breast cancer, DCIS, or LCIS.*	Current age, age at menarche, and age at first live birth First-degree relatives with breast cancer Prior benign biopsies, atypical biopsies Race/ethnicity: white, African American, Hispanic/Latina, Asian American, American Indian/Alaska Native, unknown	The calculator returns lower risk estimates for women who are African American, Hispanic/Latina, or Asian American (e.g., Chinese).	Though the model is intended to help conceptualize risk and guide screening decisions, it may inappropriately discourage more aggressive screening among some groups of nonwhite women.
Breast Cancer Surveillance Consortium Risk Calculator[19] (https://tools.bcsc-scc.org/BC5yearRisk/calculator.htm) *Estimates 5- and 10-yr risk of developing breast cancer in women with no previous diagnosis of breast cancer, DCIS, prior breast augmentation, or prior mastectomy*	Age Race/ethnicity: white, black, Asian, Native American, other/multiple races, unknown BIRADS breast density score First-degree relative with breast cancer Pathology results from prior biopsies	The coefficients rank the race/ethnicity categories in the following descending order of risk: white, American Indian, black, Hispanic, Asian.	Returns lower risk estimates for all nonwhite race/ethnicity categories, potentially reducing the likelihood of close surveillance in these patients.
Endocrinology			
Osteoporosis Risk SCORE (Simple Calculated Osteoporosis Risk Estimation)[20] (https://www.mdapp.co/osteoporosis-risk-score-calculator-316/) *Determines whether a woman is at low, moderate, or high risk for low bone density in order to guide decisions about screening with DXA scan*	Rheumatoid arthritis History of fracture Age Estrogen use Weight Race: black or not black	Assigns 5 additional points (maximum score of 50, indicating highest risk) if the patient is identified as nonblack	By systematically lowering the estimated risk of osteoporosis in black patients, SCORE may discourage clinicians from pursuing further evaluation (e.g., DXA scan) in black patients, potentially delaying diagnosis and intervention.
Fracture Risk Assessment Tool (FRAX)[21] (https://www.sheffield.ac.uk/FRAX/tool.aspx) *Estimates 10-yr risk of a hip fracture or other major osteoporotic fracture on the basis of patient demographics and risk-factor profile. Calculators are country-specific.‡*	Age and sex Weight and height Previous fracture Parent who had a hip fracture Current smoking Glucocorticoid use Rheumatoid arthritis Secondary osteoporosis Alcohol use, ≥3 drinks per day Femoral neck bone mineral density	The U.S. calculator returns a lower fracture risk if a female patient is identified as black (by a factor of 0.43), Asian (0.50), or Hispanic (0.53). Estimates are not provided for Native American patients or for multiracial patients.	The calculator reports 10-yr risk of major osteoporotic fracture for black women as less than half that for white women with identical risk factors. For Asian and Hispanic women, risk is estimated at about half that for white women. This lower risk reported for nonwhite women may delay intervention with osteoporosis therapy.
Pulmonology			
Pulmonary-function tests[22] *Uses spirometry to measure lung volume and the rate of flow through airways in order to diagnose and monitor pulmonary disease*	Age and sex Height Race/ethnicity	In the U.S., spirometers use correction factors for persons labeled as black (10–15%) or Asian (4–6%).	Inaccurate estimates of lung function may result in the misclassification of disease severity and impairment for racial/ethnic minorities (e.g., in asthma and COPD).[23]

* BIRADS denotes Breast Imaging Reporting and Data System, BMI body-mass index (the weight in kilograms divided by the square of the height in meters), CKD-EPI Chronic Kidney Disease Epidemiology Collaboration, COPD chronic obstructive pulmonary disease, DCIS ductal carcinoma in situ, DXA dual-energy x-ray absorptiometry, LCIS lobular carcinoma in situ, and MDRD Modification of Diet in Renal Disease study.
† The current calculator uses Ethnicity/Race, with the following options: American Indian or Alaska Native, Asian, Black or African American, Hispanic/Latino, Native Hawaiian or Other Pacific Islander, White, and Multiracial.
‡ Three countries' calculators are further subcategorized by race, ethnicity, or location: China (Mainland China, Hong Kong), Singapore (Chinese, Malay, Indian), and the United States

D.A. Vyas et al. “Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms” (2020) *NEJM*

Bias

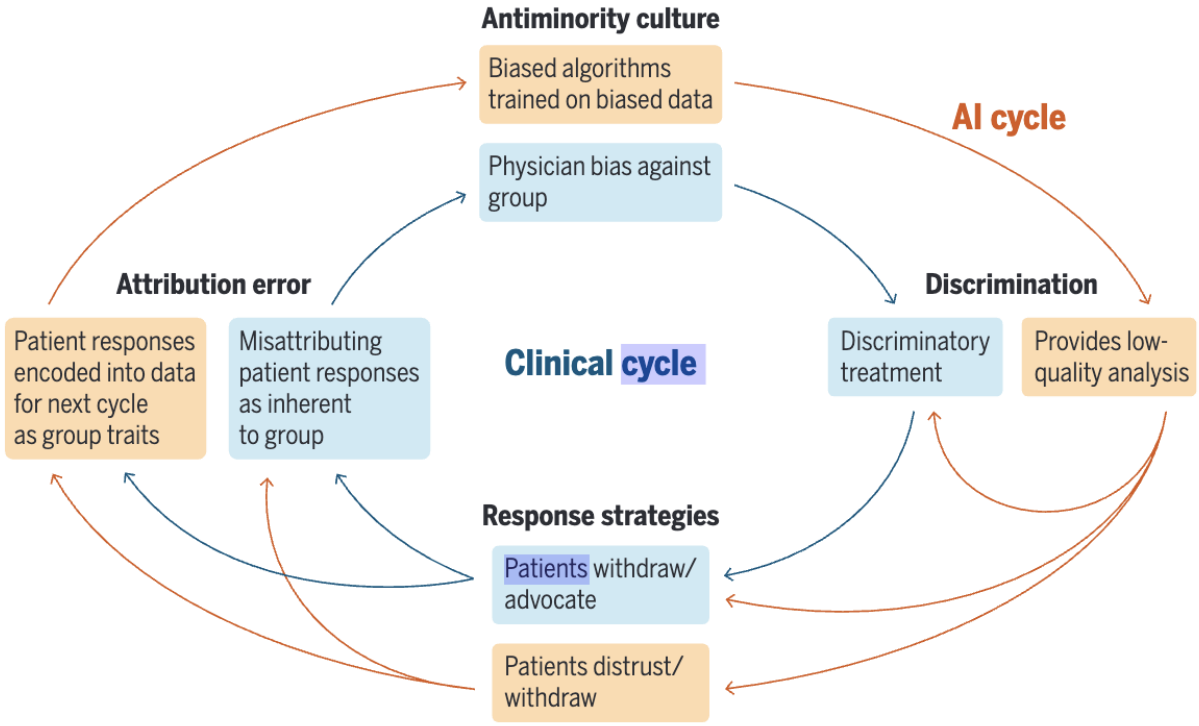
In medicine, substantial disparities exist…, with origins in systemic racism, implicit bias, historical practice…
This framework highlights particular dangers that may arise through expanding use of big data and AI–based systems in medicine,

making bias especially intractable unless tackled directly and early.

Science, 8 Sep 2022

Medical practice and AI create overlapping exclusion cycles

Around a generalized structure of the four-step cycle, we depict two interacting exclusion cycles: clinical encounters (blue) and artificial intelligence (AI) products that result from, and influence, data surrounding those clinical encounters (orange). Each cycle self-perpetuates, but the cycles also interact at various points.



CDM nuovo 78: # 2

Il medico e il paziente

- Informazione su interlocutore, motivi di utilizzo, limiti e rischi (consenso informato)

Es: Loi de bioéthique
(August 2021)

Art. 17

A health care provider who decides to use ... a medical device that includes algorithmic processing ... must ensure that the person concerned

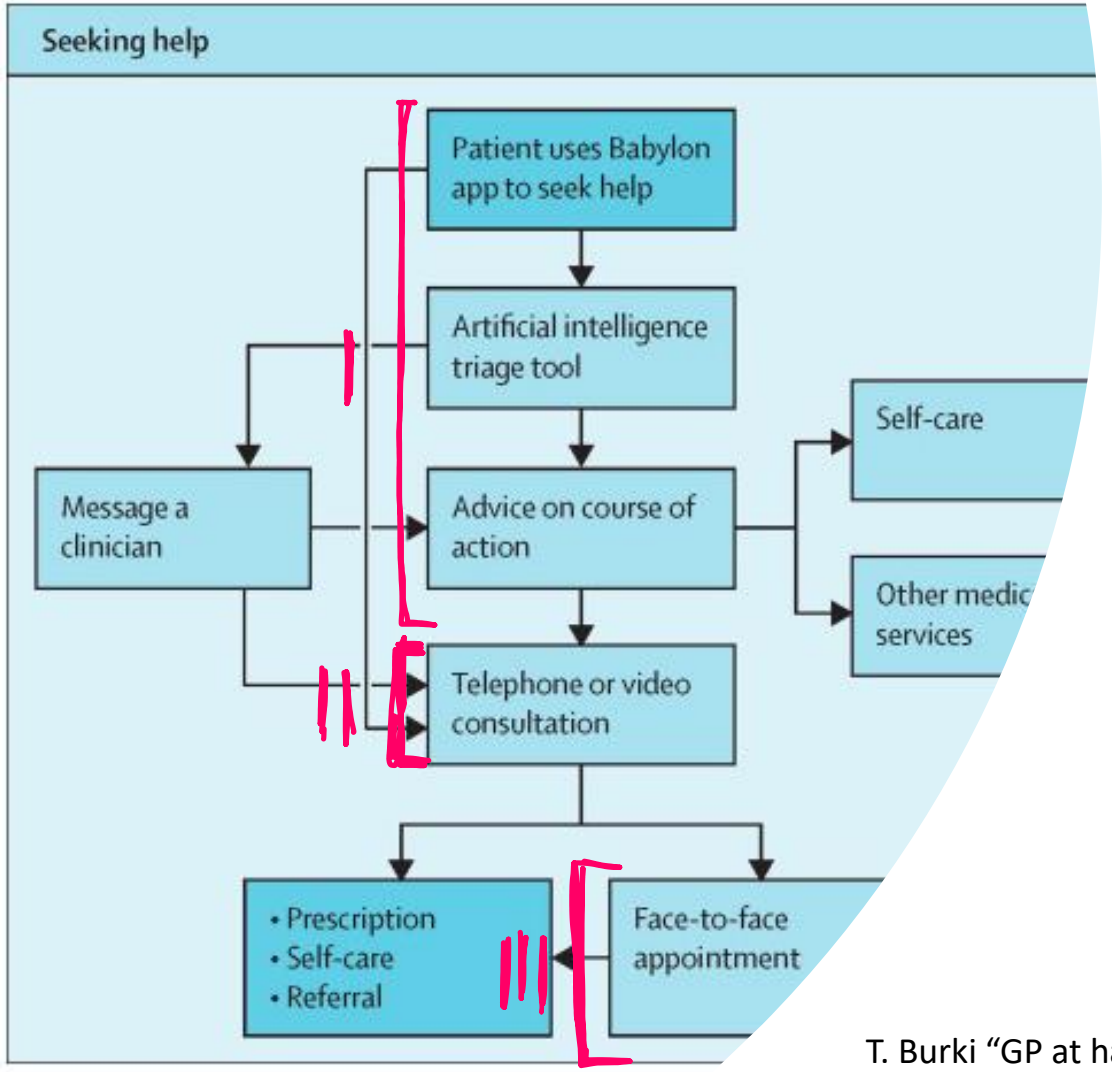
- has been informed and that

- is, where appropriate, informed of the resulting interpretation

CDM nuovo 78: # 2

Il medico e il paziente

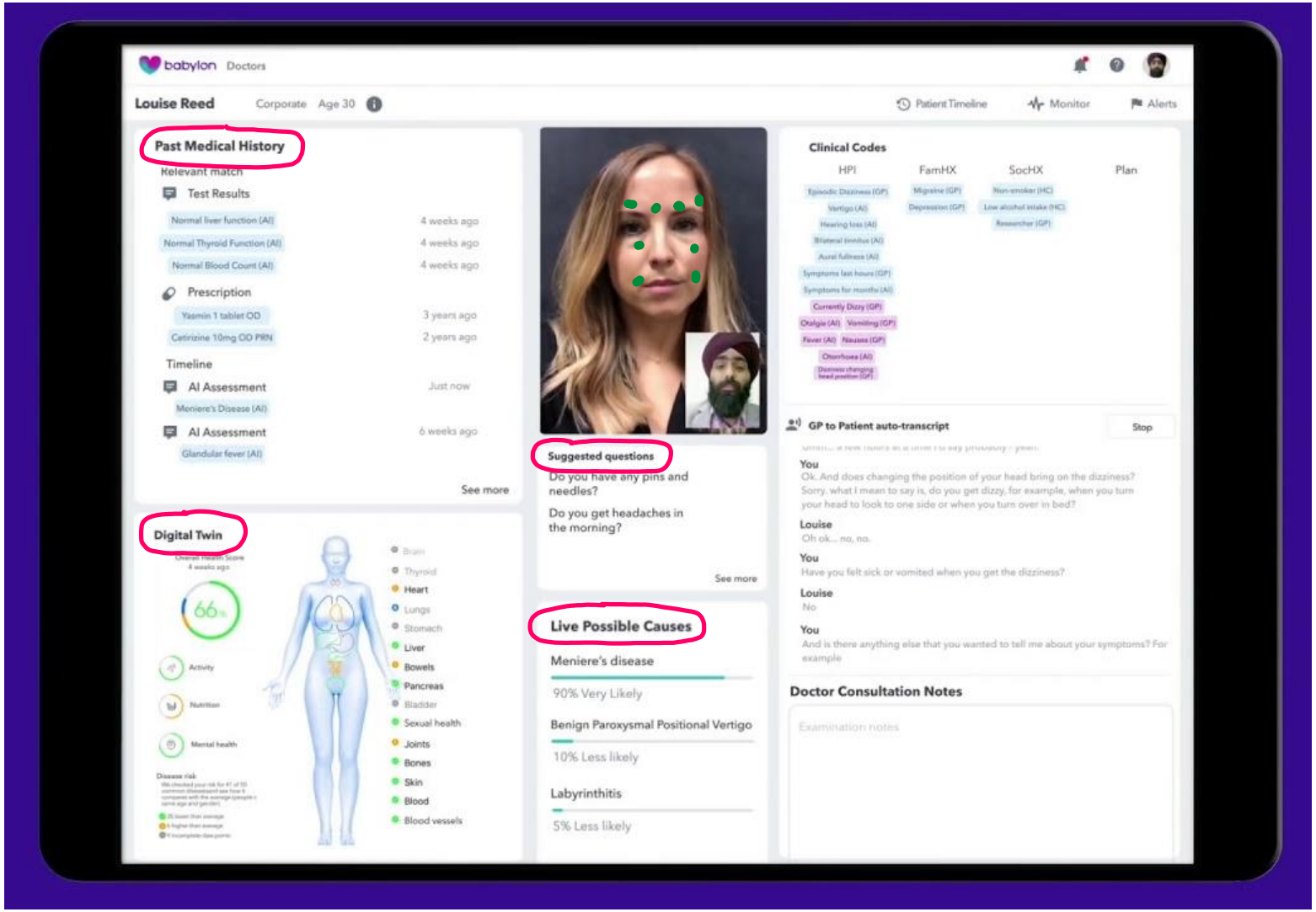
- Relazione di cura
- Rapporto umano
- Comunicazione empatica



Ma in pratica?

GP at Hand (Babylon)

T. Burki “GP at hand: a digital revolution for health care provision?” (2019) *The Lancet*

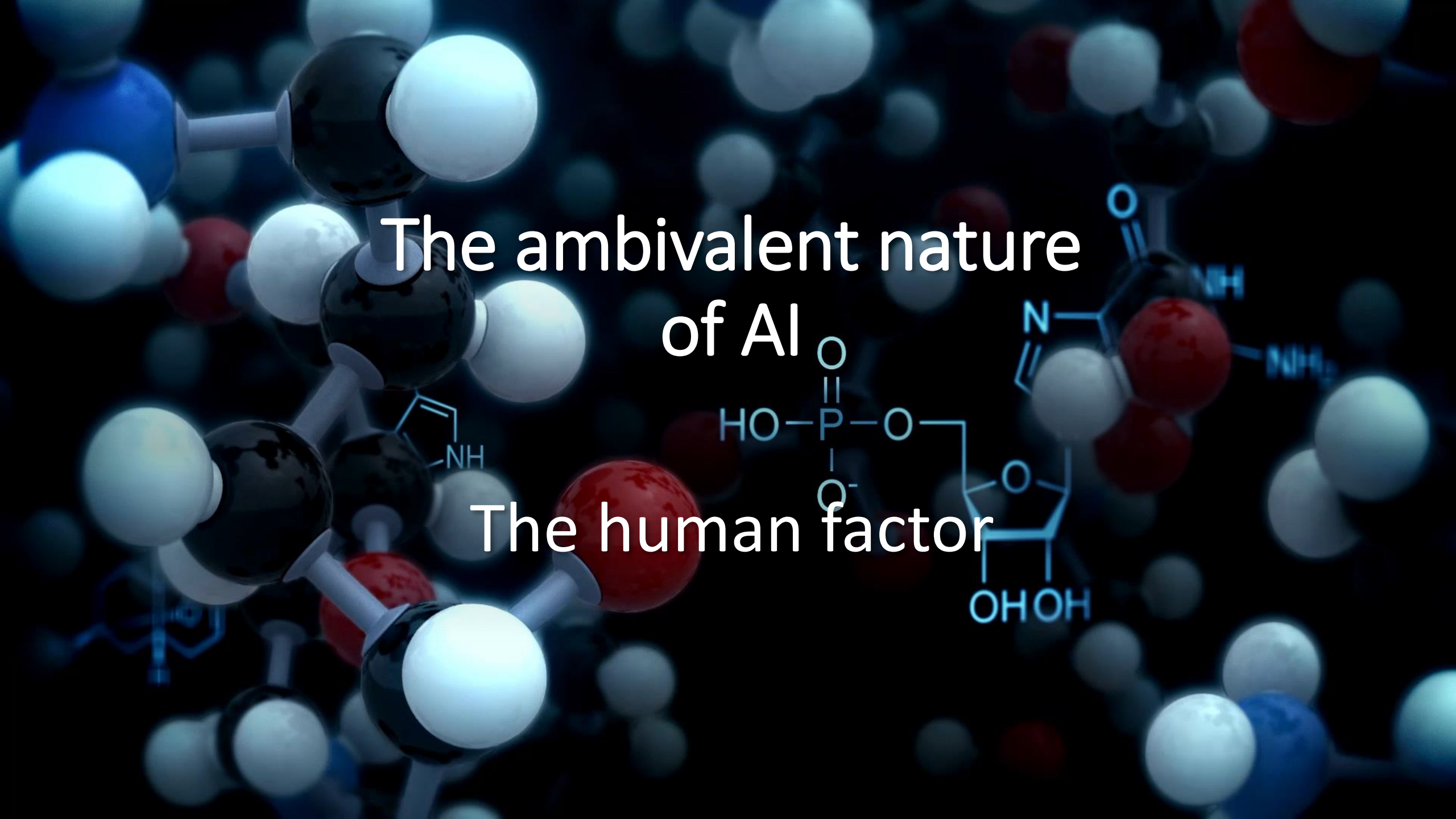

babylon Doctors
Louise Reed
Corporate
Age 30
Patient Timeline
Monitor
Alerts
Past Medical History
Relevant match
Test Results
Normal liver function (AI)
4 weeks ago
Normal Thyroid Function (AI)
4 weeks ago
Normal Blood Count (AI)
4 weeks ago
Prescription
Yasmin 1 tablet OD
3 years ago
Cetirizine 10mg OD PRN
2 years ago
Timeline
AI Assessment
Just now
Meniere's Disease (AI)
AI Assessment
6 weeks ago
Glandular fever (AI)
See more
Digital Twin
66%
Activity
Nutrition
Mental health
Brain
Thyroid
Heart
Lungs
Stomach
Liver
Bowels
Pancreas
Bladder
Sexual health
Joints
Bones
Skin
Blood
Blood vessels
Suggested questions
Do you have any pins and needles?
Do you get headaches in the morning?
See more
Live Possible Causes
Meniere's disease
90% Very Likely
Benign Paroxysmal Positional Vertigo
10% Less likely
Labyrinthitis
5% Less likely
Clinical Codes
HPI
FamHX
SocHX
Plan
GP to Patient auto-transcript
Stop
You
Ok. And does changing the position of your head bring on the dizziness? Sorry, what I mean to say is, do you get dizzy, for example, when you turn your head to look to one side or when you turn over in bed?
Louise
Oh ok... no, no.
You
Have you felt sick or vomited when you get the dizziness?
Louise
No
You
And is there anything else that you wanted to tell me about your symptoms? For example
Doctor Consultation Notes
Examination notes

CDM nuovo 78: # 3

Il medico e la società

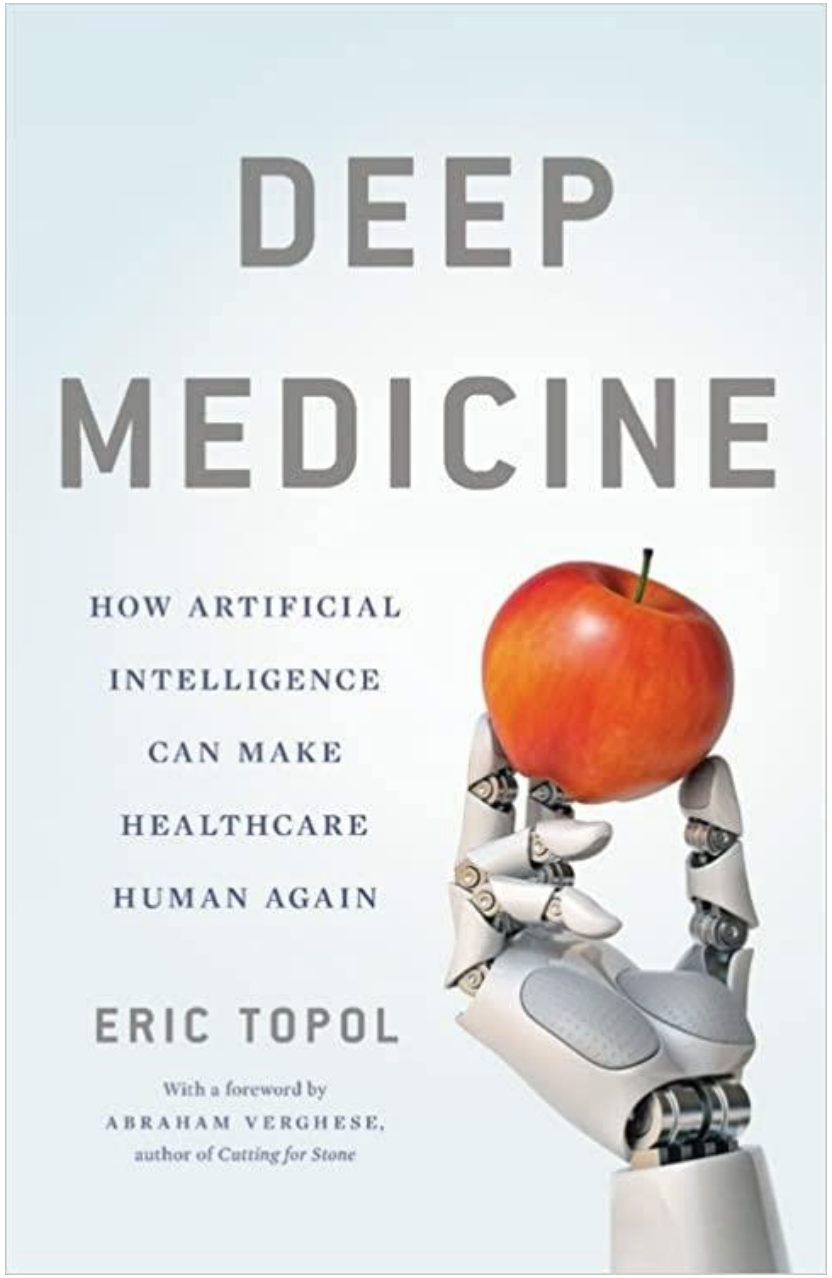
- Valutazione interdisciplinare
- Sostenibilità, equità solidarietà: bene comune e salute pubblica
- Diritto a AI?

The ambivalent nature of AI



The human factor

Pros


DEEP
MEDICINE
HOW ARTIFICIAL
INTELLIGENCE
CAN MAKE
HEALTHCARE
HUMAN AGAIN
ERIC TOPOL
With a foreword by
ABRAHAM VERGHESE,
author of Cutting for Stone

Cons

THE HASTINGS CENTER REPORT

Essay | Free Access

High Hopes for "Deep Medicine"? AI, Economics, and the Future of Care

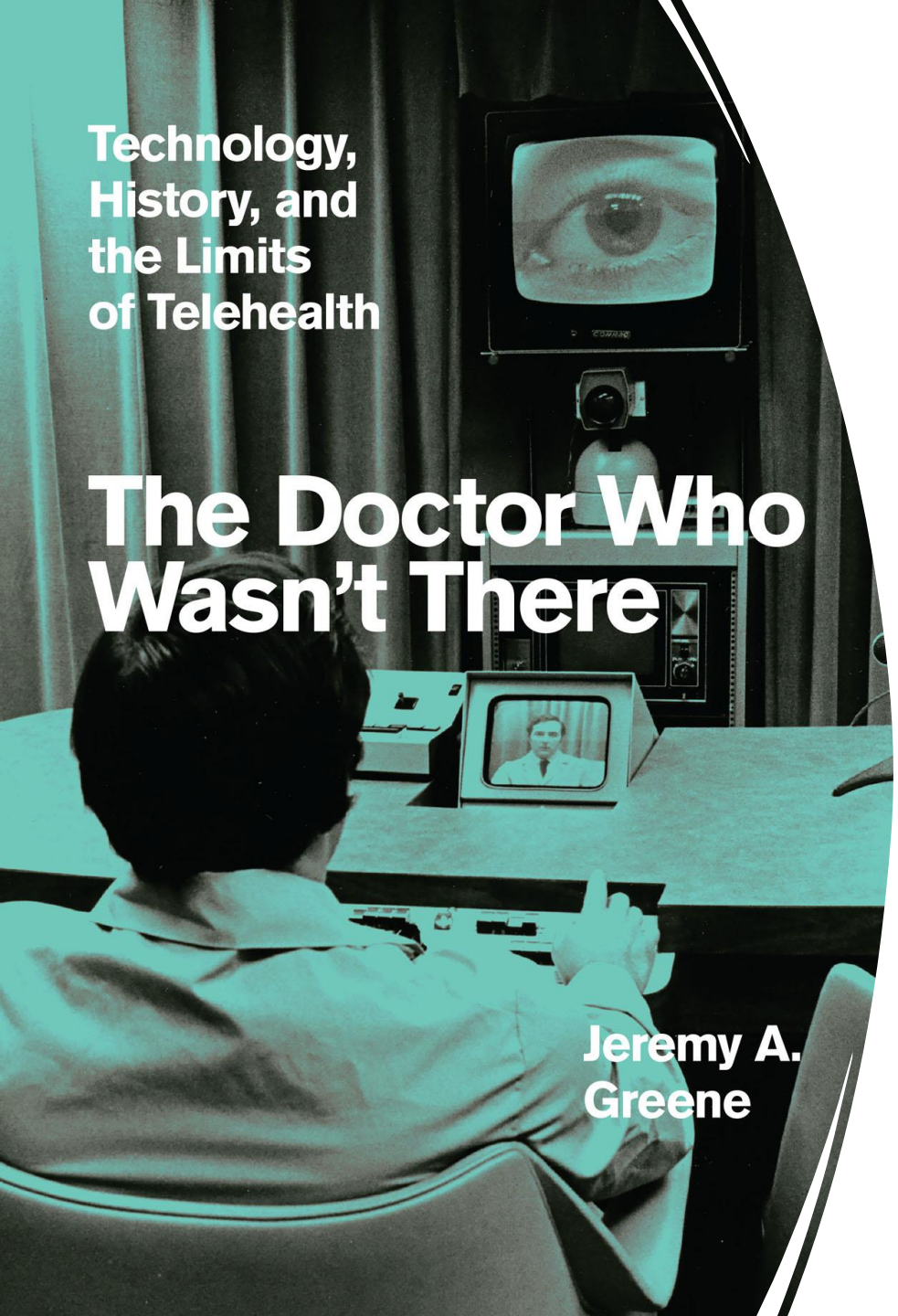
Robert Sparrow, Joshua Hatherley

First published: 18 February 2020 | https://doi.org/10.1002/hast.1079 | Citations: 2

SECTIONS PDF TOOLS SHARE

Abstract

In the much-celebrated book Deep Medicine, *Eric Topol argues that the development of artificial intelligence for health care will lead to a dramatic shift in the culture and practice of medicine. In the next several decades, he suggests, AI will become sophisticated enough that many of the everyday tasks of physicians could be delegated to it. Topol is perhaps the most articulate advocate of the benefits of AI in medicine, but he is hardly alone in spruiking its potential to allow physicians to dedicate more of their time and attention to providing empathetic care for their patients in the future. Unfortunately, several factors suggest a radically different picture for the future of health care. Far from facilitating a return to a time of closer doctor-patient relationships, the use of medical AI seems likely to further erode therapeutic relationships and threaten professional and patient satisfaction.*



Science and technology alone will never be able to deliver a more just and equitable society

V. Rampton, *Science*, Nov 4 2022