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DIGITALIZZAZIONE UMANA IN SANITA' – FOCUS REGIONE TOSCANA
A cura di ALTEMS Advisory
26 NOVEMBRE 2024 - 14.30-18.30

Digitalizzazione umana in sanità: aspetti etici

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Agenda

- **Lo scenario**
- **Il dibattito sulla digitalizzazione: due esemplificazioni**

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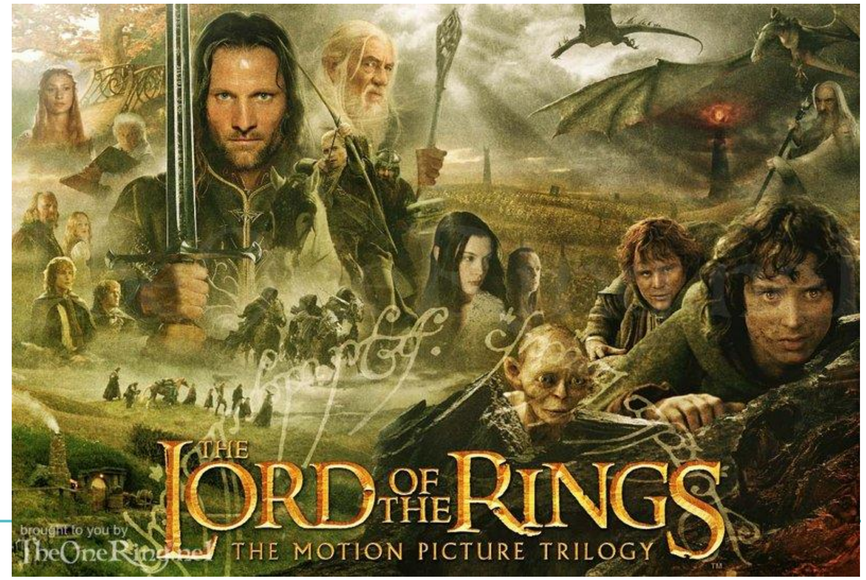
The scenario – AI (within Biomedicine & healthcare): welcome to the “Middle earth”, the realm of «complexity»…



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La "questione della tecnica"

"Chi è nato all'interno della civiltà occidentale e gode dei prodotti che la tecnica gli mette a disposizione fatica a comprendere che esista una "questione della tecnica".
Al più potrà ammettere l'ambivalenza della tecnica e accettare una distinzione, generica, tra un uso buono e uno cattivo della tecnica"
"Attraverso strategie diversificate,… veniamo indotti a pensare all'inevitabilità del cosiddetto progresso, comunque esso venga rappresentato, in termini di condanna o di plauso, di paura o di speranza"

(A. Pessina, 1999)

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La “questione della scienza”

- Positivismo e neoPositivismo hanno affermato che le scienze empiriche sono la sola forma di conoscenza possibile e il metodo scientifico è l’unico valido
- In quanto tale, il metodo scientifico va esteso a tutti i settori di ricerca, compresi quelli che riguardano l’uomo e la società
- **La scienza «positiva» è neutrale e priva di pregiudizi**
- **Il progresso tecnologico è positivo e inevitabile**
- **Le tecno-scienze ci salveranno (utopia)**

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La Medicina come “mera scienza”

- Spostamento dal malato alla malattia
- Assimilazione della medicina ad una scienza della natura (nomotetica)
- Marginalizzazione/rifiuto di qualsiasi considerazione biografica
- Pratica medica quale scienza quantitativa dell’organismo in salute (evidenza)
- Sviluppo della laboratoristica
- Scientismo
- Riduzionismo

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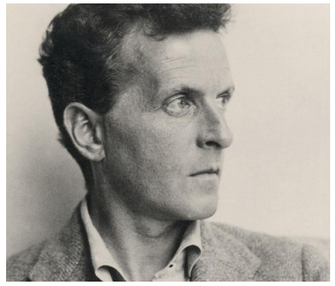
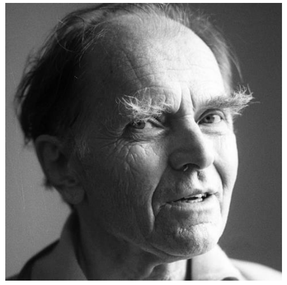
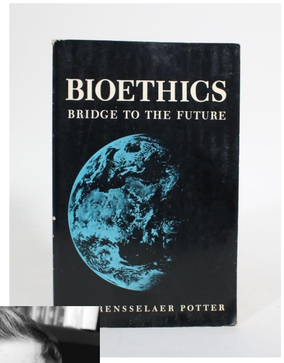




Cambio di prospettiva

- **Brusco risveglio a seguito dell'esperienza di Hiroshima e Nagasaki** (un certo sviluppo tecnologico può addirittura mettere in discussione la sopravvivenza dell'uomo sulla terra)
- **Ineliminabilità dei discorsi valoriali dal discorso scientifico**: non si può fare scienza senza riferimento a valori (Wittgenstein, Feyerabend)

- Concetto di salute ad opera dell'OMS
- Modello bio-psico-sociale di medicina
- Medicina centrata sul paziente (idiografia)
- Medicina narrativa
- Patient reported outcomes (PROs)
- Ricerca qualitativa
- Paziente «esperto»
- **Nascita della Bioetica**



Recupero della Medicina come «arte»

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The point of observation: (Bio)ethics - 1

V.R. Potter introduces the term **Bioethics as a new knowledge aimed** to:

- understand natural phenomena
- and to use wisely the scientific-technical knowledge that favors the survival of the human race, improving the quality of life of the future generations.

Bioethics: a "bridge" between two spheres of knowledge (scientific & humanistic)

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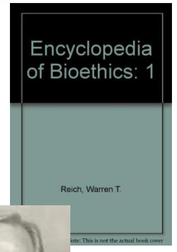
The point of observation: (Bio)ethics - 2



Bioethics was initially defined (1978) by editor of the first edition of Encyclopedia of Bioethics, Warren T. Reich as: **"the systematic study of human conduct in the area of life sciences and healthcare, insofar as this conduct is examined in the light of moral values and principles"**

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Il dibattito etico sulla Intelligenza Artificiale

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First definition of AI

"A field of study that combines computer science, engineering and related disciplines to build **machines capable of behavior that would be said to require intelligence were it to be observed in humans**"

BUT, there is no universally agreed upon definition of what AI encompasses…

McCarthy, J., Minsky, M., Shannon, C. E., Rochester, N., & Dartmouth College. (1956). *A proposal for the Dartmouth Summer Research Project on Artificial Intelligence.*

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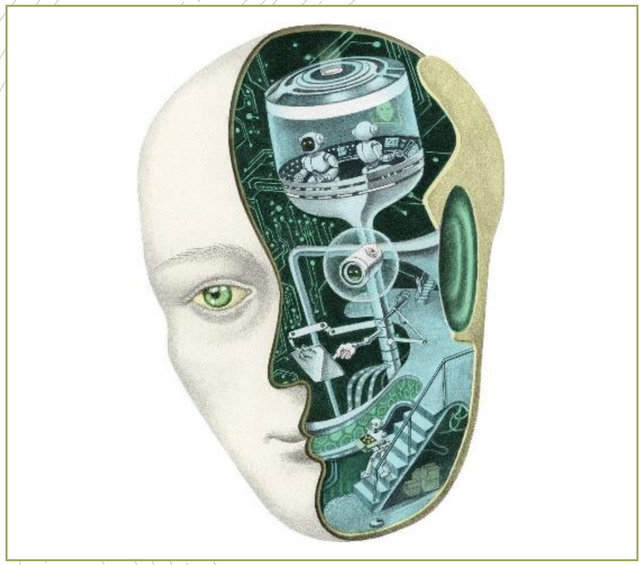

AI logic

- **AI translates difficult tasks into complex ones** (in Information Technology, complexity is expressed in terms of resources and time spent)

- **AI will develop around** those **tasks** that it will be **possible/convenient to transform from difficult to complex**

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What characterizes the most recent phase? - 1

- Especially since 2010, **increased *computing power* and *huge amount of data***
- **Transition from the use of "logic" to that of "statistics":**
  - **old AI** was mostly symbolic and could be interpreted as a branch of *mathematical logic*
  - **today's AI** is based on *statistical correlation*

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What characterizes the most recent phase? – 2
AI within the 4th Industrial Revolution…

- The A.I. determines, for the first time in human history, a **divorce** between "action" and "intelligence", although very often it is presented as a **marriage**

- The A.I. **separates the ability** to solve a problem or complete a task successfully **from the need** to be intelligent in doing so

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Is AI good or bad?

Technology itself is neither good nor bad: **it is neutral. It all depends on how we use it**

Difficulties in recognizing ethical issues related to the use of technologies:

- **Technologies have become an environment**, they are no longer just a tool, and it is difficult to perceive an environment as problematic

(Adriano Pessina, 1999)

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Trivialization and self-perception

Work of **normalization** and **trivialization** exercised by literature and fiction

Changing **self-perception** by man: machines have become our model (when we think of human efficiency, the first thing that comes to mind is the efficiency of the machine)

(**Günther Anders**, *The Outdatedness of Human Beings*, 1956)

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(Moral) Normative Dimensions

- **Beneficence**: AI should be developed for the common good and for the benefit of humanity
- **Non-maleficence**: AI must not cause harm while respecting privacy and safety
- **Autonomy**: balance between decision-making power that we reserve for ourselves and what we delegate to "artificial agents", always leaving open the possibility of deciding to decide again
- **Justice**: eliminate any possible discrimination; seek benefits that can be shared
- **Explicability/Explainability (transparency):** responsible intelligibility, which means making clear what is being done and identifying the ethical and legal responsibility for any damages

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Opacity of algorithms - 1

Opacity: the steps through which data are interpreted are not always explainable (**transparent**) and can even give **discriminatory** results

- Possibilities of the AI to make erroneous decisions that can endanger the health of patients (case of the 2015 trial where AI was used to predict which patients were more likely to have complications after pneumonia)
- Due to the classification of people into groups or subgroups with profiles like those associated with certain schemes (clustering), the algorithms may not consider the variants that a particular patient may present

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Opacity of algorithms - 2

Opacity: the steps through…

- AI can lead to favoring one class of drugs over another class that has the same indications for a specific symptom or pathology
- Algorithmic discriminations are possible with an impact on fairness and inclusiveness
- **The error does not come from the machine, but from the man who selects the data and elaborates algorithms**

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Privacy and data sharing

- The enormous collection of data, necessary for AI, brings out risks related to **their use and cross-referencing of data**, both intentional and accidental re-identification, raising the problem of *privacy*
- **Applicability of existing regulations** (e.g., the EU General Data Protection Regulation (**GDPR**)
- **Informed consent**: the patient must be aware of all possible purposes; who is the data controller?

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Physician-patient relationship

- **Better monitoring and patient access, BUT** the existence of barriers (infrastructure, digital literacy, etc.)

- **Help in decisions, BUT** possible loss of skills

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Moral responsibilities

- Machines can be misused and poorly programmed
- Liability of the designer, vendor, owner, user or third party?
- Each point in the chain has its own fragility

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Education

- Continuing Medical Education
- Medical Schools
- Risks of discrimination (exclusion of those unable to learn the required new skills)
- Ethical training for those who build the machines

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Software/Tools assessment

- **Characteristics of safety and efficacy studies for approval** since we are dealing with software (drawings, endpoints, etc.) as well hardware (AI tools, algorithms, etc.)
- **Economic sustainability**
- **Integration of skills** in the composition of evaluation bodies

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AI, Health and Ethics

The **literature**:

- highlighted a number of **common ethical concerns related to: data privacy and security, trust in AI, accountability and responsibility, and bias**
- **was primarily focused on the ethics of AI in health care**, particularly **on: carer robots, diagnostics, and precision medicine**
- **was largely silent on ethics of AI in public and population health was largely missing on ethics of AI in global health**, particularly in low-/middle-income countries (LMICs)

(K. Murphy et al., BMC Med Ethics (2021) 22:14 https://doi.org/10.1186/s12910-021-00577-8)

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AI and HTA? Work in progress

- AI application in Medicine offers **new opportunities, BUT also presents risks** that must be identified, avoided, managed
- **The "value" of these technologies will depend on** whether they are effective, safe, and cost-effective
- **Ethical issues in AI** are partly **in common**, partly **specific** for AI healthcare tools
- **Ethical issues in HTA** still need to be **widely developed** both from a methodological and operational point of view as well as specific HTA frameworks.
- We currently have **more questions than answers**

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EDiHTA

The first **E**uropean **Di**gital **Health Technology Assessment** framework co-created by all stakeholders along the value chain

www.edihta-project.eu

EDiHTA EU-project

@EDiHTAproject

Funded by the European Union (GA. 101136424) and supported by the Swiss State Secretariat for Education, Research and Innovation (SERI). The UK participant is supported by UKRI grant No 10106869 (National Institute for Health and Care Excellence). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

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- The overall goal of EDiHTA is to deliver a **HTA framework** for Digital Health Technologies that **integrates existing assessment domains** and methods with new ones to **inform decision-making.**

EDiHTA

The EDiHTA solution

- An innovative **HTA framework-platform** will be developed to allow HTA assessments to be performed **digitally in a standardised format.**
- Customised according to the type and **lifecycle stage** of the DHT and decision-making process at the macro (policy), meso (management providers) and micro (clinicians) levels.

A joint effort of **16 European partners** from 10 countries including **clinical partners, regulatory bodies, HTA agencies** and links to **technology developers** and **payers**

Piloting **the first European HTA framework** on **three digital health technologies** on TRLs 4-9, from **mApps** to **AI-based** tools

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Il dibattito etico

sulla «evidence-based logic»

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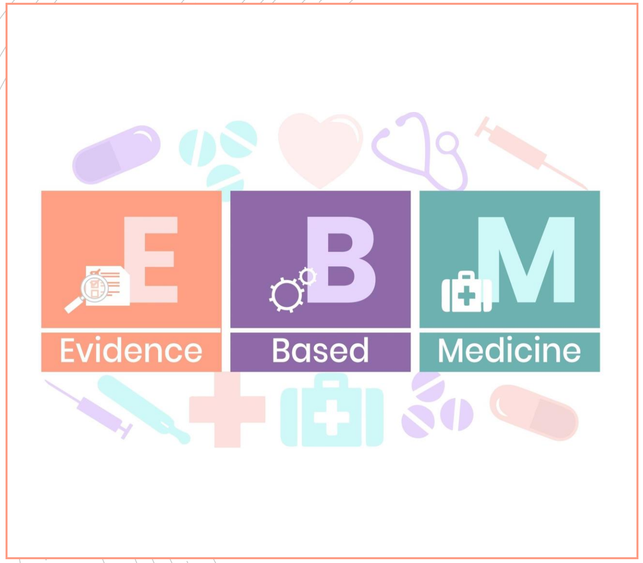
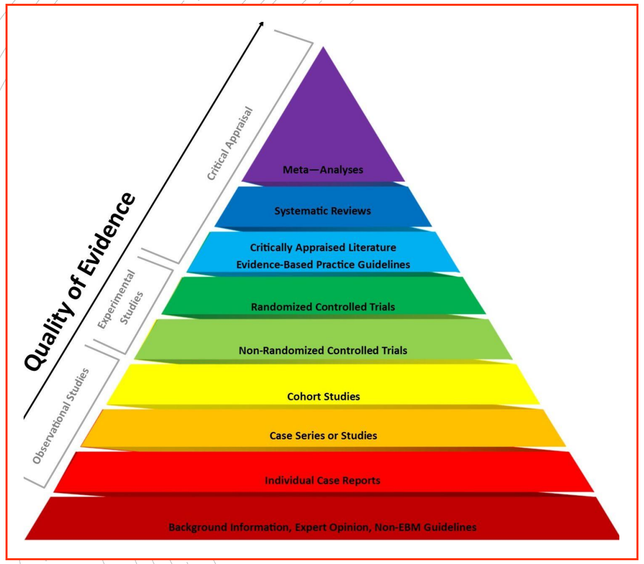


Evidenza: di che si tratta - 1

- **Evidenza**: prova di efficacia («ex video»)
- La **«Evidence-based Medicine** (EBM) afferma che «health and **clinical decisions** should not be based solely on intuition, expert opinions, and pathophysiological reasoning since they alone are potentially biased and unreliable sources" (Buts, 2021)
- Invece, tali decisioni "**should be based on the integration of individual clinical expertise and patient preferences with the best external clinical evidence that is available»** (Sackett, 1996)

Evidenza: di che si tratta - 2



The "**best clinical evidence**" places (Worrall 2007):

- **Randomized Clinical Trials** (RCTs) at the highest level
- followed by **controlled observational studies**
- and finally by **non-controlled studies**
- and **expert opinions**

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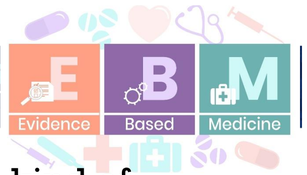
Evidenza: di che si tratta - 3

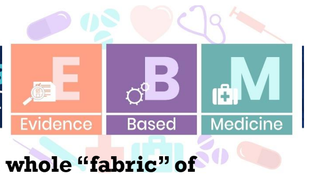
- The lay audience and some researchers at times have placed **too much trust in RCTs compared to other methods of investigation**.
- One of the principal **misunderstandings** - which has been widely clarified by literature and by the EBM movement itself over time and can be considered definitively surpassed **- is to consider RCTs findings as isolated and self-apparent pieces of information**.
- In our understanding, what has been essentially **lacking** was **the awareness of the value-context of the evidence, and in particular the value- and theory-ladenness (normativity) of scientific knowledge**.

Una sintesi - 1



- **"Evidence is not so evident"**, in the sense that no kind of scientific evidence can be deemed to be self-apparent or neutral.
- Rather, **evidence acquires relevance depending on**:
  - the agreed questions to be addressed and the values at stake
  - and, therefore, it should be always placed in framework of meaning

(Refolo, Sacchini et al, 2023)



Similar considerations can help to better clarify the role of RCTs and, more generally, **the whole "fabric" of evidence** (Refolo, Sacchini et al, 2023):

- Firstly:
  - **RCTs are not theory-free**
  - **RCTs findings are not automatically simply generalizable, or automatically usable outside of the context in which they are obtained** (poor external validity and generalizability).
  - **RCTs do not reveal the "truth" about the world, BUT the truth in the trial sample only and within the conditions of the trial**, that is, of an ideal or at least controlled world.

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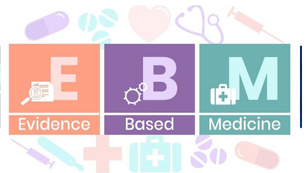

Similar considerations… (Refolo, Sacchini et al, 2023):

- Secondly, **the type of scientific evidence and the methodologies needed to analyze that evidence will depend on the research question being asked.** The specific question at stake and the kind of background assumptions that can be acceptably employed will determine the most suitable methods to be used and in which combinations.
- Under this perspective, RCTs have no special status, and **"RCT or no RCT" is not the same as "evidence or no evidence", or worse "truth or non-truth".**
- The **EBM itself recognizes that the best core of evidence for different questions cannot be reached at all times through RCTs.**

Similar considerations… (Refolo, Sacchini et al, 2023):

Thirdly

- **Affirming that RCTs are the best experimental design in some circumstances does not exclude that further and also better designs could be developed for the same circumstances.** Prior to the COVID-19 pandemic, the practice of clinical research had seen minimal revisions, having remained relatively unchanged for at least three decades. Somebody defined this phase as "stagnation of RCTs"

(Subbiah, 2023; Hernán et al, 2016; Hernan, 2021, 2022)

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Similar considerations… (Refolo, Sacchini et al, 2023):

Thirdly

- Furthermore, there are distinguished voices and scientific approaches that demonstrate that **other alternatives could produce robust evidence to support decisions under certain conditions and can demonstrate even causality** (Subbiah, 2023; Hernán et al, 2016; Hernan, 2021, 2022)

Similar considerations… (Refolo, Sacchini et al, 2023):

Fourthly

- **there is no dichotomy between RCTs findings and other types of evidence.**
- In recent times, a number of issues have been raised about **the increasing incorporation of non-randomized Studies and Real-World Data/Evidence** (RWD/RWE)
- Il ruolo delle **AI-driven technologies**

(Kent et al, 2021; Hatswell et al, 2017; Crispi et al, 2019; Pongiglione et al, 2021; Facey et al, 2020; Kang, 2023)

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Similar considerations… (Refolo, Sacchini et al, 2023):

the future IS NOT about "RCTs *vs*. RWE"

BUT…

"RCTs *and* RWE"

with a more proper understanding of how they inform each other.

- **If one recognizes the role of the whole "fabric" of evidence** and the normativity which accompanies any kind of empirical research, then **that incorporation will not be seen as source of concern but rather, as a resource**.

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Similar considerations… (Refolo, Sacchini et al, 2023):

- **RWD:**
  - can be utilized to help **to complement information when extrapolating the long-term survival curve beyond the trial period for economic evaluation.**
  - can help **to provide information about the comparators** (such as the choice of relevant comparators reflecting clinical practice and treatment effects)
  - can be employed **to increase information on the generalization of evidence which is hardly captured in RCTs**. All of this is based on the varying values involved and the research questions that need to be addressed.

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- **Normativity (value-/theory-ladenness) is a key element of any kind of scientific enterprise.**
- **Scientific evidence-production is value-laden.** This is particularly true in the production of medical evidence, considering that medicine is a moral undertaking.
- **Disclosing the normative dimensions** which accompanies any kind of empirical research **can help to recognize the role of evidence.**
- **RCTs have no special status and no form of evidence is self-apparent.**

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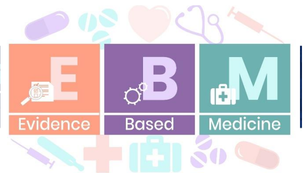

- The **research questions themselves define the best research design possible.**
- This observation can reinforce the idea that **HTA is not a mechanical activity**. It could be **considered an "art" rather than a "geometry"**, where the mosaicists (HTA researchers) paint their picture (evaluation) of a health technology by putting together the different pieces (information) with effects of light and shade

(Hofmann, 2013, Refolo, Sacchini et al, 2016)

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Digitalizzazione: Nella tecnica, conversione di grandezze analogiche in informazioni digitali, effettuata mediante un dispositivo, detto digitalizzatore o convertitore analogico-digitale.

Umana: Dell'uomo, che è proprio degli uomini (in quanto distinti rispetto agli altri esseri animati o inanimati); che ha i sentimenti proprî dell'uomo; che riguarda l'uomo; che ha l'uomo per oggetto.

Sanità: L'organismo preposto a tutelare lo stato di salute di una collettività

(Da: www.treccani.it)

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Il trinomio terminologico indica che la digitalizzazione in sanità è comunque il risultato di una attività umana, dunque come tale “human-driven”, sebbene con gradi diversi di autonomia

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La **sanità futura,** corredata di supporto digitale richiede:

- **Capacità di visione**: vedere «oltre»
- **Priorità di valore definite**: la centralità della persona (con bisogni di salute)
- **Interazione forte tra tutti gli stakeholders** (istituzionali [Min. Sal., Agenas, ISS, Regioni], professionali/scientifici, sociali [pz. / cittadini], industriali)
- **Strumenti e competenze atte a gestire la complessità della realtà medico-sanitaria**: HS; HTA; VB-HC; EBM&RWD; LEA (puntuali ed organizzativi), PDTA, L-G, DRG aggiornati tempestivamente

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Domenico di Bartolo, *Cura e governo degli infermi* (1439-1444), Sala del Pellegrinaio, Ospedale di s. Maria della Scala, Siena, Italia

Grazie per l'attenzione