IA e Diagnostica per Immagini: opportunità e sfide

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SFIDE PER L'IMPLEMENTAZIONE

Livello infrastrutturale

- Infrastrutture digitali locali, regionali o nazionali per la gestione e la governance dei dati (Cloud Nazionale; EHR 2.0; Spazio Europeo dei Dati Sanitari, EHDS)
- Le iniziative di open data dovrebbero essere promosse (principi FAIR)
- **Interoperabilità dei sistemi**
- Cybersecurity (sicurezza informatica)

Livello normativo/etico

- Protezione della privacy (**Regolamento Generale sulla Protezione dei Dati, GDPR**)
- AI – Act, MDR 2017/745
- Protezione della proprietà intellettuale
- Rispetto dei diritti umani e dell'interesse pubblico
- Distribuzione ed accesso equo
- Sostenibilità economica e ambientale

Livello gestione locale

- Coinvolgimento del top management ospedaliero
- Barriere interne (management intermedio)
- **Complessità del team di lavoro (CFO, IT, DPO, ingegneri biomedici, data scientist, clinici)**

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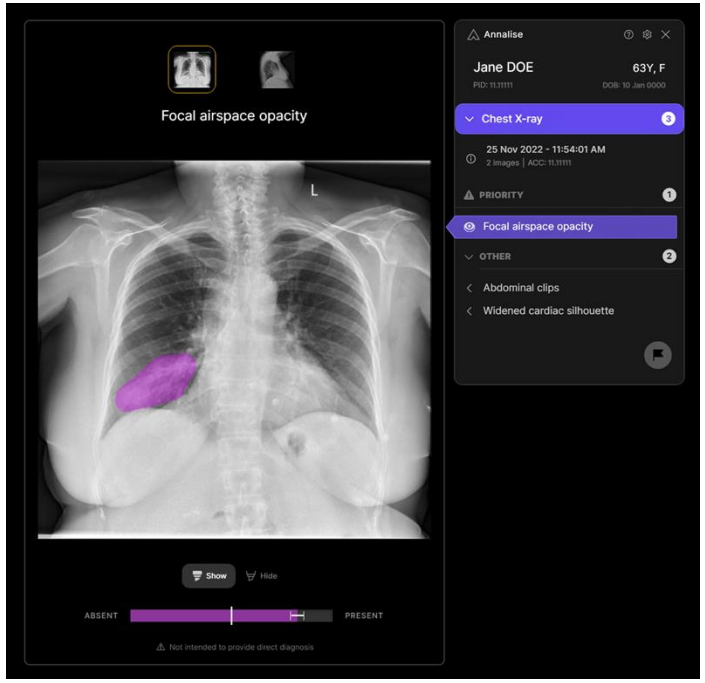

16 months

- June 2023 — 1st meeting
- Sept 2023 — 2nd meeting
- Dec 2023 — RSNA
- Jan 2024 — Internal meetings with administration
- Mar 2024 — Public notice
- June 2024 — Procurement contract
- July 2024 — Meetings with DPO
- Oct 2024 — Start of deployment

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Livello Professionale

- Professionisti sanitari

- "Divario digitale» del personale sanitario dovuto a scarsa conoscenza / sfiducia / autoreferenzialità / mancanza di incentivi per implementare soluzioni digitali

- Promozione dell'educazione a livello pre-laurea, post-laurea e di laurea

Livello Professionale

- Dispositivi medici

- Trasparenza "insoddisfacente" sui dati di validazione in molti prodotti
- Principi HTA per la validazione dell'intelligenza artificiale

- Attento monitoraggio e sorveglianza della sicurezza post-commercializzazione

Livello Paziente

- Coinvolgimento e responsabilizzazione del paziente
- Campagne educative sull'intelligenza artificiale in ambito sanitario

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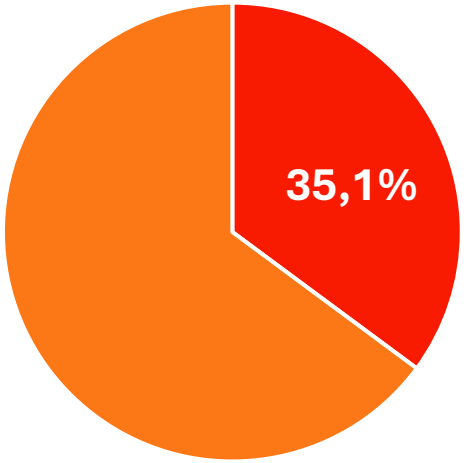
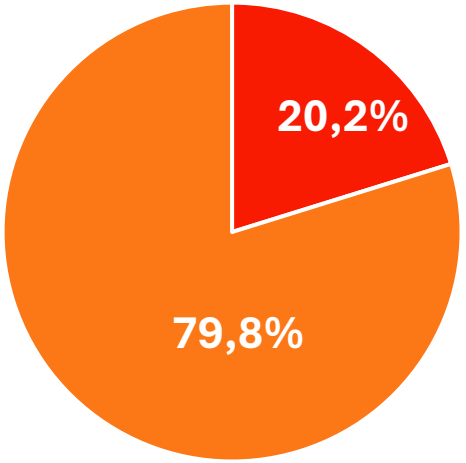
- **2022: Giu-Dic**
- Utilizzo: 35,1%





- Difficoltà/tempo di invio
- Auto-referenzialità
- Mancanza di fiducia nell'IA
- Problemi "medico-legali"

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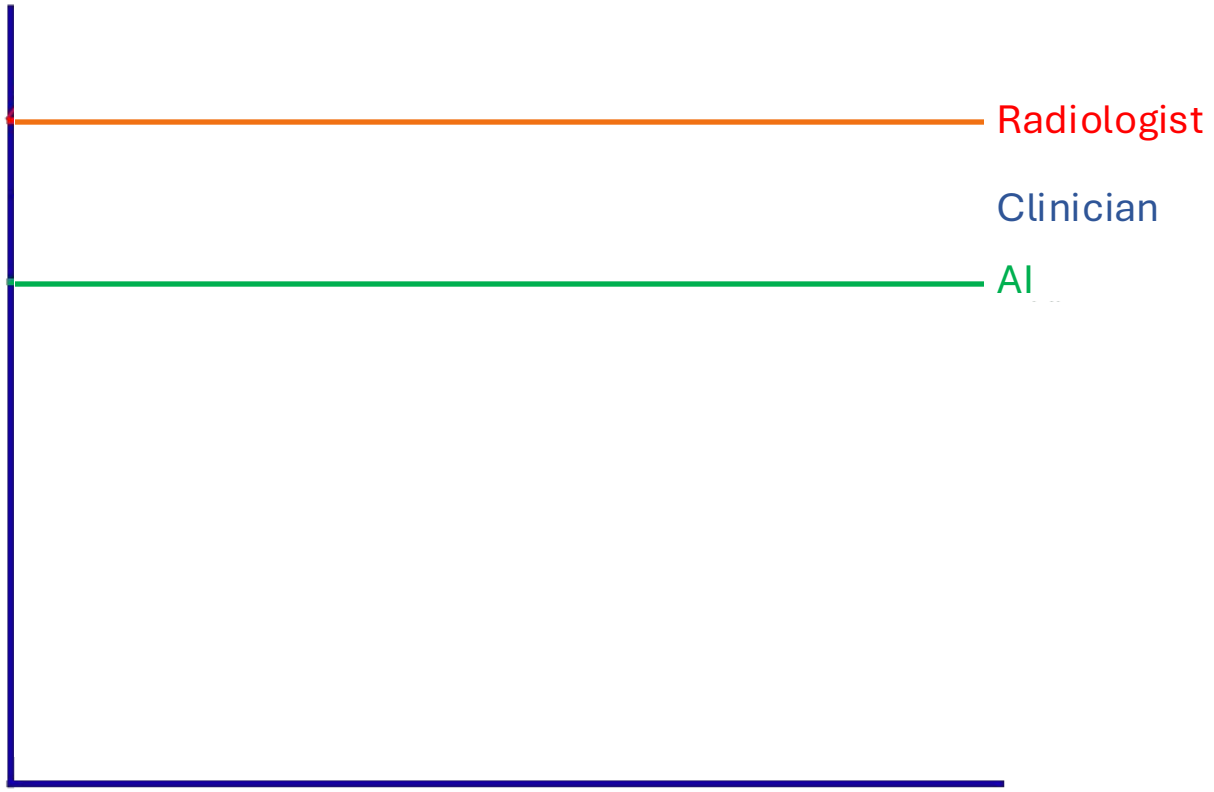
Diagramma prestazionale del radiologo durante il giorno

NHS
University Hospitals of Morecambe Bay
NHS Foundation Trust



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- **DISPOSITIVI MEDICI (AI)**
  - Progetto AIR, (Radboud Univ, NL)
    - "Insoddisfacente" trasparenza sui dati di accuratezza
      - Mancanza di una evidenza scientifica sull'efficacia di 64/100 prodotti
      - Impatto clinico potenziale, 18/100

van Leeuwen KG et al. Eur Radiol 2021

- **RISCHI**: spreco di risorse; perdita di credibilità; ritorno all'"inverno" dell'IA

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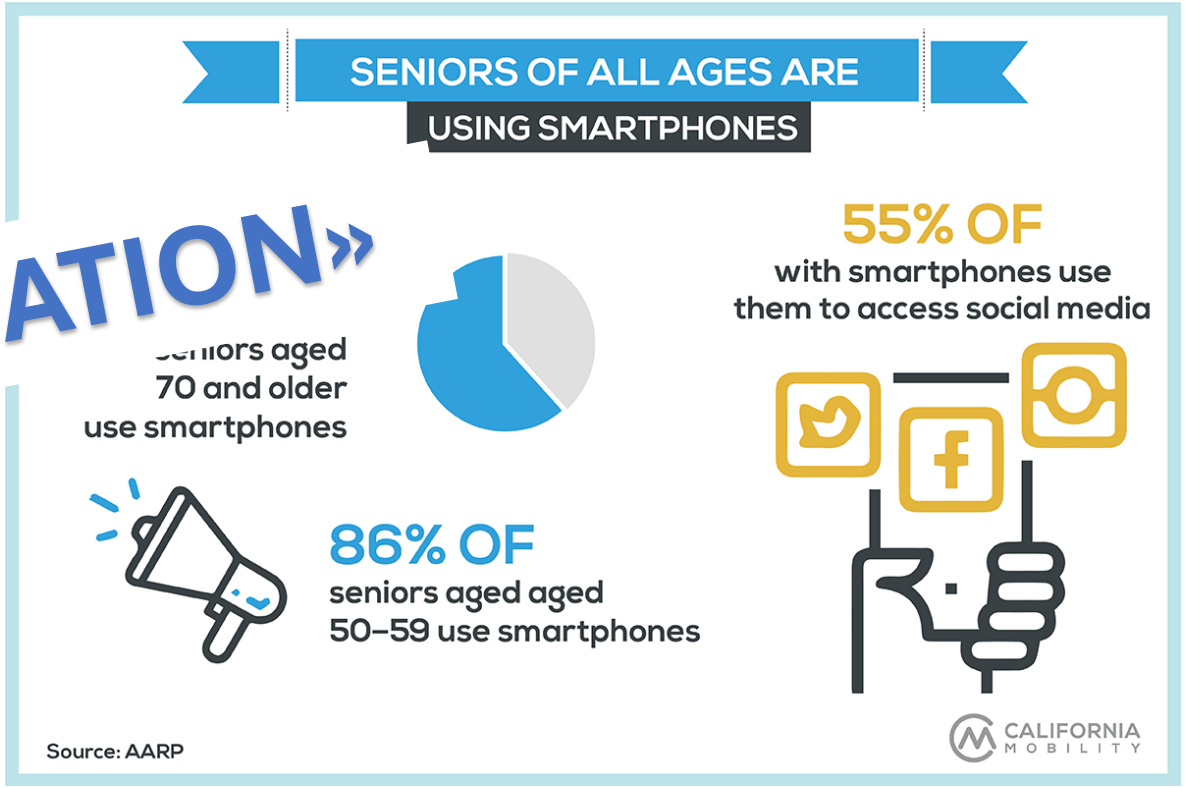
"You can try to change people's minds, but you are just wasting your time. Change the tools they have in their hands and you will change the world"

Stewart Brand

«GAMIFICATION»



CONCLUSIONI

JAMA Revisited

June 8, 1964

The Challenge of the Computer

The average physician is unlikely to build a computer in his basement from a kit. But the principles of computer analysis are not difficult to master. Evidence of the growing importance of these complex electronic machines is found in the announcement that the potential of the computer in medicine will be discussed at the 13th Annual Meeting of the American Medical Association in San Francisco on Thursday, June 25th.

Besides the data carrier, which may be magnetic tape, punched paper tape, or punched cards, an electronic computer usually has four main parts: an input device, a storage pool, a processing unit, and an output device. Input devices transmit information from a carrier by means of electrical current to a "store." In the store, coded information is magnetically recorded and laid away in specified locations. The processing unit removes information from the store or directly from the input device. After various mathematical operations, the results are made accessible via the output device, which provides the data on one of the carriers mentioned above.

Computer analysis of medical data has been carried out with increasing frequency over the past five years. Although, according to Warner et al,[1] rapid advances are being made in the collection of data from a patient concerning his illness, similar progress has not been made in analyzing and improving the logical process by which the diagnosis is reached. In essence, a computer system attempts to translate the deductive processes, by which a physician moves from signs and symptoms to a diagnosis, into mathematical formulae.

Hard work is required to program a specific computer system for a particular disease problem. For example, in applying computer procedures to the diagnosis of thyroid function, Overall and Williams[2] evaluated 21 variables (sign, symptom, or laboratory finding) from 879 patients. Next, the relative likelihood of occurrence of each variable was estimated for hypothyroid, euthyroid, and hyperthyroid populations. A program was then set up to evaluate the probability with which a patient with any combination of the 21 signs, symptoms, and laboratory measures would belong to the three diagnostic types. The last computation is the one of interest, since the ultimate aim of the computer system is to assist in the diagnosis of disease. Other situations in which the computer has been used include the diagnosis of congenital heart disease, classification of cardiopulmonary disability, prediction of coronary artery disease, analysis of electrocardiograms, and the diagnosis of psychoses. Smith[3] proposes that computers are applicable also to medical record-keeping.

The accuracy of diagnosis by a suitably programmed computer compares well with that by expert clinicians in problems such as the diagnosis of thyroid function and congenital heart disease. Of course, the more pertinent variables there are for analysis, the more likely is an accurate diagnosis. In psychiatric diagnosis it was found that, whereas "typical" archetypal profiles could be effectively classified by the computer ... the specific computer diagnosis disagreed with the specific clinical diagnosis in a high percentage of cases. Nevertheless Overall and Hollister,[4] in a recent evaluation of computer procedures, note substantial validity for the computer in selecting the proper treatment. This would be expected, since psychopharmacologic therapy is determined usually along broad, archetypal lines rather than for the specific disease.

The future of the computer in medicine is summarized by Smith,[3] who defines their challenge clearly, as follows:

"A great deal depends on what we are willing to spend, rather than on what engineers can do. Industry and commerce will foster the necessary technical developments whether medical men take part or not in the computer revolution. We have on hand an invention which will probably transform our lives and our society as strikingly as they were transformed by the harnessing of electricity. If we are to apply it to the development of more informative recording of medical observations, we shall need intensive research and much development work. The results may permit a revolution in our ability to interpret medical observations for the benefit of individual patients and of medical science."

jama.2023.18312

1. Warner, H.R., et al: Mathematical Approach to Medical Diagnosis, *JAMA* 177:177 (July 22) 1961.
2. Overall, J.E., and Williams, C.M.: Conditional Probability Program for Diagnosis of Thyroid Function, *JAMA* 183:307 (Feb 2) 1963.
3. Smith, A.: Automation of Medical Record-Keeping, *Lancet* 1:395 (Feb 22) 1964.
4. Overall, J.E., and Hollister, L.E.: Computer Procedures for Psychiatric Classification, *JAMA* 187:583 (Feb 22) 1964.

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JAMA. 1964;188(10):928-929. efi a medica".