

The Fate of Laboratory in Digital Health Eve

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Although every laboratorian knows that clinical diagnosis is made for at least 70% by laboratory data, and in some cases of molecular tests also 100%, this concept is not clear to the majority of politicians who try to save money only by reducing the number of tests available, without taking into consideration their informativeness and usefulness; in one word: appropriateness.

The reduced budget in many cases prevents the achievement of an early diagnosis only because the appropriate test is expensive, without considering that such expensive cost could be amortized by a reduced length of stay in hospital.

This is the battle that the laboratories and scientific societies of the laboratory area have conducted in recent years; but now the challenge gets even bigger because of digital health and related digital therapies that, if underestimated, may be a tombstone for laboratories.

But what is digital health? In a smart article issued last October 3 2019, G. Recchia [1] addresses the problem of digital therapies explaining what they are, what they are not and what they will become. Within the category of Digital Health Technologies there are hundreds of thousands applications, from diagnosis to monitoring of the disease to supporting the doctors' decisions to intervene against the disease. Those used by the patient is represented by support programs (or Patient Support Programs #PSP). These are interventions of various types without therapeutic properties, but the purpose of optimizing therapy (pharmacological or otherwise) that the patient is taking [2].

Digital therapies are sometimes confused with so-called "digital medicines", drugs with a sensor integrated which is activated in the stomach after ingestion and determines the release of a signal that - collected by a patch applied for example on the arm and then transmitted to the app of a smartphone - to signal to the doctor or to the caregiver the actual assumption of the therapy. They are therefore tools for monitoring adherence to therapy, not therapy.

So, Digital Therapies are therapeutic interventions, indicated for a specific disease and designed to modify a patient's behavior in order to improve the outcomes of his disease.

These interventions in particular are:

- Developed through randomized and controlled clinical trial,
- Authorized for use in clinical practice by regulatory bodies,
- Subjected, when necessary, for the purposes of reimbursement to HTA assessments
- Reimbursed in some cases to public health services, such as in England or shortly in Germany or by insurance companies
- Prescribed - in most cases - by the doctor, even if some therapy that meet all these criteria are offered to the patient directly by the manufacturer, as in the case of over-the-counter medication.

What differentiates Digital Therapy from drug (being able to appear until now the description common to both technologies) is the Active Principle, or the element of the therapy responsible for the clinical effect (both favorable and unwanted, as in the case of adverse reactions): chemical or protein molecule in the case of the drug, an algorithm in the case of digital therapy.

And this is the key! Algorithms are familiar in the laboratory and we are able to manage them. So we must ride algorithms.

To avoid the death of the laboratory, we only should modify our mode of delivering the results of the tests: using reports obtained from algorithms instead of the simple data, that unfortunately often are accompanied by reference values. The support to the clinical diagnosis is fundamental for doctors who should navigate in a sea of dozens of tests, many of which are not familiar to them. The paradox is that the sequence of steps in the unfolding of a diagnostic problem will be changed. Actually the patient goes to his doctor who orders some tests; the laboratory performs such tests and return them to the doctor, who unravel the diagnosis to the patient. The future will not cut the laboratory from the line, but instead will cut the ordering doctor, if the result with a comprehensive explanatory report will be sent directly to the patient.

And this will be the renaissance of the laboratory.

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