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Innovative Medical Devices and/or Procedures "How to Simplify the organization"

The complexity of the authorization and financing circuits for medical devices (MD) and procedures is aggravated by the delays linked to the congestion at the level of the High Health Authority ("Haute Autorité de Santé") for France and of the Notified Bodies (NBs) in the European Union with the European reform of the Medical Device Regulation (Cf. report by J. Caton and Y. Juillet: The implementation of European Regulation 2017/745/EU on medical devices).

This leads to:
- a **delay** in the development of innovative diagnostic or therapeutic procedures
- a **lack** of registration of a significant number of medical procedures which are nevertheless carried out routinely, often for several years in France, recommended by learned societies and published abroad. A caricatural example is laparoscopic visceral or urological surgery which, for several years have not been not registered, only partially in 2005, in the Common Classification of Medical Acts (CCAM; "Classification Commune des Actes Médicaux"), even though this French innovation was expanding worldwide.
- a quotation by assimilation generally carried out for these unregistered acts. Prohibited by the French Social Security Code, therefore without entitlement to reimbursement, Medicalisation of Information Systems Programme (PMSI, "Programme Médical des Systems d'Information") coding is nevertheless compulsory in the French Public Health Code for Health Establishments , which therefore requires, de facto, a so-called "assimilation" coding using the medically closest nomenclature tariff code. In 1998, the first coelio prostatectomies were developed, and in 2000 the first robotic prostatectomies were carried out by French urologists. A few months later the Food and Drug Administration (FDA) approved these interventions. In 2023 they were still not

registered in France and therefore 85% of acts rated “coelio” are assimilations for robot assistance.
- a “**Black Box**” was thus formed within databases which discredits the epidemiological data of SNIRAM (“Système national d'information inter-régimes de l'Assurance maladie”, National health insurance inter-regime information system), as the code chosen does not correspond exactly to the act carried out, thus distorting its valuation, and polluting the clinical results of cohorts. This phenomenon was aggravated by the lack of prospective maintenance by the CCAM (IGAS report, 2012, “Interministerial General Inspection for the Social Sector”), since modifications linked to medical progress not having led to corrections of the wording of these procedures.
In this context, transitional corrective procedures for access to innovation have been created, but in a heterogeneous manner, in silos, depending on the categories of products or health technologies concerned (medical devices, drugs, digital health technology, biological acts, each having its own eligibility criteria) They are also often perceived as too slow and complicated. Finally, these procedures do not apply to medical procedures not using a Medical Device.

It is therefore **imperative** to **simplify this organization** by creating a procedure usable for all innovative acts, whatever they are, and taking into account the following three invariants:

> **Traceability:** need for a national directory, kept up to date, of all medical procedures, whether the codes are tariff-based or descriptive, as soon as they are performed on a patient (ANC Surgery National Academy, HDH Health Data Hub, HCN High Committee Nomenclature).
>
> **Scalability:** sustainability of the prospective maintenance of all nomenclatures to enable them to evolve and adapt to innovation (HCN
>
> **Effectiveness:** harmonisation of all early access systems with common eligibility criteria simplifying and **accelerating** patient access to **innovation** (AIS: Agence d’Innovation en Santé, Health Innovation Agency)

The process architecture proposed by the AIS corrects many of the dysfunctions mentioned above:

Early access for all innovative acts meeting 4 common criteria of eligibility, readability, industrial commitment and funding.

Assessment by the HAS on optimized criteria supplemented by real-life records of defined and controlled duration.

Systematic creation of a descriptive code, a registration with transitional pricing, and an obligation to monitor with a real-life register.

The French National Academy of Medicine very strongly supports these proposals to harmonize and simplify early access mechanisms, allowing patients to benefit from **rapid innovation**, thanks to provisional registration with obligation to register results in real life, with transparency of therapeutic procedures, regular updating of the nomenclatures of acts, and wishes their registration in the Social Security Financing Bill ("Projet de Loi de Financement de la Sécurité Sociale"; PLFSS 2024).

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