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Telemedicine: What Framework, What Levels of Proof, Implementation Rules

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Abstract – The concept of telemedicine was formalised in France in the 2009 "Hospital, patients, health territories" (*loi hôpital, patients, santé, territoire*) law and the 2010 decree through which it was applied. Many experiments have been carried out and the regulatory institutions (Ministry, Regional Health Agency [*Agence régionale de santé*, ARS], French National Health Authority [*Haute autorité de santé*, HAS], etc.) have issued various guidance statements and recommendations on its organisation and on the expectations of its evaluation. With this background, the round table wanted to produce recommendations on different areas of medical telemonitoring (the role of telemonitoring, the regulatory system, the principles for assessment, methods of use and conditions for sustained and seamless deployment). Whilst many studies carried out on new medical telemonitoring approaches have led to the postulate that it offers benefit, both clinically and in terms of patient quality of life, more information is needed to demonstrate its impact on the organisation of healthcare and the associated medico-economic benefit (criteria, methods, resources). Similarly, contractual frameworks for deployment of telemonitoring do exist, although they are complicated and involve many different stakeholders (Director General fo the Care Offering [*Direction générale de l'offre de soins*, DGOS], ARS, HAS, Agency for Shared Health Information Systems [*Agence des systèmes d'information partagés de santé*, ASIP], French National Data Protection Commission [*Commission nationale informatique et libertés*, CNIL], French National Medical Council [*Conseil national de l'Ordre des médecins*, CNOM], etc.) that would benefit from a shared approach and seamless exchange between the partners involved. The current challenge is also to define the conditions required to validate a stable economic model in order to promote organisational change. One topical issue is

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placing the emphasis on its evaluation and operation. Access to patient data, particularly data from the health insurance funds and the use of these data, may enable the process to be more effective. In addition, the budgetary non-fungibility of the various financial envelopes for the different areas of work, restricts the consolidation of financial impact. Funding methods will need to be adapted to this new distribution of roles, both at the centre of the healthcare system and in the industrial ecosystem. All of these changes will help the leaders of our healthcare system to bring this new ambition closer to all of the people working in the health economy.

Abbreviations: see end of article.

1. Preamble, definitions, and limitations of the subject matter

Telemedicine is defined in the 2009 the "Hospital, patients, health territories" (*loi hôpital, patients, santé, territoire*, HPST) law[1] as "A remote form of medical practice using information and communication technologies. It links one or more health professionals to each other or to a patient, and includes by necessity a medical professional and, where applicable, other professionals providing care to the patient. It enables a diagnosis to be made, provides preventive monitoring or post-treatment follow-up for an at risk patient, a treatment decision to be prepared, substances to be prescribed and services or acts to be prescribed or performed or patients' state to be monitored. The definition of telemedicine and the conditions in which it is used and reimbursed financially are set by decree, taking account of the deficiencies in the care offering due to insulation and geographical isolation".

The telemedicine decree of 19 October 2010[2] sets out the regulatory framework for telemedicine, defining 5 telemedicine acts: teleconsultation, tele-expertise, medical telesupervision, medical tele-assistance and medical regulation by telephone of the emergency number 15 (French call triage system).

It was with this background that the round table (RT) N°5 of the XXIX National Meetings for Pharmacology and Clinical Research, Innovation and Assessment of Health Technologies dedicated to telemedicine was set up.

The participants in this round table wish to limit their work to the subject of medical telemonitoring. Medical telemonitoring involves a situation in which a doctor is responsible for the remote monitoring and interpretation of a patient's medical parameters, recording and transmitting data which may be gathered automatically or produced by the patient him/herself or by a health professional. The RT defined the scope of its medical telemonitoring work to chronic diseases in patients with a severe disease and/or complex treatment, managed by the ambulatory or hospital sector. During the RT debates, the chronic diseases for which experiments are already conclusive or are being analysed, included diabetes requiring complex insulin therapy, heart failure, severe renal failure on dialysis or post-transplant and severe respiratory insufficiency.

The RT wanted to review the current situation and propose recommendations to promote the deployment of home medical telemonitoring solutions in France.

2. Conceptual framework for medical telemonitoring

Although the level of clinical evidence for medical telemonitoring still remains to be confirmed for some chronic diseases (see below), the RT considered that the clinical/social benefit of home telemonitoring has been proven together with its acceptance by patients, who see an improvement in their quality of life. This has now been confirmed in scientific literature.

It is important firstly to emphasise that medical telemonitoring is only one component of the care pathway. It needs to be designed, assessed, deployed and managed as one of the parts of the coordinated organisation of a care pathway dedicated to one or more chronic diseases. As a result, it is important to always be aware of the organisational and coordination methods which may differ depending on the people involved.

The assessment model has not yet been formalised and it is often difficult in published assessments to distinguish what can be specifically attributed to the telemonitoring component from what is due to the organisation and coordination of the care pathways. These care pathways are occasionally constructed around new telemonitoring solutions. On other occasions it is the introduction or change in the telemonitoring system which is often (but not always) based on a medical device which is offered within a pre-existing care pathway. In each case it is the entire system, the telemonitoring solution within a care pathway, which needs to be assessed.

At present, most of the medical telemonitoring solutions are in their early days, mostly for clinical purposes, with no consolidated model for financial reimbursement, and practical operational difficulties still need to be resolved. These difficulties are due, amongst other things, to a need for consensus clarification of the regulatory scope covered by the concept of a telemonitoring communicating medical device (MD) [particularly for the software part], to optimising the governance of the telemonitoring solution and to introducing cooperation protocols. In addition, most of the experiments are carried out regionally and a model for inter-regional or national roll-out still needs to be defined.

One conceptual framework has been proposed in which the patient, either at home or in a replacement residential facility for dependent elderly (*établissement hospitalier pour personnes âgées dépendantes*, EHPAD), is positioned at the centre of the organisation of a care pathway (figure 1). The telemonitoring data are recorded