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Special funding schemes for innovative medical devices in French hospitals: The pros and cons of two different approaches☆

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ABSTRACT

Financing innovative medical devices is an important challenge for national health policy makers, and a crucial issue for hospitals. However, when innovative medical devices are launched on the European market there is generally little clinical evidence regarding both efficacy and safety, both because of the flaws in the European system for regulating such devices, and because they are at an early stage of development. To manage the uncertainty surrounding the reimbursement of innovation, several European countries have set up temporary funding schemes to generate evidence about the effectiveness of devices. This article explores two different French approaches to funding innovative in-hospital devices and collecting supplementary data: the coverage with evidence development (CED) scheme introduced under Article L. 165-1-1 of the French Social Security Code; and national programs for hospital-based research. We discuss pros and cons of both approaches in the light of CED policies in Germany and the UK. The CED policies for devices share common limitations. Thus, transparency of CED processes should be enhanced and decisions need to be made in a timely way. Finally, we think that closer collaboration between manufacturers, health authorities and hospitals is essential to make CED policies more operational.

1. Introduction

In 2009, the market for medical devices in France was €19 billion, with between 800,000 and 2 million marketed products [1]. The French National Health Insurance (NHI) repaid €8.3 billion (43%) [1]. The rest was borne by private insurers and patients and consisted mainly of medical aids such as hearing aids, glasses or dentures. Most medical devices for individual use in French hospitals are covered by a diagnosis-related group (DRG)-based payment. However, hospitals can be reluctant to use new and costly technologies until the DRG-based payment system is updated to account for their additional costs [2,3]. Thus, to facilitate the adoption of innovative health technologies by hospitals, most European countries using a DRG-based payment system have established additional payment instruments [2].

In France, additional payments for in-hospital devices reached €1.5 billion in 2009 [1]. In contrast, additional

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payments for expensive hospital drugs reached €2.5 billion at the same time. Additional payment for in-hospital devices is only applicable to implantable devices and to those included on the list of products and services qualifying for reimbursement (LPPR). Applications for reimbursement are made solely by manufacturers and not by the institutional users (hospitals) [4]. For innovative devices and for devices that do not match any existing definition on the LPPR, a dossier is submitted by the manufacturer to the National Committee of Medical Devices and Health Technologies (CNEDIMTS) for assessment [5]. To be included on the LPPR, there must be clinical data demonstrating the expected clinical benefit of the device, including the efficacy/safety ratio, and also showing that it is superior to existing technologies or alternative treatments [4,5].

However, for most medical devices arriving on the EU market, there is little efficacy evidence available and even less evidence about cost-effectiveness [6]. This is mainly due to deficiencies in the EU regulations and particularly the vagueness of EU Directives on medical devices about requirements for premarketing trials (Directives 90/385/EEC, 93/42/EEC and 98/8/EC updated and amended by Directive 2007/47/EC) [6–8]. In addition, short product life cycles, methodological difficulties for designing trials (particularly for randomization and blinding) and managing the operator's learning curve, do not encourage manufacturers to set up long-term studies to generate evidence [9–11]. To manage the uncertainty surrounding the reimbursement of innovative devices, health authorities in European countries, and particularly Germany, UK and France propose temporary reimbursement, commonly called coverage with evidence development (CED) schemes, and simultaneously collect clinical effectiveness and/or cost effectiveness data [12,13]. Apart from reimbursement schemes, special funding for national research projects may also be made available to collect evidence within a given period of time for innovative medical devices; this is the case in France and in the UK [14,15].

Using the viewpoint of the hospital, we assess these two different approaches to temporary funding for innovative devices, both of which are currently implemented in France. We then consider the pros and cons of both approaches and compare the French CED scheme to comparable schemes used in two other European countries: Germany which has very recently introduced a CED scheme, and the UK where this type of scheme has been operational for many years [16,17]. Finally, we discuss potential improvements for CED policies applied to devices in these three European countries.

2. Special funding schemes for innovative medical devices in French hospitals

2.1. The CED approach from Article L. 165-1-1

Generally, the aim of CED schemes is to provide provisional access to new medical products while collecting the evidence needed to determine whether definitive coverage is warranted [18]. This method differs from traditional postmarketing evidence generation in that the objective of the supplementary evidence collection is to reduce uncertainty around a specific aspect of the evidence base [19]. Thus, the value of CED is that it allows healthcare decision makers to make available a medical product in a controlled manner while also defining what evidence is required to support further diffusion of the technology [20].

Article L. 165-1-1 of the French Social Security Code has set rules, established in 2009 and applicable since March 2010, of conditional coverage for innovative health products, services or interventions [21]. This has been developed for promising health products for which the CNEDIMTS is not able to establish the clinical benefit due to insufficient data. Only the CNEDIMTS can select eligible products and does so on the basis of technological intelligence or applications for LPPR reimbursement. Thus, manufacturers cannot apply for the CED scheme. The opinion issued is submitted to the French Ministry of Health for a decision; the Ministry establishes a decree indicating the number of patients to be involved, the specific conditions of use, the funding period and the list of hospitals leading the study. The French Ministry of Health has to specify requirements for studies, but the law is unclear on this point and clinical and/or cost effectiveness studies may be involved. Finally, a temporary fee including intervention, hospitalization and product costs is granted for two years by the NHI [14]. Currently, only very few devices have been designated as eligible by the CNEDIMTS and a single decision from the French Ministry of Health has been taken very recently.

2.2. Programs for hospital-based research

The French Ministry of Health also provides grants to hospital-based research programs to promote innovation within hospitals. After annual national and regional calls for proposals, lump sums are delivered to cover a limited period; this is funded by an envelope dedicated to public interest missions. Research teams in university hospitals identify candidate health technologies and submit projects in response to the relevant national or regional calls for tender [22]. Projects are reviewed and ranked by independent experts in accordance with French priorities for public health. Among five programs, only two are relevant to innovative medical devices: the Program for Hospital Clinical Research (PHRC) and the Program for Medical Economic Research (PRME).

The purpose of the PHRC is to promote the transfer of drugs or devices at an early stage of development from fundamental research to clinical research [23]. Projects are designed as clinical research trials for demonstrating safety and efficacy and have to conform to the national research priorities established by the French Ministry of Health. In 2012, 112 PHRC projects were funded nationally: nine (8%) concerned devices and together received a total funding of €3.9 million [24].

Unlike the PHRC, PRME projects do not involve devices at a pre-marketing stage, but only CE-marked devices [23]. PRME projects have to focus on cost-effectiveness analysis and should expressly provide an incremental cost-effectiveness ratio (ICER). In 2011, six PRME projects

dedicated to devices were funded by the French Ministry of Health for a total amount of €5.5 million [25].

3. Pros and cons of the two different approaches

3.1. Pros

The French CED permits the early involvement of health authorities which establish guidance for reducing uncertainty in view of national reimbursement. This point is decisive because, at the end of the temporary coverage, a decision has to be taken in a timely way to avoid a gap in the funding for the technology which could be financially detrimental for hospitals [26]. Another advantage of the French CED involve the financial arrangements: full coverage is offered, not requiring any refunds by the manufacturer. This approach is economically attractive to the manufacturer, because collecting supplementary evidence does not involve making a loss [13].

PHRC/PRME programs confer on hospitals the job of identifying promising innovations and thereby ensure responsiveness and better acceptability by end-users [27]. These programs are in great demand by hospitals. For example, there were 582 PHRC projects for drugs and devices submitted in 2012 [24]. Clearly, they help French hospitals undertaking studies on specific medical devices and can be used for, in particular, costly and non-implantable devices not covered by additional payments. Furthermore, they increase the clinical data available, and especially data specific to the French context [14].

3.2. Cons

Both approaches provide funding for a limited period. In the context of PHRC/PRME programs, hospitals sometimes have to find supplementary funding for longer-term projects or, worse, stop the project before the programmed end [1]. With the French CED, manufacturers receive financial support for two years, but the law does not specify what happens at the end of this period.

Only the CNEDIMTS is empowered to determine whether a device meets the criteria of the French CED [21]. No official definition of an innovative product or intervention is available and this is consequently left to the interpretation of the committee. Furthermore, the leading French medical device industry association indicates that the process for innovations is much too slow [28]. Indeed, three health technologies were selected by the CNEDIMTS in December 2011 with no further decision taken. Very recently, and to everyone's surprise, the French Ministry of Health gave its approval for a retinal prosthesis system which had not even been selected among the three technologies in 2011.

By providing data specific to the French context, PHRC/PRME studies are, in theory, upstream from CNEDIMTS evaluations for additional payment. Consequently, the French Ministry of Health recently decided that the CNEDIMTS should undertake no evaluation of a device undergoing PHRC/PRME studies [29]. Thus, implementing a PHRC/PRME study may paradoxically introduce delay in CNEDIMTS evaluation and the final reimbursement process [14]. In addition, these programs are not an option of the national reimbursement scheme. As a result, there is no guarantee that the device, even if the data collected are sufficient, will ultimately be reimbursed. Finally, PHRC/PRME programs run by hospital-based teams can in some cases be redundant with the international clinical research programs run by the manufacturer [14].

4. Comparison to other European countries

The three European countries with the largest expenditures on medical devices – Germany, France and the UK – have all applied CED to innovative procedures and devices [3,14,16,17]. The main features of these CED schemes are presented in Table 1.

In Germany, a law of the German Social Code in 2012 (Section 137e SGB V) introduced a CED scheme run by the Federal Joint Committee (G-BA) [17,30]. Under this scheme, the manufacturer applies for assessment by the G-BA; note that this is impossible with the French CED scheme [31]. Then, if the procedure is deemed to have "potential" after evaluation by the G-BA and if a device is involved, health authorities offer a partial financial support, up to 50%, to the manufacturer for evaluations [17,31]. It is important to note that the German CED focuses on new diagnostic and therapeutic treatment methods rather than on the device itself. The company is also obliged to refund the G-BA once the device is finally reimbursed. By contrast, as we describe above, French health authorities provide a full financial support with no refunds required. However, the French CED only concerns one manufacturer at a time, whereas the German system makes it possible for more than one manufacturer with similar devices to become involved in the trial [17,31]. Since 1999, the National Institute for Health and Clinical Excellence (NICE) may recommend the use of a health technology (drugs, procedures or devices) in the context of evidence development [16]. Two different recommendations for collecting evidence can be issued: "Only In Research" (OIR) for which the technology is used solely for patients participating in a research program; or "Approval With Research" (AWR) for which the health technology can be used routinely with further research needed. In contrast to the German and French policies, the funding process is not formally described by the NICE [32]. Indeed, research can be funded by the manufacturer or the public sector, for instance the National Institute for Health Research (NIHR) and the National Health Service (NHS). Like the French and German health authorities, NICE specifies the nature of the evidence required, but not clearly how studies should be designed [32].

OIR/AWR recommendations, like the French CED, are perceived by manufacturers as an additional delay in making innovations generally available [16,28]. Since 2006, NICE has proposed a faster process which makes possible issuing guidance closer to the time of marketing authorization [33]. This process, called the "single technology appraisal" (STA) process, was designed to appraise a single health product with a single indication [34]. OIR/AWR recommendations can be used within the STA process.

Table 1
Main features of CED schemes in Germany, France and the UK.

Country	France	Germany	UK
CED scheme	Article 165-1-1	Section 137e SGB V	OIR/AWR
Year established	2009	2012	1999
Actors involved	CNEDIMTS, French Ministry of Health	G-BA, IQWiG	NICE, NIHR
Health technologies	Procedures and devices	Procedures and devices[†]	Procedure, devices and drugs
Financial support	Full coverage	Partial coverage (50% maximum–70% for rare diseases)	No standard
Funding period	2 years	No standard	No standard
Refund by the manufacturer	No	Yes	Manufacturers or NIHR fund the trial
Number of manufacturers involved	Only one	One or more	Only one
Number of decisions for procedures/devices	1	Unpublished data	13[*]

AWR: Approval With Research; CNEDIMTS: National Committee of Medical Devices and Health Technologies; G-BA: Federal Joint Committee; IQWiG: Institute for Quality and Efficiency in Healthcare; NIHR: National Institute for Health Research; NICE: National Institute for Health and Clinical Excellence; OIR: Only In Research.

[*] Between 2000 and 2010 [16].

[†] Focus on new diagnostic and therapeutic treatment methods rather than on the device itself.

However, it seems that the use of OIR/AWR recommendations has dramatically declined since the introduction of the STA process [16].

5. Discussion and policy implications

Most European countries using a DRG-based payment system have introduced additional reimbursement components to facilitate the adoption of innovative medical devices in hospitals [2,3]. In France, many in-hospital devices for individual use do not fulfil the requirements for additional payments; this is particularly true for many costly and innovative non-implantable devices or implantable devices for which only little evidence is available. For such devices, the CED scheme and PHRC/PRME programs can help to narrow the gap and to fund studies for collecting evidence. In the light of the experience of three large European countries, as described in Section 4, it appears that CED schemes still require improvements to make them more operational.

Indeed, the transparency of CED processes should be enhanced, in particular by clearly stating the selection criteria for devices that may benefit from such approaches [14,31,32]. Also, CED decisions need to be made more quickly [28,32]. This point has already been highlighted before and lessons could be learned from what has been done by NICE with the STA process [20,34]. If CED schemes were no longer to be perceived as a supplementary barrier, it would contribute to improve collaboration between manufacturers, health authorities and also hospitals. Indeed, effective collaboration between all stakeholders is undoubtedly the cornerstone of success for the CED approach [35]. From the viewpoint of the hospital, PHRC/PRME programs work well because physicians are involved early in the process. As a result, projects are more likely to be successfully established, because they correspond to the hospitals' expectations in accordance with local needs. Therefore, French health authorities are currently considering cooperation networks with university hospitals to strengthen evidence collection [1]. Finally, trial funding seems to be a key issue for CED policies. In France, funding in both schemes is for a limited period whereas, in the UK, research budgets are not clearly designated by NICE. This has to be modified, especially for the many small companies in the medical device sector which do not necessarily have sufficient resources to conduct long-term trials [36]. This is a particularly important point, because manufacturers have no assurance that the device will ultimately be reimbursed. Thus, the German approach which involves the manufacturer refunding the financial support once the innovative device is reimbursable could also be exploited in, or adapted to, other countries [31].

In conclusion, CED schemes for innovative medical devices offer great potential for collecting evidence and reducing uncertainty. However, transparency, timeliness, closer collaboration between all stakeholders and predictability for manufacturers are key challenges that need to be addressed in order to make CED policies more effective.

References

[1] Morel A, Kiour A, Garcia A. Evolution et maîtrise de la dépense des dispositifs médicaux. In: Inspection générale des affaires sociales; 2010. ⟨http://www.ladocumentationfrancaise.fr/rapports-publics/114000137⟩.
[2] Scheller-Kreinsen D, Quentin W, Busse R. DRG-based hospital payment systems and technological innovation in 12 European countries. Value in Health 2011;14:1166–72.
[3] Schreyögg J, Bäumler M, Busse R. Balancing adoption and affordability of medical devices in Europe. Health Policy 2009;92:218–24.
[4] Chevreul K, Durand-Zaleski I, Bahrami SB, Hernández-Quevedo C, Mladovsky P. France health system review. Health Systems in Transition 2010;12:1–291, xxi–xxii.
[5] Huot L, Decullier E, Maes-Beny K, Chapuis FR. Medical device assessment: scientific evidence examined by the French National Agency for Health—a descriptive study. BMC Public Health 2012;12:585.
[6] Storz-Pfennig P, Schmedders M, Dettloff M. Trials are needed before new devices are used in routine practice in Europe. BMJ 2013;346:f1646.
[7] Cohen D, Billingsley M. Europeans are left to their own devices. BMJ 2011;342:d2748.
[8] Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. New England Journal of Medicine 2012;366:848–55.
[9] Beaussier H, Junot H, Lancrenon S, Faure P. New medical device hospital assessment: what kind of clinical data? Annales Pharmaceutiques Francaises 2012;70:35–45.
[10] Sedrakyan A, Marinac-Dabic D, Normand S-LT, Mushlin A, Gross T. A framework for evidence evaluation and methodological issues in implantable device studies. Medical Care 2010;48:S121–8.

[11] Boudard A, Martelli N, Prognon P, Pineau J. Clinical studies of innovative medical devices: what level of evidence for hospital-based health technology assessment? Journal of Evaluation in Clinical Practice 2013;19:697–702.
[12] Chalkidou K, Tunis S, Lopert R, Rochaix L, Sawicki PT, Nasser M, et al. Comparative effectiveness research and evidence-based health policy: experience from four countries. Milbank Quarterly 2009;87:339–67.
[13] Stafinski T, McCabe CJ, Menon D. Funding the unfundable: mechanisms for managing uncertainty in decisions on the introduction of new and innovative technologies into healthcare systems. Pharmacoeconomics 2010;28:113–42.
[14] Gilard M, Debroucker F, Dubray C, Participants of Round Table No. 1 of Giens Workshops XXVIII, Allioux Y, Aper E, et al. Scientific evaluation and pricing of medical devices and associated procedures in France. Thérapie 2013;68:201–8.
[15] National Institute for Health Research. Invention for innovation. National Institute for Health Research, Central Commissioning Facility; 2013. ⟨http://www.ccf.nihr.ac.uk/i4i⟩.
[16] Longworth L, Youn J, Bojke L, Palmer S, Griffin S, Spackman E, et al. When does nice recommend the use of health technologies within a programme of evidence development? Pharmacoeconomics 2013;31:137–49.
[17] Gemeinsamer Bundesausschuss. Verfahrensordnung Verfahren für Anträge und Richtlinien nach § 137e SGB V. Gemeinsamer Bundesausschuss; 2013. ⟨http://www.g-ba.de/informationen/beschluesse/1573⟩.
[18] Miller FG, Pearson SD. Coverage with evidence development: ethical issues and policy implications. Medical Care 2008;46:746–51.
[19] O'Malley SP, Selby WS, Jordan E. A successful practical application of coverage with evidence development in Australia: Medical Services Advisory Committee interim funding and the PillCam Capsule Endoscopy Register. International Journal of Technology Assessment in Health Care 2009;25:290–6.
[20] Hutton J, Trueman P, Henshall C. Coverage with evidence development: an examination of conceptual and policy issues. International Journal of Technology Assessment in Health Care 2007;23:425–32.
[21] Article L165-1-1 modifié par la Loi no. 2009-879 du 21 juillet 2009 - art. 5 (V). JORF 1er mars 2010, (http://www.legifrance.gouv.fr).
[22] Marguet P-O, Armoiry X. Le financement des dispositifs médicaux innovants. IRBM News 2012;33:21–30.
[23] Circulaire no DGOS/PF4/2013/105 du 18 mars 2013 relative au programme hospitalier de recherche clinique, au programme de recherche médico-économique, au programme de recherche sur la performance du système de soins, au programme de recherche infirmière et paramédicale, au programme de recherche translationnelle, pour l'année 2013, (http://www.sante.gouv.fr/grippe/soutien-aux-techniques-innovantes-couteuses-stic-l-appel-a-projets.html).
[24] Ministère des Affaires sociales et de la Santé. Le programme hospitalier de recherche clinique (PHRC): les dossiers retenus. Ministère des Affaires sociales et de la Santé; 2013. ⟨http://www.sante.gouv.fr⟩.
[25] Ministère des Affaires sociales et de la Santé. Programme de Recherche Médico-Economique (PRME). Ministère des Affaires sociales et de la Santé; 2013. ⟨http://www.sante.gouv.fr⟩.
[26] Trueman P, Grainger DL, Downs KE. Coverage with evidence development: applications and issues. International Journal of Technology Assessment in Health Care 2010;26:79–85.
[27] McGregor M, Brophy JM. End-user involvement in health technology assessment (HTA) development: a way to increase impact. International Journal of Technology Assessment in Health Care 2005;21:263–7.
[28] Ducruet C. Les industriels du matériel médical à la peine sur le marché français; 2012. ⟨http://www.lesechos.fr⟩.
[29] Ministère des Affaires sociales et de la Santé. Prise en charge de l'innovation par la DGOS: de la recherche clinique à la diffusion aux patients. Ministère des Affaires sociales et de la Santé; 2013. ⟨http://www.sante.gouv.fr⟩.
[30] Ozegowski S, Sundmacher L. Ensuring access to health care—Germany reforms supply structures to tackle inequalities. Health Policy 2012;106:105–9.
[31] Sauerland S. Implementing the new German law on coverage with evidence development for non-drug interventions. In: ISPOR 15th annual European congress—. 2012.
[32] Dhalla IA, Garner S, Chalkidou K, Littlejohns P. Perspectives on the National Institute for Health and Clinical Excellence's recommendations to use health technologies only in research. International Journal of Technology Assessment in Health Care 2009;25:272–80.
[33] Kaltenthaler EC, Dickson R, Boland A, Carroll C, Fitzgerald P, Papaioannou D, et al. A qualitative study of manufacturers' submissions to the UK NICE single technology appraisal process. BMJ Open 2012:2.
[34] Sculpher PM. Single technology appraisal at the UK National Institute for Health and Clinical Excellence. Pharmacoeconomics 2010;28:347–9.
[35] Carbonneil C, Quentin F, Lee-Robin SH. A common policy framework for evidence generation on promising health technologies. International Journal of Technology Assessment in Health Care 2009;25:56–67.
[36] Garber AM. The price of growth in the medical-device industry. New England Journal of Medicine 2006;355:337–9.