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Improving care in End-Stage Renal Disease (ESRD): from belief in market tools to the need for complexity management

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Contents

List of acronyms

ABM: Agence de la Biomédecine

AGGIR: Autonomie Gérontologie Groupes Iso-Ressources

ANAP: Agence Nationale d'Appui à la Performance

APD: Automated Peritoneal Dialysis

ARF: Acute Renal Failure

ARH: Agence Régionale de l'Hospitalisation

ARS: Agence Régionale de Santé

ASHD: Assisted Self HaemoDialysis

ATIH: Agence Technique de l'Information sur L'Hospitalisation

AV: ArterioVenous

CAPD: Continuous Ambulatory Peritoneal Dialysis

CKD5D: Chronic Kidney Disease stage VD

CEO: Chief Executive Officer

CMS: Centers for Medicare and Medicaid Services

CNAMTS: Caisse Nationale d'Assurance Maladie des Travailleurs Salariés

CNI: Commission Nationale d'Internat et de Post-Internat

CNP: Comité National de Pilotage

CPO: Coordination Prélèvement d'Organes

CPOM: Contrat Pluriannuel d'Objectifs et de Moyens

CSP: Code de la Santé Publique

DGOS: Direction Générale de l'Offre de Soins

DGS: Direction Générale de la Santé

DPC: Développement Professionnel Continu

DREES: Direction de la Recherche, des Études, de l'Évaluation et des Statistiques

DRG: Diagnosis Related Group

DSS: Direction de la Sécurité Sociale

EFG: Etablissement Français des Greffes

ENA: Ecole nationale d'administration

ENCC: Etude Nationale des Coûts à méthodologie Commune

ERE: Erreur Relative d'Echantillonnage

ESRD: End-Stage Renal Disease

ESRF: End-Stage Renal Failure

FAG: Forfait Annuel Greffes

FFS: Fee-For-Service

FNAIR: Fédération Nationale d'Aide aux Insuffisants Rénaux

GDP: Gross Domestic Product

GFR: Glomerular Filtration Rate

GHM: Groupe Homogène de Malades

GHS: Groupe Homogène de Séjours

GP: General Practitioner

HCFA: Health Care Financing Administration (HCFA)

HAS: Haute Autorité de Santé

HD: HaemoDialysis

HDC: Hospital or in-Centre Haemodialysis

HHD: Home Haemodialysis

HPST: Hôpital, Patients, Santé, Territoires

INSERM: Institut National de la Santé Et de la Recherche Médicale

ISHCOF: International Study of Health Care Organisation and Financing

KCE: Centre fédéral d'Expertise des soins en santé en Belgique

KDQOL: Kidney Disease Quality of life

LRD: Living Related Donors

LURD: Living UnRelated Donor

MOS SF 36: Medical Outcome Study Short- Form 36 item health survey

NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases

OECD: Organisation for Economic Co-operation and Development

OFAS: mission sur l'Organisation et le Financement des Activités de Soins de l'ABM

OQOS: Objectif Quantifié de l'Offre de Soin

ONDPS: Observatoire National pour la Démographie des Professions de Santé

PD: Peritoneal Disease

P4P: Pay For Performance

PO: forfait Prélèvement d'Organe

PPS: Prospective Payment System

QALY: Quality-Adjusted Life-Year

QIP: Quality Incentive Program

QoL: Quality of Life

RAND: Research ANd Developement corporation

RCT: Randomized Controlled Trial

RCP: Réunion de Concertation Pluridisciplinaire

REIN: Renal Epidemiology and Information Network registry

RMNP: Risk Management National Programs

RRT: Renal Replacement Therapy

RTR: Renal Transplant Recipient

Self-HD: Self-HaemoDialysis (within satellite facilities)

SHD: Satellite HaemoDialysis

SIOS-PRS: Schéma Interrégional d'Organisation des Soins – Programme Régional de Santé

SROS: Schema Régional d'Organisation Sanitaire

SROS-PRS: Schéma Régional d'Organisation des Soins – Programme Régional de Santé

T2A: Tarification à l'activité (French PPS)

TEC: Technicien d'Etudes Cliniques

TP: Transplantation

UDM : Unité de Dialyse Médicalisée

URCAM: Union Régionale des Caisses d'Assurance Maladie

USRDB: United States Renal Data Base

Introduction

The core question in the following analysis is: **Is it possible (and, if yes, how?) to improve the way in which End-Stage Renal Disease (ESRD) patients are being guided towards the various treatments available by applying a better pricing policy to these treatments?**

Firstly why choose this particular disease: Why ESRD? Why is it interesting to look at this specific topic?

There are many reasons for doing so, but the main one is probably that it presents itself as a major challenge in most OECD (Organisation for Economic Co-operation and Development) countries.

Why is ESRD a special case and what exactly is this disease, also referred to as End-Stage Renal Failure (ESRF) or Chronic Kidney Disease stage VD (CKD5D)? In simple terms, it is the final stage of chronic insufficient cleansing of body fluids by the kidneys. *It is characterized by severe irreversible kidney damage (measured by the level of PROTEINURIA) and a reduction in the GLOMERULAR FILTRATION RATE to less than 15 ml per min (Kidney Foundation: Kidney Disease Outcome Quality Initiative, 2002).*

The concern of OECD countries can be easily understood when considering the available epidemiologic data. Renal function declines with ageing; diabetes and hypertension are major causes for ESRD (37% and 27% respectively in the USA according to the USRDB 2008 annual report) ***(***63***)***. Accordingly, ESRD is a major issue in countries where the life expectancy increases every year and where lifestyle and eating habits tend to lead to an ever-increasing incidence of diabetes and hypertension. In France the number of individuals with chronic renal disease was estimated by the Ministry of Health in its "Programme d'actions insuffisance rénale chronique 2002-2003-2004" to be in the range 1.7 – 2.25 millions in 2002. Added to this broad estimation, we know from the REIN, the French Renal Epidemiology and Information Network registry, that, on 1 January 2009, roughly 1 in 1000 individuals in France (68 000 people) were identified and treated for ESRD ***(***45-52***)***. This number equates to the OECD 2007 average: 0.99/1000. Japan and Iceland are at the extremities of the scale with 1.9/1000 and 0.5 /1000 respectively. The rate in the USA is also quite high at 1.7/1000 ***(***47***)***.

The increase in the prevalence of individuals treated for ESRD between 1985 and 2007 is a striking feature in the OECD comparisons: an average annual percentage increase of +5.9% (+5.1% in France, +6.3% in the USA). The increase means good and bad news at the same time. On the one hand, it illustrates the improvement achieved in ESRD management and thus the life expectancy of treated patients but on the other hand, it also

reflects the greater number of patients affected by the disease. ESRD incidence in France in year 2009 was around 9400 new cases/year, which represents around 150 per million of population (pmp). Incidence growth in the 5 regions, which have been part of the national registry since 2005, reached an average of +1.5% for the period 2005-2009, mainly due to diabetes, which accounted for 41% of new cases in 2009.

In a period when countries are trying to contain health expenditure (which amounted to 11.8% of French GDP in 2009, 8% in 1985) taking the slow down in average GDP growth into consideration (2% from 1991 to 2004 in France, 2.7% on average at OECD level), the fast growing prevalence of a particular disease can quickly transform into a matter of acute concern from a financial point of view[1], even more so when treatment costs are high, which is especially true for a chronic disease like ESRD. ESRD marks a stage when kidney function is so limited that Renal Replacement Therapy (RRT) or kidney transplantation are the only options. *In France, on 1 January 2009, it was estimated that 37 000 patients were on dialysis and 31 000 lived with a functioning graft* ***(***39***).*** There are two main RRT alternatives: haemodialysis (HD), an "extra-corporal approach" using a dialyzer outside the body, or peritoneal dialysis (PD), an "intra-corporal approach" using the natural functionality of the peritoneum membrane.

According to the CNAMTS, the total cost reimbursed by National Health Insurance for these three methods was four billion Euros at the end of 2007 (2.7% of its total expenditure). ***(***14***)***.

Consequently, from this broad picture, we can see that ESRD is a challenging disease from both an epidemiologic and an economic standpoint with potential for medico-economic improvement, if we consider the conclusions of the CNAMTS report.

The reasons why, in the present study, discussion will focus mainly on the possibility and means of improving ESRD treatment pricing policy, requires further explanation.

Firstly, there are methodological reasons that deserve emphasis. One stems from my personal involvement in the field: structuring pricing policy is one of my present duties with the Directorate for the Supply of Care (DGOS: Direction Générale de l'Offre de Soins) which is currently working on this issue, a core component in the current risk management policy being implemented by the Ministry of Health and the CNAMTS. ESRD is one of 10 selected priorities. The following analysis will be based on my own current experience enhanced by international comparisons available in many articles and reports published in respect of this shared OECD challenge. Some theoretical concepts will also be taken into

[1] *It is not the purpose of this paper to discuss whether more resources should be allocated or other expenditure cut to cover these new health needs. We take the current situation as a context postulate and leave to all other debate to the political arena.*

account in formulating this analysis, leading us to its main purpose, which is providing an operational answer to this practical question**.**

Besides, there is also a contextual reason for studying this "market tool" in greater detail. Seven years ago, the Regional Hospitalization Agencies (ARH) set up a so-called "third generation" of Regional Health Organization Schemes" (SROS) and decided on an ambitious goal for PD development: 11% expected average share of dialysis in 2011. However it did not happen: in year 2008, the percentage had even decreased slightly down to 7.6 % compared to 2003 (8.8%) ***(***39***)***. In the meantime, starting in 2004, an activity-based payment model was implemented. Taking this poor outcome into account, a theoretical, if not doctrinal, debate emerges about the reasons for this disappointing result: for some it is a demonstration of the limits of this activity-based model, other observers express the opinion that a step further is needed in implementing the market approach.

Finally we might question not only the possibility and means of improving pricing policy but also its potential endogenous limits and the dangers of an overestimation of this component of the regulation toolbox **(Part 1).**

Then, considering the need for interaction, or at least complementarities, with other tools within the broader regulatory framework, a second part of the analysis will focus more on the decision-making process, allowing us to contemplate and structure a more integrated, adaptive and learning framework **(Part 2).**

It is the aim of this work not only to assess ESRD treatments pricing policy but also, to appraise how to build and what might be adopted as a comprehensive ESRD policy looking forward to guarantee a supply of accessible, cost-effective, appropriate, ethical and high quality care, giving due consideration to all the challenges posed by ESRD that will be explored in the following pages.

1 The need to improve ESRD treatments pricing policy

The CNAMTS report concludes on the need for developing renal transplant and PD, due to their relative lower cost and better, or at least equivalent, results compared to HD. Therefore, it suggests aligning price incentives accordingly.

However, before considering ways of improving the pricing policy **(1.2)**, the solidity of the CNAMTS' cost-effectiveness analysis needs to be assessed **(1.1)**. The limits and potential dangers of overestimating pricing policy potential will be studied secondarily **(1.3)**.

1.1 Pre-requisite: gain better insight into ESRD treatment cost-effectiveness

It is quite interesting to note that cost-effectiveness analyses in the USA originally used an amount of $50 000 per life-year or Quality-Adjusted Life-Year (QALY) gained, based on the estimated cost of dialysis, as a reference for assessing whether it was appropriate to cover the cost of a new intervention (cost utility analysis). Several ESRD management alternatives at different costs are available too and this requires a cost-effectiveness comparison. The "Tend & al." study *(*61*)* published in 1994 is worth mentioning as an impressive attempt to classify the relative cost-effectiveness in the USA of more than 500 life-saving interventions (not only medical): the medical median cost is estimated at $ 19 000 per year of life saved, renal transplantation being below this price, home dialysis slightly above and hospital dialysis two to three times higher. Although it has been a subject of scientific interest and investigation for a while, the cost-effectiveness of each method of treatment is still debated as much in terms of outcomes **(1.1.1)** as in terms of cost analysis to build price incentives **(1.1.2)**.

1.1.1 Need for a better knowledge of renal replacement treatment outcomes

A) From a medical point of view

Considering the three main approaches, there is no discussion about kidney transplantation being the optimal ESRD treatment although there has obviously been no Randomized Controlled Trial (RCT). However, ex post studies aiming to minimize

confounders and to compare similar patients tend to show a better patient survival rate ***(***43***)***.

Indications favouring kidney transplants have increased largely in recent years. Older patients, diabetics, patients with severe co-morbidities, ABO-incompatible patients can now be transplanted with success. For instance, in August 2011, the staff at the Evelina Children's Hospital, part of Guy's and St Thomas', visited in September as part of the EHMBA programme, had just pioneered an ABO-incompatible transplant on a child: this procedure, developed in the 1990's on adults, is now safe enough to carry out those kidney transplants regardless of blood type compatibility.
However, the extension of the benefits of kidney transplantation to potential high-risk recipients remains limited to the number of organs available for transplant. This is also the reason why scientific literature concentrates more on comparing indications and outcomes of HD versus PD in terms of survival.

Dialysis is without doubt a life-saving treatment. A better knowledge of relative HD and PD outcomes is needed before choices between HD and PD can be better defined. There is a need for better outcome knowledge on patient comfort and long-term evolution.
A recent study published by the KCE, a Belgian Federal Organisation concluded on the basis of a literature review that:
"Early observational studies comparing PD and HD had multiple methodological problems related to their observational and retrospective nature and presented design flaws as well as important case-mix differences.
Some more recent and better-designed observational studies (listed in the reproduced **Table 1**) *suggest that after correction for base-line co-morbidities, there may be an early survival benefit with PD (first 1 to 2 years) with a tendency toward improved outcomes with HD in later years. (…)*
Overall, the existing data show that the apparent benefits for one modality over the others are modest compared with the influence of other more important prognostic factors such as age, diabetes and heart disease." ***(***43***)***

Thus, we can assume that neither treatment option PD and HD, can be fully used as a substitute for the other. Despite the lack of randomized studies on this issue, the French National Authority for Health (HAS) published a recommendation on indications and counter-indications for PD in 2008. However, just like the KCE data, the HAS recommendations leave a great deal of room for choices between HP and PD ***(***29***)***.

Table 1. Observational studies comparing survival between PD and HD

Country	Study design	No. of patients	Hazard Ratio of Death and comments
USA	Registry & Billing Data	398 940	PD = HD Except Diabetics + 65y (in which PD < HD)
USA	Registry & Billing Data	107 922	PD < HD Congestive heart failure
USA	Cohort	1 041	1 year PD = HD 1-2 years PD < HD
USA	Registry	107 922	PD < HD in patients with coronary disease
Netherlands	Cohort	1 222	< 2 years PD = HD > 2 years PD < HD in elderly
USA	Cohort of candidates for TP only	12 568	PD=HD Except BMI > 26 where PD < HD
Canada	Cohort	822	PD = HD
Denmark	Registry	4 921	PD > HD during the first 2 years
Netherlands	Registry	16 643	PD > HD within first 15 months PD < HD after 15 months in > 70 years old diabetics (No adjustment for co-morbidity, only for primary renal disease)

However, the CNAMTS and DGOS recently issued a request to the HAS to achieve a better knowledge of the cost-effectiveness of PD versus HD. An interesting reformulation of the initial question has been discussed and agreed between the HAS, CNAMTS, DGOS, professionals, patients' representatives and the ABM *(*31*)*. Finally the HAS with the help of the ABM's and the REIN's data, will focus more on patients pathways rather than studying each treatment option separately as it appears that, during a course of treatment, patients often move from one technique to the other. Economic and medical outcomes of different pathways will be assessed through a statistical approach based on a Markov chain with Memory. This should provide us with a better understanding of the how these two treatment options fit together in the long-term.

First recommendation: try to procure better scientific evidence and knowledge of the medical outcomes of ESRD patient pathways.

B) From a patient point of view

The outcome from the patient perspective is a major point that should be considered before studying the costs of the available dialysis options in more details. This approach may be useful from a "pro-market" point of view, as price setting is supposed to be the by-product of supply juxtaposed against customer demand. However, it is also necessary from a more pragmatic standpoint to consider the impact of such therapies on daily life. The French Epidemiology Institute (INVS) in collaboration with the ABM launched two

very interesting surveys in 2005 and 2007 to assess the quality of life (QoL) of ESRD patients either under dialysis or Renal Transplants Recipients (RTR). The method was based on *two cross-sectional studies among patients over 18 in one of the eight REIN Network regions, in dialysis patients and RTRs. In each survey, patients were randomly selected after stratification for region and age. Quality of life was measured using the generic MOS-SF36 questionnaire, and one condition specific questionnaire, either the KDQOL (Kidney Disease Quality of Life) for dialysis patients or the ReTransQol for RTR. It was compared to the QoL of the general population. 832 dialysis patients and 1 061 RTRs were included. Participation rates were 67.1% and 72.5% respectively. The QoL scores were higher (from 10 to 30.6 points) among RTRs than among dialysis patients for all SF-36 dimensions.* ***(***25-37-38-39***)****.* These RTR data are not that surprising. However, they need to be considered in the light of those learned in another original survey about the quality of life of donors led by the ABM ***(***1***)***. It is one thing to say that ESRD patients' QoL is better after a kidney transplant, it is entirely another to convince potential living donors that the donation process is safe and that it will not impact significantly on his/her future daily life. This report favours coelioscopy rather than surgery for the kidney retrieval, to prevent post-surgical problems. It also highlights the need to ensure that the psychological environment of the donor is of a high enough quality.

Another interesting lesson of this survey in terms of dialysis, from a health policy-maker's point of view, is that it emphasizes the importance of taking not only medical criteria into account in the choice of the dialysis option but also the patient's environment, his/her psychological ease with the use of either HD or PD. Patient comfort with the chosen option has a major impact, in the long-term, on his/her QoL. Accordingly, the results of this survey call for an adapted individual approach to the choice of dialysis care.

This survey's second significant conclusion is the importance of offering care that maintains patient independence to the greatest possible degree this being another major aspect of daily quality of life. At this stage, regardless of the PD and HD costs, it would appear appropriate to promote HD/PD facilities delivering home care or care located as close as possible to the patient's home.

Second recommendation: press for renal transplant and, if not possible, QoL for dialysis patients through:

- **development of an individual approach to care, to assess patient capacity and psychological ease in the use of HD or PD,**
- **maximum preservation of patient autonomy based on home care or close to home HD/DP facilities.**

1.1.2 What cost knowledge is needed to improve incentives?

Thus, regardless of the respective TP, HD and PD costs, there is no doubt that TP offers the best outcome from a medical and patient's QoL point of view. HD versus PD raises more questions, but there is a need to promote patient autonomy through home care or close to home care facilities.

What kinds of dialysis care facilities are available in France?

There are 4 levels,[2] which are subject to an authorisation procedure pursuant to the Government Decrees issued on 23 September. They can be classified according to their proximity to the patients' home:

1- Hospital HD also called in-centre HD (HDC), requiring full time nephrologist supervision;
2- Two levels of what, in Belgium, they call Satellite of Low-Care HD (SHD) located in facilities closer to the patient's home and requiring less assistance from a nephrologists or nurse assistance:
   - Medical Dialysis Units (UDM) with part time nephrologist supervision;
   - Auto-dialysis facilities offering both Assisted Self-HD (ASHD) with nurse supervision in a satellite facility or Self-HD in a dedicated unit away from home;
3- Home dialysis which includes: Home HD (HDD), Automated PD (APD) requiring a mechanical device to assist in the delivery and drainage of the dialysis fluid and Continuous Ambulatory PD (CAPD) which does not require a specific machinery but needs daily fluid exchanges.

What knowledge do we have of their relative costs and of their cost-effectiveness in order to adjust price incentives accordingly?

A) From Macro-thinking …

The HAS, which is currently working on a medico-economic analysis of the efficiency of ESRD patients pathways (most of the course of their care requiring the alternative use of PD/HD and, for the more fortunate, TP), pointed out in its literature review that it is very difficult to transpose international studies. Every health system has indeed specific rules and individual functioning constraints ***(***31***)*** even if mainstream analyses conclude that the HD technique is more expensive than PD and, generally, that in terms of modalities: HDD < *(cheaper)* SHD < HDC and DPCA < DPA. The "Just & al." study ***(***41***)*** supports HAS conclusions: *Cost drivers differ for PD and HD. PD is driven mainly by variable costs such as solutions and tubing, while HD is driven mainly by fixed costs of facility space and staff.* Considering these drivers, it is hardly surprising from a developed country's point of view,

[2] *We will only focus on adults' facilities.*

as payer, PD is cheaper than HD. This assumption is potentially less valid in the developing world where the main fixed costs, wage levels, are sometimes lower than variable costs.

In this macro-approach, costs will be analyzed from the health care funding authority's perspective. As explained in the Just & al. paper, *the choice of dialysis modality has not been proven to independently affect a patient's ability to maintain employment,* so this social cost dimension will not be explored here.

In a study published in March 2010, the CNAMTS indicated an annual mean cost per patient of 64 k€ for DP, 89 k€ for HD, 86 k€ for the year of transplantation and 20 k€ for the following years ***(***14***)***. These costs are detailed in **table 2** (taken from the CNAMTS paper).

Table 2. Mean costs for the CNAMTS per ESRD patient per type of expenditure

	PD	HD	TP (first year)	TP (following years)
Hospital (Excluding liberal nephrologists fees)	48 016 €	66 425 €	66 075 €	9 789 €
Nephrologists fees	742 €	3 317 €	1 245 €	480 €
Medical auxiliaries	8 670 €	1 229 €	439 €	323 €
Biological costs	689 €	1 668 €	1 220 €	411 €
Pharmaceutical costs	4 237 €	4 037 €	11 340 €	7 717 €
Medical device	736 €	584 €	444 €	309 €
Transport	1 313 €	11 147 €	5 586 €	1066 €
Other costs	48 €	200 €	122 €	52 €
Total	**64 450 €**	**88 471 €**	**86 471 €**	**20 147 €**

Source : SNIIR-AM / PMSI, Régime Général hors SLM, 2007, France entière

The CNAMTS concluded from these data that a 25% increase of DP would allow a decrease in the annual cost of 155 millions Euros and an extra 900 transplantations per year over 10 years a decrease of 2.5 billions Euros.

However, from this macro-perspective, considering our first conclusions that "proximity" care should be promoted to preserve maximum patient autonomy, we can also conclude that, through the pricing policy, we need to sustain not only PD but more largely HDD or SHD to keep different care options open. The CNAMTS found indeed that the main difference between HD and PD global was transport cost and hospital costs.

While waiting for HAS conclusions on pathways cost-effectiveness, there is also a need for a better understanding of cost utility to move from one option to the other from a structural or/and a nephrologist's point of view in order to adapt pricing policy accordingly.

B) … To micro-economic levels

Behind the idea of improving pricing policy lies the economic belief that the "homo economicus" reacts to the evolution of prices according to an opportunity cost evaluation. Therefore, once expected outcomes are identified, it is important to have a good knowledge of the costs involved.

Should we rely on the Diagnosis Related Groups (DRG) cost analysis to acquire this knowledge? This has been a much-debated question in recent exchanges with French professionals concerning dialysis.

Firstly, the relationship between the cost of a patient's care and his/her diagnosis needs to be examined: are co-morbidities a sufficient determinant of costs? If we consider the REIN analysis of patient co-morbidity profiles per type of treatment, there is a clear correlation ***(***39**-**52***).*** However, where does the fact 21% of HDC patients have no co-morbidities fit in this analysis: could they be treated in other low-care structures or are there other autonomy parameters to be taken into consideration? An interesting study by "Peters & al." on "workload during haemodialysis sessions" ***(***50***)*** concluded that *apart from heart failure, co-morbidities were not linked to greater workload during HD sessions.* Age of 60 years or more, elevated C-reactive protein and HD catheters were found to be associated with more difficult HD care.

There is also an acute debate concerning the process of data collection. This is an onerous task for health professionals because the patients on dialysis have several appointments per week and data have to be collected each time. A less frequent collection of data mixing a DRG and Autonomy Related Groups (AGGIR) approach would probably be more in line with data collection capacity and identifying homogenous patient groups in terms of costs. The possibility of combining the collection of some data from the REIN registry and those needed for costs analysis and payment procedures should also be explored to interconnect some part of the data collected for should also be explored to reduce the cost of data collection itself.

However, under the surface of this open debate, there is also the unexpressed fear of losing the right to choose between one option or another according to socio-psychological parameters that are hard to measure and quantify in cost requirement terms.

Considering all those issues, there is a need to work on an adapted version of the ESRD/DRG approach before there can be an all-facility implementation[3]. This was one of the conclusions of a recent meeting held at the French Health Ministry attended by representatives of professionals on the 9 September 2011 ***(***Appendix 1***)***.

[3] *DRG is only applied to HDC and UDM in Public Hospitals in France*

Third recommendation: decide on a suitable method and content for *"DRG like"* data collection for dialysis, more relevant to per-patient-type cost analysis

On the issue of dialysis in the public health sector, the French model relies on the so-called GHM (Groupes Homogènes de Malades), inspired by the Health Care Financing Administration (HCFA) system introduced in 1983 under the US Medicare system, with further additions ***(***57***)***. However, there is only one GHM for HDC structures and one for UDM (SHD) structures[4]. Therefore, although a cost analysis DRG system is officially in place for HDC and SHD in the public sector cost analysis is mainly structure-based. In contrast with Great-Britain that currently includes data from all hospitals that use DRGs (public and non-profit hospitals), France relies on a sample of hospitals for its so-called ENCC (French DRGs public and private sector cost analysis, based on shared principles). Although sampling may be less representative, this is supposed to be offset by better data quality.

As pointed out in the DREES report on price incentive effectiveness ***(***24***)***, private sector and non-profit association prices are the result of average former regional prices adjusted after applying rules imposed in 2002, concerning different authorisation levels and their functioning obligations implying new costs (e.g. nurse cost for Assisted self-HD). However, cost changes have not been monitored other than for HDC and UDM, on the same basis as the public sector. It is crucial to collect cost data from the private sector and non-profit associations because they are the principal suppliers of PD, Assisted self-HD, Self-HD and HHD services. Accordingly, the French National Agency responsible for cost analysis and of the payment system (ATIH) recently launched a dedicated cost study based on the same principles as the ENCC. The results are expected at the end of 2011.

There are also dedicated GHMs for transplants, but not for kidney removal on living donors, which is part of a broader GHM. Therefore, no specific cost analysis is available for this activity. So far, this "heavier cases" GHM has been deemed suitable arriving at an incentive price for kidney retrieval. However, from a cost analysis perspective, it could probably be improved by the identification of a specific GHM ensuring that pricing is correct, especially as alleged under-pricing is a source of recurring complaint from the physicians.

There is no GHM for kidney removal from deceased donors, GHM methodology is only applied to live individuals. The alternative methodology does not include cost analysis monitoring.

[4] *There are also training session GHMs. Here we will focus on care sessions.*

Fourth recommendation: improve cost monitoring of all treatments associated with the ESRDs *(including donor kidney removal with an individualisation of cost data for kidney retrieval from living donors)*.

Table 3 shows the evolution of ENCC results for GHMs linked to ESRD treatments, the *ENCC results adjusted to the healthcare expenditures voted by Parliament and the final prices adopted in year 2011 (explained below)*.

Table 3: Difference between ENCC cost analysis and 2011 pricing policy

Code GHM	Activity	ENCC 2006	ENCC 2007	ENCC 2008	ENCC 2009	ERE*	Adjusted ENCC 2010	Price 2011
11C031	Living donors, kidney removal (part of a larger GHM) public sector	4 967.00 €	4 972.64 €	5 065.00 €	5 298.00 €	2.90%	5 658.35 €	4 313.25 €
11C031	Living donors, kidney removal (part of a larger GHM) *private sector*	3 984.00 €	3 306.75 €	*not available*	3 508.00 €	4.40%	2 409.11 €	2 485.64 €
27C061	Kidney transplant (level 1)**	15 217.63 €	14 571.24 €	16 130.00 €	16 761.00 €	5.50%	11 581.86 €	11 632.79 €
27C062	Kidney transplant (level 2)	17 333.44 €	19 465.96 €	20 733.00 €	19 944.00 €	7.30%	14 756.14 €	14 639.98 €
27C063	Kidney transplant (level 3)	25 681.27 €	24 149.59 €	29 996.00 €	27 389.00 €	8.80%	20 148.04 €	20 436.92 €
27C064	Kidney transplant (level 4)	27 562.02 €	45 119.82 €	39 161.00 €	35 903.00 €	6.40%	27 393.65 €	32 054.29 €
28Z04Z *GHS 9605*	HDC public sector	360.00 €	325.00 €	335.00 €	365.00 €	4.80%	330.45 €	338.45 €
D 09	HDC *private sector*	349.00 €	297.00 €	*not available*	*not available*	*NC*	*not available*	285.79 €
28Z04Z *GHS 9618*	UDM public sector	*not available*	303.00 €	*not available*	304.00 €	*NC*	*not available*	244.00 €

**ERE = an ATIH indicator of sample representativeness, the lower the percentage, the more representative it is*
***GHMs 11M171 to 11M174 should also be mentioned = hospital monitoring of renal transplant recipients in the public or private sector; but renal transplantation itself is limited to the public sector.*

However, aside from the fact that this ENCC cost analysis approach has only been partially and/or imperfectly implemented, it raises other issues in terms of methodology and usability for fixing prices.

The ENCC itself is neither used directly nor completely for fixing prices. There is an intermediate phase, which tends to be a blur to non-specialists. It results in some of the ENCC costs being excluded from the price structuring of the related dialysis or transplant hospital stay payment (GHS). The reason for that is that the excluded costs are paid through other price mechanisms: e. g. the annual transplant fixed budget (FAG) covers the coordination costs of the activity. Accordingly, it is impossible to make a direct comparison between the ENCC published data and GHS prices.

The “adjusted ENCC”, which is not published, is supplied to the Ministry of Health by the ATIH. It is based on the ENCC less costs not covered by GHS'. Remaining costs are then recalculated to take account of the constraints imposed due to the health expenditure voted by Parliament. Thus, the ENCC costs are adjusted proportionally so that by

multiplying them by the related volume, the total amount is equal to the budget voted by Parliament. Finally, this is no longer a cost analysis in real terms but rather a theoretical price, if no other parameters (e. g. health priorities) were taken into account in the price fixing process. Meanwhile, this does not help to provide a clear vision of the difference between GHS prices and their real costs. An explanation of this lack of clarity may be the fear of explicitly showing the potential gaps between some comparable costs and prices. However, this will probably lead to an even more dangerous and false understanding of those gaps by practitioners who, for the most part, compare published ENCC' costs with the related GHS prices.

Fifth recommendation: publish ENCC costs analysis comparable with the GHS prices.

However, more critical in this cost analysis methodology is probably the lack of focus on the performance of the production process reflected by the cost.

Kaplan insists in his paper "How to Solve the Cost Crisis in Health Care?" ***(***42***)*** on the need to establish meaningful cost accounting per type of stay in all hospitals so that they can have a better understanding of their production process and their potential operating margins. This is surely true at an organisational level, but this sounds also pertinent for cost-analysis by the payer. For example, if we estimate the mandatory costs involved in the HDC care process with regard to the 2002 legislation[5], the point of financial equilibrium is theoretically obtained at roughly a 72% rate of occupancy based on the 2011 public GHS price (338.75 €)[6]. Occupancy above this rate leads to high positive operational margins considering the fact that the costs are mainly fixed costs. However, this question has been largely debated: some argue that applying this approach may significantly increase total healthcare expenditure, other activities' "*process costs*" being far in excess of their prices. Others think that processes seeking to achieve greater productivity are constantly evolving and differ from one place to the other so that no model can or should be applied to measure the expected costs of the process.

Although costs are supposed to form a logical basis for pricing policy, it seems more relevant to focus on potential profit margins than on gaps between average costs and prices. As this cost-benefit analysis is performed at a micro-economic level, there is no reason not to be able to implement a mechanism to collect margin data.

Furthermore, what is true for structures in terms of cost understanding is also relevant for nephrologists working in the private sector. The time spent supervising a PD patient (the nephrologist's cost) is probably less than time spent with HDC patients. However, it more

[5] *This is close to the empirical method used in 2004-2005 to fix the private sector dialysis prices.*
[6] *For a structure operating 12 hours per day, 5/7 days with 8 dialysis stations.*

frequently involves hard-to-plan-for problem scenarios and frequent treatment linked complications, which need to be taken into account.

Sixth recommendation: have a better knowledge of the operational margins of the organisations and nephrologists rather than focusing on average costs not linked to best practices approaches

1.2 Room for improving pricing policy

Once the relative cost-effectiveness of each treatment and their production cost mechanisms have been identified, it is time to consider a way of promoting an incentive pricing policy and improve ESRD patient orientation accordingly. In doing so, before questioning the potential dangers and limits of such a pricing policy (in **1.3**), it would be useful, firstly, to take an empirical approach based on identifying lessons learned from the various routes followed in other countries, and from the French pricing system, with their respective successes and limits (**1.2.1**). We will then look at P4P "Pay for performance" more closely to identify the potential and limits of this alleged new concept (**1.2.2**).

1.2.1 Different ways of pricing but a shared incentive alignment goal

A) Various options tried all over the world for the payment of health facilities and independent nephrologists

As pointed out in the ISHCOF (International Study of Health Care Organization and Financing) 2007 publication ***(***22***),*** in most countries, *ESRD delivery programmes are administered separately from the rest of the health care system or at least have payment rules specific to ESRD, a consequence of the unique disease model it represents*.
This study focuses on 12 countries (Australia, Belgium, Canada, France, Germany, Italy, Japan, New Zealand, Spain, Sweden, United Kingdom and United States).
ESRD pricing systems appear to be a mix of basic payment approaches but also extreme creativity depending on the kind of treatment or profile concerned. Although this reflects each country's cultural and historical background, some major trends can be identified.
The pricing of transplants and donor kidney removal is usually in line with the all-inclusive payment system. Spain offers generous compensation to physicians and hospitals. It currently ranks at the top of the renal transplant table, which tends to suggest that higher provider compensation for organ collection results in higher transplant rates and shorter

waiting lists.

For dialysis, there are few innovations identified in terms of physician and nephrologist pricing models. It is mainly a capitated system versus fee-for-service (FFS). Each approach has its pros and cons ***(***16***)***: a risk of volume of care increases if FFS is chosen and a risk of restriction of access to suitable care with a capitated system approach. Germany's negotiated "caps and limits" approach applies to the FFS for nephrologists to limit these risks while maintaining a competition incentive. However, incentives targeted at nephrologists probably deserve more attention considering the atypical mix of private and public practitioners and care structures in the dialysis field.

On the contrary, there is a great deal of innovation in most of the countries to refine their dialysis facilities pricing to encourage competition and efficiency gains in dialysis treatments. New Zealand is the exception, moving towards *an abandonment of DRGs and fee-based reimbursement systems altogether and returning to a system of population-based budgeting for hospitals.*

3 main payment models can be outlined:

- *Per-treatment prices that are administratively set at a national level;*
- *Capitated payments per patient of episode of care;*
- *All-inclusive budget, whereby a regional administrative authority or a major hospital at the head of a local network is responsible for allocating an overall budget to various activities and units under its administrative control.*

As mentioned in the "Just & al." article ***(***41***),*** Ontario managed to stabilize the use of PD and SHD, unlike other Canadian regions, largely through a change in its reimbursement system. It moved from a fee-for-service method, with rates for HC sevenfold higher than those for SHD and PD to a modality-independent weekly capitation fee. However, the most interesting approaches are the mixed models. Two integrated systems are worth exploring: the Belgium and Australian models. Both have tried to establish interconnected payment mechanisms. HDC, satellite and home dialysis are indeed often performed by different organisations with different status and therefore, different interests. However, satellite and home dialysis facilities are usually under the supervision of nephrologists from the HDC structures. Considering the main fixed costs of HDC, hospitals are logically tempted, firstly, to increase their volume to absorb those fixed costs and then make high margins with additional cases.

In Belgium, as explained in the KCE report ***(***43***),*** to overcome this problem *the financing mechanisms of the different dialysis modalities have undergone many changes throughout recent years and,* among the objectives, was the increase in the use of alternative dialysis modalities (PD and satellite HD). Now, hospital HD is paid by means of a fixed payment per session and, more interestingly, a bonus that increases up to the point where the hospital supervises 35% of dialysis treatments performed in satellite or

home HD/PD facilities. However, the results in terms of alternative modalities are relatively disappointing (33.7% in 2006 compared to 33.4% in France or 40.8% if UDM is included in French alternative modalities). KCE considers that this is linked to the fact the profitability of HDC remains, higher than that of alternative modalities, which is more linear due to higher variable costs.

In Australia, a very atypical system of public payment for dialysis services comprises two components: a "capitation grant" covering medical services at the local centre but payable to the "parent organization" (hospital systems) and a diagnosis-related group (DRG) payment to the dialysis centre to cover variable costs. This leads to a fairly high level of PD (24.6% ESRD patients under PD in 2002 compared to a 8.7% in France).

From the ISHCOF study, it also appears that the level of price per dialysis modality impacts clearly on the level of production costs. In the long run, it is obviously impossible for a service to have higher costs than the revenues it receives. This is particularly true in the USA where cost-containing production efficiencies have been stimulated by Medicare payment rates that have barely budgeted. It remains to be seen, if the newly implemented ESRD Prospective Payment System (PPS) will achieve the same results as the former "basic case mix adjusted" all-inclusive budget approach.

So, even if they have shared trends, it appears that the ESRD pricing models are economic tools deeply rooted in each country's historical and cultural background and at the same time the product of various levels of creativity.

B) In France, a need for more visibility and alignment of different organisations and nephrologist price incentives

The report published in 2011 by the Directorate for studies and statistics (DREES) of the French Ministry of Health pointed out weaknesses in the current French price incentives for ESRD treatments ***(***24***)***. Unfortunately, it only focuses on increases in the different dialysis modality prices without considering increases in renal removal and transplantation prices. In terms of amounts, there has been an increase in the prices of HHD and PD but it was somewhat limited between 2005 and 2008: only +3.6% for PD throughout this whole period in the private sector. This is far below the increase in inflation in the same period, illustrating ultimate margin erosion. For UDM and HDC, a slight fall was observed in the same period (-0.8% in the private sector). In the public sector, despite this fall, HDC prices were above ENCC costs until 2009[7]. Furthermore, the progressive implementation of the new price mechanism introduced in the public sector somewhat clouded effective

[7] *Taking into account all the limits of this cost analysis discussed in part **1.1***

visibility of these price incentives. The report also insists on the fact that margin is not itself the issue. Rather, the key issue is the relative margins earned from HDC versus UDM, HHD and DP. Transplants and donor kidney removal should be added to this list of margins for comparison, even if, from a strict medical point of view, these treatments are not full substitutes for each other. However, in a university hospital, this could contribute to cost-utility managerial decisions.

So, in this price environment, hospitals have not been encouraged to develop HHD or DP while home care associations have tried to maintain a financial balance by increasing HDC and UDM… Another argument is probably even more important. The DREES report acknowledges that the introduction in the public sector of an adapted version of PPS for ESRD in 2004-2005[8], as a new price mechanism replacing the former all-inclusive budget system, has had a detrimental effect due to the specificity of the ESRD market. Indeed, in France, according to FINESS 2010-2011 data, 104 authorised organisations out of 237 are public (43.9%), 99 are for-profit organisations and 34 non-profit organisations (with a large number of authorised sites). However, 64% of nephrologists' work in the public sector (French Health Professions Demography Observatory, ONDPS' 2009 report ***(***49***)***), including nephrologists working in university hospitals. They supervise most of the non-profit dialysis associations. Nonetheless, hospitals and associations remain different stakeholders and separate legal entities. Therefore, in a period when there have been greater budgetary constraints on hospitals due to PPS, nephrologists have been asked to fill their capacities first, especially as the HDC operating margin potential was high.

Another pricing issue pointed out in the DREES report is the lack of financial incentive for nephrologists working in the private sector[9] to guide their patients towards satellite or home care ESRD facilities. The CNAMTS identified that the income of these nephrologists is currently 4.5 times higher for HDC than for PD and more than 2 times higher than income earned from follow-up of a renal transplant recipient (RRT) ***(***14***)***.

A final argument that is not much discussed in the ESRD economic and pricing literature is the danger of "bespoke" price structuring. Although creativity is probably welcome in the price devising and structuring process, it is important to keep in mind that it is often more difficult to adapt specific tools smoothly at a macro-level. Fixed rates per treatment applied in the case of satellite and home HD and PD pricing, completely disconnected from the DRG approach, may partly explain their slow increase due to a lack of downstream cost analysis. For transplants, the Annual Transplant Fixed Budget (FAG) and the fixed price for a surgeon's intervention in removing a kidney from a deceased donor (PO) are also complicated price mechanisms blurring margin analysis by organisations themselves, which is probably more problematic.

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[8] *This change was part of a broader move towards PPS in the public sector.*

[9] *It concerns also the private services that nephrologists working in the public sector are allowed to provide.*

What operational actions could be taken out of this French ESRD price mechanism diagnosis?

Some have already been launched. For instance, the CNAMTS is currently working on introducing a capitation price mechanism for the follow-up of DP patients by private sector nephrologists. The fixed rate should be 50 € per week, so around 2 600 € for a full year of treatment monitoring, i.e., just below the income for HDC. If the expected progress rate of 100 new DP incident patients should happen, this extra-cost would be reimbursed through lower transport costs within 3 years.

The same reflexion would be worth conducting for satellite and HD home care patient follow-up but also for the RTR supervision that could also be delegated by transplant surgery nephrologists to dialysis nephrologists, the former currently being over-pressured due to the growing number of prevalent RTRs (+19.7% between 2005 and 2008).

The following proposals could be the subject matter for further discussions on dialysis and transplantation structures:

Firstly, it should be possible, in the short-term, to adjust TP, HDC, satellite and home HD and PD prices according to an improved cost and comparative margin analysis (ATIH results expected in December 2011). This adjustment should obviously prioritise transplants and kidney removals that are the most cost-effective from a social and patient point of view.

Then, to further limit the risk of silo approaches[10] induced by the PPS, the same fixed price system as the one planned for private nephrologists could be applied to public hospital HD. Meanwhile, public hospital HD may also be encouraged to supervise patients under satellite or home dialysis care. This would be very close to the Australian "*capitation grant*" given to the "*parent organization*".

Furthermore, dialysis payment system should be adapted to get more readability, while keeping in touch with the logics and constraints of the mainstream price mechanisms. From this point of view, dialysis being part of chronic ambulatory care, requiring a hospital environment only for the heavy cases, the ambulatory price mechanisms should be applied to all the dialysis levels. In other words this means:

1. A lump sum to cover the non-medical workload and structure costs per patient,
2. For the physician[11]: a capitation lump sum (like the one planned for DP) or fee-for-service (system in place for HDC private nephrologists) per patient supervised whether within or outside the structure.

As usual for ambulatory care, the same prices would apply to the public and private sector whose HDC prices have already converged[12].

[10] *Between satellite and home facilities on one side and in-centre HD on the other side*

[11] *Or her/his structure if she/he is salaried.*

[12] *Indeed, the DGOS, General Direction for Care Offer, decided to make public and private in-Center HD prices converge in 2011. This led to a 2,7% price fall in the private sector. The total*

Considering the workload variations depending on the patients' profile, different lump sums should be billable at each authorization level. But this would require first to make sure of the possibility to set up a simple cost and activity data record system so as to allow, on the one hand, health insurance control on the validity of the medical records and, on the other hand, price evolution.

Those are just first proposals but they traduce quite simple principles that can be learnt from foreign and from the French experience on how to build ESRD pricing policy. This pricing policy needs indeed to be goal-oriented taking into account both the macro-social outcomes expectations and the operator micro-economic margins analysis, therefore it should be based on incentives alignment, contextually adapted, easily readable, and regularly assessed.

Seventh recommendation: To build an ESRD pricing policy based on financial incentives alignment, contextually adapted, easily readable, and regularly assessed to promote patients' orientation towards the best cost-effective treatments.

1.2.2 Pay for performance? Pay first for public health involvement

Besides this call for adaptation of the ESRD treatments' prices in a way consistent with a more cost-effective orientation of patients, there is a growing interest for the so-called pay for performance (P4P) approaches.

A) Should we P4P or look into the black box?

The study of small area variations in care options by Wennberg ***(***67***)*** is somehow the starting point of this P4P success story. Indeed, the discovery that variations of practices for a particular care option could be found not only in different countries but also within very small areas started a closer focus on production processes by insurers and providers. This is what has been called "managed care", the purpose of which was to improve the cost-effectiveness of the process. However, there was a backlash due to patient perception that the managed care concern was more cost reduction than patient health outcome improvement. Physicians were also increasingly upset because their art was subject to more and more procedural recommendations. P4P is supposed to solve this problem by allowing for more freedom in the shaping of care production process but

amount generated by this operation was invested in a + 4% increase of satellite (excepted UDM) and home HD and PD.

at the same time, applying greater scrutiny to outcomes. Consequently, in P4P, one does not open the "black box", one just checks its results. The Centres for Medicare and Medicaid Services (CMS) issued the End Stage Renal Disease (ESRD) Quality Improvement Program (QIP) Final Rule on 29 December 2010. This ESRD QIP is presented as the first P4P programme in a Medicare prospective payment system ***(***11***).*** In the USA *the history of quality improvement efforts, the availability of data systems and quality standards, and consensus on opportunities for quality improvement combined to make ESRD a good candidate for this P4P initiative* ***(***10***)***. France shows roughly the same background but should we go down this P4P road? One of the arguments advanced to promote US ESRD P4P is that it offers a means of mitigating the unintended consequences of bundled payment (ESRD PPS was launched at the same time) such as potential adverse effects on quality or access. As shown in the ISHCOF study ***(***22***)***, in Germany and the United States, ESRD payment rates have, in the long-term, been declining in real terms, providing incentives to reduce costs. So, to ensure increased efficiency, both countries have favoured some form of quality monitoring. However, whether P4P will succeed remains a matter of concern. The three "outcomes" criteria selected, including two measurements of anaemia management and one of adequacy of haemodialysis[13], are based on data collected since 2001, so there is not too much debate on the burden of data collection. However, whether these criteria are appropriate outcomes criteria has been a subject of much greater discussion ***(***5***)***. Is there any risk of adverse selection to reach the expected level of the indicators? How far do the organisations influence the outcomes? What role is played by patient behaviour and environment? Should a good result be rewarded or should P4P be a *"Penalize for (non) Performance"* system. This is the option favoured by the CMS? In this approach, it is important to consider the length of time left for providers to progress so that there is no vicious circle making it more difficult for the penalized providers to achieve the quality outcome expectation due to a lack of resources.

However, without totally embracing P4P, these cross purposes between quality monitoring and PPS, are also a matter of concern from a French perspective, to make medical structures more accountable for how they are spending the money they are paid. They are many complaints about due to the fact that PPS funding remains fungibles as between units. This should remain the case to comply with the vision, shared with the US approach, that we should not scrutinise the organisation of the care process too closely. This is also relevant to the need for organisation financial equilibrium considering each unit's potential surpluses and deficits.

[13] *Percentage of Medicare patients with an average Haemoglobin <10.0g/dL;*
Percentage of Medicare patients with an average Haemoglobin >12.0g/dL;
Percentage of Medicare patients with an average Urea Reduction Ratio (URR) ≥ 65 percent.

Nonetheless, France tends to be less reluctant to peek into the "back box" and, through financial incentives, to encourage some practices considered to bring added outcomes value. For instance, the French Health Ministry is currently working on offering a financial incentive for using machine perfusion to preserve kidneys available for transplant. This is expected to attain better preservation outcomes than the use of cold storage and, therefore, a better outcome for patients. The ISHCOF also pointed out that despite strong evidence that vascular access is the *"Achilles' Heel"* of haemodialysis care in terms of outcomes, *the explicit use of differential incentives to motivate this choice has so far been uncommon*. Indeed, among the three predominant types of haemodialysis vascular access (AV (arteriovenous) fistulas, AV grafts, and catheters) fistulas[14] clearly exhibit the lowest rate of complication. Those complications are estimated to cost between 8 and 10 k$ per year of treatment. However, the ISHCOF concludes that the kind of incentive payments that are proving effective are not so much differential payment rates to surgeons but rather a *"zero payment"* for practices that should not occur (e.g. payment will be denied if dialyzers are reused), which is not possible for vascular access options. However, a structure price differential according to the use of one AV or another may incite some process improvement.

This P4P and *"managed care"* financial incentives are still much debated and need to be assessed carefully before, if implemented, making sure that their implementation costs are merited.

Eighth recommendation: study carefully the possibility of setting up an incentive price policy for the use of AV fistulas

B) Pay for public health involvement

However, as mentioned by Meredith Rosenthal ***(***53***)***, Pay for Performance and payer preference for incentives linked to health outcomes, which are perceived as more compatible with medical ethics, induces a more interesting evolution of pricing policy. It makes more room for both individual or collective practitioner involvement in public health. Indeed, financial incentives focus increasingly on collective outcomes, which rely more on screening, patient empowerment through information and therapeutic education… The ISHCOF ***(***22***)*** notes, for instance, that *in the United Kingdom, target payments seem to have a positive impact on vaccination or screening rates (simple observation "before-after"). Results from randomised studies are however contradictory: no impact on cancer*

[14] *AV fistulas are surgically created by connecting a patient's own artery and vein, usually in the forear.*

detection among Medicaid clients, but a positive impact on the vaccination of Medicare clients. On the specific issue of pre-dialysis patient education, the few randomised controlled trials and cohort studies that have been performed conclude that, when detailed information on the various dialysis modalities is provided early, more patients are likely to start with a self-care modality such as PD or home HD. The European Best Practice Guidelines also recommend that *"Patients whose GFR (glomerular filtration rate) is <30 mL/min and declining despite therapy should be under the care of a nephrologist and be prepared for the onset of end-stage renal failure. This preparation includes choosing the most appropriate location (e.g. home or hospital) and the form of treatment (e.g. HD, CAPD, pre-emptive transplantation or conservative treatment). This choice will involve discussion between patients, their families and nephrology staff (…)."*In Belgium ***(***43***),*** a system of so called *''ambulatory care pathways''* also called *''shared care''* is applicable for chronic kidney disease-affected patients. *Within these Care Pathways, the management, treatment and follow-up of patients with a chronic disease are streamlined. This trajectory is based on a close cooperation between patient, general practitioner and specialist doctor. The main aim of this system is to enhance collaboration between all parties and ultimately enhance patient care. Moreover, it offers financial and other benefits to both patients and treating physicians.* It will be interesting to assess the cost-effectiveness of this particular process.

Patient financial incentives to take part in regular check-ups, that are increasingly effective in growing predictive medicine, somehow look more attractive than messages launched by public health authorities to manage their behaviour because they imply more freedom and therefore appeal to patients.

Applying new principles adopted in the new 2011 National Medical Convention[15], the CNAMTS is currently planning a weekly performance fee of 20 € that could be given to nephrologists. The French health payer is still working on indicators to be taken into account in allocating these fees, but data about information activity, participation in screening of chronic kidney disease patients at an earlier stage than ESRD would be interesting targets. General practitioners, who are the main door entrance into the health care system, should also be encouraged to better inform at early stage diabetes on how to prevent and what to do in case of CKD and ESRD.

All these measures appear to be potential answers to Larry Brown's conclusions in his article "The Political Face of Public Health" ***(***7***)*** on the weakness of public health. Indeed, he insists that this weakness, compared to curative care, is largely linked to the lack of stakeholder financial interest, although their cost-effectiveness and positive outcomes are well known.

[15] *The framework for physicians payment mechanisms*

Ninth recommendation: promote patient and physicians involvement in public health activities through financial incentives

1.3 Potential dangers and limits of over-focusing on economic tools

From the previous argument, it appears that there is room for improving the health pricing mechanisms, but how far should we go? How much should we rely on this price tool? In view of the worldwide investigation into price potentiality in the health field, particularly in ESRD, the ethical issues at stake and the danger of over-focusing on price tools will be explored first of all **(1.3.1)**. Secondly, the endogenous limits of this tool in improving ESRD care will prompt further questioning on how to shape a more comprehensive ESRD health policy **(1.3.2)**.

1.3.1 Ethical issues and danger of market tools perceived as goals

A) How far should we go in the use of the cost-effectiveness and price approach from an ethical point of view?

Firstly, the cost-analysis of the various ESRD therapeutic options from a macro and social perspective may lead to patient cost-sharing approaches. The ESRD patient is also a citizen living in a country making financial choices and subject to constraints. If the patient favours a treatment costing more than the cheapest available option giving due consideration to medical indications and expected outcomes (for instance SHD rather than PD), should he or she pay part of the differential cost? Research studies, particularly the RAND Health Insurance Experiment ***(***13-62***),*** show that *although people do reduce their use of health care when faced with a charge, they are unable to distinguish low value from high value care.* Therefore, people across income groups facing a user charge reduced the use of effective care almost to the same degree as they reduced the use of ineffective care. Finally, this does not appear efficient, especially for chronic diseases like ESRD whose costs could potentially lead, in the long run, to a shortage of access to care for the most disadvantaged people. However, international studies in OECD countries interestingly show that there is a convergence towards a single payer approach with very little out-of-pocket participation from the patient, even in the USA through the Medicare system.

Also, if we think in depth about what are, in the final analysis, provider price incentives, it can itself be seen, to some extent, as a rationing process, an induced limitation of choice, which raises an ethical issue and may lead to detrimental outcomes. For example, Mexico is known as the developing country with the highest level of PD practice ***(***17***).*** *PD*

accounts for 85% of all renal replacement therapy. Some years ago, it was used by more than 93% of the Mexican dialysis population. This situation is largely linked to a price option, PD being the only ESRD treatment that benefits from a long-term cost reimbursement. However, a deeper analysis *of outcomes and of the real costs of the treatment -including the costs associated with complications in patients not receiving adequate treatment- has motivated a change in the last few years*. Collective efforts to maximize ESRD health care expenditure should not over-value any of the treatment options available. Some may even argue that prices should just be neutral, leaving the choice to the nephrologists' medical expertise.

Having said that, there is no doubt, looking at international comparisons, that the number of patients identified and treated for ESRD grows roughly along the same lines as the GDP so that, in most countries, there are exclusion processes. Most of the time this exclusion is implicit. Politicians and society are not comfortable with the idea of making such exclusions conditional upon cost-effectiveness analysis. This need for transparency remains an open political and ethical debate. The expansion of palliative care programs in UK renal units, as an alternative to renal replacement therapy, suggests that kidney failure patients in the UK sometimes do not have a dialysis or transplant option, as pointed out in a recent report of the ISHCOF ***(***22***)***.

However, ESRD is necessarily in the middle of this ethical debate about limited access to care as far as transplantation is concerned. From a strict cost-effectiveness point of view, pre-emptive renal transplantations, i.e. grafts before starting dialysis treatments, appear to have the best medical outcomes but from a social and ethical point of view it is hard to defend only this pre-emptive approach considering all the ESRD on renal transplant waiting lists. In France, the Biomedicine Agency applies a mixture of criteria giving particular emphasis to recipient compatibility and to his/her distance from the renal transplant.

A lack of transplants, whether from deceased or living donors, raises another question in terms of price policy. Should we pay living donors? "Matas & al" conducted a cost-effectiveness analysis on this topic in 2003 ***(***46***)***. This study concluded that a *LURD (Living Unrelated Donor) transplant saved $94 579 (US dollars, 2002), and 3.5 quality-adjusted life years (QALYs) were gained. Adding the value of QALYs, a LURD transplant saved $269 319, assuming society values additional QALYs from transplantation at the rate paid per QALY while on dialysis. At a minimum, a vendor program would save society >$90000 per transplant and provides QALYs for the ESRD population. Thus, society could break even while paying $90 000/kidney vendor.* Such a result is frightening in terms of potential "merchandising" of human body parts. No OECD country has yet crossed this ethical Rubicon. However, care needs to be taken not to go a step too far in the use of such price mechanisms. As far as France is concerned, the financial focus on living related donors is

marginal and deals only with making sure that they do not have to pay any of the costs associated with their donations (health care, child care during the hospital stay, transport, lost income from inability to work).

All these ethical issues are a good reason not to allow price mechanisms to be shaped and implemented only at expert level.

Tenth recommendation: ensure political awareness and that society contributes towards the decision making-process in shaping health price mechanisms

B) Those economic tools are tools not goals

In an article entitled *"Manacled competition": market reform in German health care* published in 1999 ***(***6***)***, Larry Brown wondered whether Germany and its pre-competitive continental confreres (Dutch notably) would conclude from their reform, inspired by Enthoven's concept of managed competition ***(***27***),*** that: "*the market game is not worth the medical candle and turn to the old "new paradigm" on subtle display in France wherein political power improvises innovative but incremental policies shaped by myriad reform visions but mastered by none".* To him, the more diverse theoretical background of the French elite (forged in the ENA, the French National School of Administration) largely explains the different routes followed by France compared to other European countries, like Germany and the Netherlands, where the market ideology and economic background of the elite has played a greater role in the health care reform. Whether this somewhat idealistic assumption is still true after the 2004 T2A (French PPS: Prospective Payment System) reform is questionable! The over-focus on this T2A market tool enforcement had a major impact on health care provider behaviour, including HDC public sector structures and physicians, as pointed out in the DREES 2011 report on financial incentives ***(***24***)***. This has also changed the way they perceive themselves. The ferocity of the debate on binding OQOS, i.e. a system of caps and limits similar to the German one, and the shared opposition of the public and private sector traduces this evolution. Both sides have expressed a wish to improve their market share freely. For this particular reform, the caps and limits approach has finally been abandoned. The solution finally adopted was a closer control by the CNAMTS of the hospital stays data and related reimbursements.
Providing the best cost-effective answer to health needs and, in our case, to the ESRD needs of a particular geographical area, should remain the goal of the policy maker: whether market tools alone can achieve this goal remains to be discussed.

Eleventh recommendation: keep in the policy maker's mind that market tools are tools not goals

1.3.2 The need to integrate economic tools in a more comprehensive ESRD health care policy

Aside from the ethical debate and the dangers of over-focusing on market tools, the internal limits of planned market tools need to be considered to make using pricing policy part of a more comprehensive and high-performance ESRD health care policy.

A) The magic of the "invisible hand": from theory to grass roots application

From a neoclassical economic perspective, price should come out of the action of supply and demand, the *invisible hand of the market* spontaneously channelling self-interest towards socially desirable ends. So somehow in health care the limits of market tools would be linked to their incomplete implementation and to the administrative set up of prices. It sounds preferable to follow economic analysis that considers health as a special good with externalities that cannot be valued by market free rider behaviours. The market is also limited in terms of producer-consumer self-exchange capacity due to the asymmetrical situation of patients who lack information and knowledge to chose optimal care. On this concept side, we should also state that the so-called *"homo economicus"* is an abstraction: the economist Herbert Simon demonstrated the human bounded rationality, and sociologists challenge the thirst for profit as being the main motor of human action.

Therefore, there is a need to have a better and "grass roots" understanding of the ESRD environment, ESRD health care providers and ESRD patient behaviours and motivations.

Many authors have worked on this aspect to try to understand why in most OCDE countries satellite and home dialysis (HD or PD) are difficult to develop.

Schlessinger pointed out in the USA in the 1980's ***(***56***)*** that there is a difference of behaviour according to provider status: for-profit facilities providing more HDC care and non-profit and public facilities offering more satellite and home care treatments. This is partly true in France now. The public sector offers mainly HDC care. Later, Walker added to this US analysis (65) the fact that the *utilization of home dialysis was positively associated with facility size, percent patients employed full- or part-time, younger population, and number of years a facility was Medicare certified.*

In France, considering the huge regional discrepancies in the use of PD[16], Bouvier studied in 2008 ***(***8***)*** *the nephrologists' perception of what should be the optimal ratio in incident dialysis patients. The results were 29 ± 15% in public centres, 27 ± 12% in non-profit clinics and 14 ± 8% in the private sector.* According to them, barriers to PD development included the lack of available nurses for patient care (48%), low reimbursement of PD (25%), limited training (23%) and hospital care facilities in case of PD problems (23%). The training issue is also highlighted in Chanliau's French study ***(***12***)*** and also in Viglio's study ***(***16***)***[17]. Chanliau adds lack of patient information to this diagnosis. This is also mentioned in scientific publications worldwide.
The DREES 2011 report adds interesting data to this ESRD landscape description ***(***24***)***. Firstly, on the issue of patient preferences: nephrologists argue that patients are increasingly reluctant to let their disease treatment enter their home and prefer to go in safe facilities close to home. In contrast, patients' associations explain that once a patient tries or has tried home dialysis he favours this option that brings him/her a better quality of life and greater autonomy. It highlights another issue: 1 patient out of 4 starts his/her dialysis as an emergency, which limits the possibility of preparing them for self-dialysis. Furthermore, patients are getting older and, even if in most cases there is no medical problem for the elderly to use PD, they need more help in their daily life with home dialysis and sometimes there is a lack of nurses in rural areas.

This quickly and partially drawn landscape clearly demonstrates that the complexity of the environment, the diversity of the stakeholder behaviour and expectations call for a bigger toolbox than just market financial incentives.

B) Need to focus not only on what you build but also on how you build the ESRD Policy framework

Our purpose in this analysis is to make operational recommendations. However, at this stage, before going into a more empirical approach of the hows and wherefores of a better ESRD policy framework, we should be clear about the theoretical basis on which the proposals will be based. Herbert Simon's *bounded rationality*, led him to focus on organisational procedures and control processes that could improve economic outcomes. This is a justification for ESRD *managed care* or P4P approaches. However, such an approach would appear to be too limited an answer when considering the whole complex ESRD environment. A policy maker would rather consider a more global framework.

[16] *It goes from less than 2% in Aquitaine to more than 25% in Franche-Comté according to the ABM CNAMTS report* ***(****14****).***
[17] *But Viglio's study focuses on Italy.*

From the Sicotte and Champagne integrative approach, based on Parson's functionalist model, a few lessons can be learned on how to build a more comprehensive though still efficient ESRD health care policy ***(***58***)***. Although mainly dedicated to health care organisations looking for performance improvement, it emphasizes the need to take 4 performance dimensions simultaneously into account: the goal attainment-related dimensions (improvement of renal transplants and home dialysis), the culture and value-related dimensions (freedom of access to care…), the production-related dimensions (cost-effectiveness analysis, T2A, operators: for-profit, public and non profit facilities…) and the adaptation-related dimensions (new recommendations, innovation…). All those dimensions interact with each other and call for in between alignments that should be taken into account in shaping a more comprehensive ESRD policy.

But building a health care policy also involves a challenging decision-making process, if to start we consider the difficulties induced by Weber's *bureaucratic* ideal type, seen by him as the key process in the ongoing rationalization of the Western society. The role of experts and the need for a democratic debate involving patients and all stakeholders should also be taken into consideration.

Armand Hatchuel ***(***33***)*** offers also a very stimulating theory of "*collective action*" that is worth looking at before going through a more empirical approach to ESRD health care policy. In his theory, based on lessons learned from management sciences, action is the atom of the collective learning process: it is the heart where inter-*relations* influence individual and collective *knowledge*, and vice versa. Although it may sound very theoretical and far from our operational purpose here, it leads to this other core issue: how do we build a learning framework for ESRD health care policy? How can we adapt to the fact that an action, for instance the introduction of T2A, brings new knowledge to operators and at the same time changes their behaviours calling for new actions…?

Considering these different theoretical contributions, the following analysis of the current French ESRD health care policy will focus both on potential improvements to its decision making processes and on other less economic pieces in the toolbox with the aim of reaching a more democratic, comprehensive, integrated and learning *collective action* for ESRD.

2 From a new policy-making process to a more democratic, comprehensive, integrated and learning *collective action* for ESRD

In analysing these decision-making processes and outcomes, it would be interesting to look firstly at the potential contributions of the General Directorate for the Supply of Care (DGOS) the newly reorganised French administrative authority for health care regulation **(2.1)**, before studying what added value can be expected from Public Health Plans versus the current "ESRD risk management" policy **(2.2)**. We will then assess the crucial role of Regional Health Authorities (ARS) and the Biomedicine Agency (ABM) in the learning and adaptive policy-making process for ESRD healthcare **(2.3)**.

2.1 Rethinking regulatory policy taking a more integrated and adaptive approach

2.1.1 Improvement of the regulatory policy-making in progress: new organisation of the DGOS

A) Regulation *stricto sensu*

As pointed out by Saltman ***(***54***),*** *the desire of national policymakers to encourage entrepreneurial behaviour in the health sector has generated not only a new structure of market-oriented incentives, but also a new regulatory role for the State.* This "*Steer more row less*" movement spread all over Europe, starting in the Netherlands in the late 80's (WHO's 1997 report ***(***68***)***). States have now been compelled to abandon the former more bureaucratic command-and-control approach in favour of a subtle equilibrium of mandatory requirements (sticks) and behavioural inducements (carrots). He also noted, following the transaction cost analysis, that if the planned market economy generates efficiency and savings at grass roots level it may cost more at a more complicated regulation level.

In France, the DGOS clearly endorsed this planned market move in 2004 with the generalisation of PPS. However, the main regulatory body, the DGOS, did not change its organisation until April 2010. It is even interesting to note that an "expert office" away from the usual command-and-control organisation, was the principal motor in T2A implementation. Finally, in 2010, it managed to integrate parent organisation, in quite an

innovative organisational structure ***(***Appendix 2***).*** The services in charge of organising health care and licensing various activities merged with the former "T2A mission" and the services in charge of regional budget notification. They are now part of a sub-directorate explicitly in charge of regulation. This may sound a little anecdotal but considering the silos approach that largely prevailed in central administration this should facilitate rule and incentive alignment. For instance, if we look at ESRD facilities over the past few years UDMs have been promoted by the organisational side of the DGOS as satellite structures, whereas financial services considered UDMs as another light form of HDC that could not be implemented at any distance from an HDC[18]. The new organisation provided a means of dispelling this ambiguity. The other, and probably even more important, improvement in this organisational structure is the wider scope covered by the directorate: it is no longer limited to hospital and "clinic" facilities, it now also covers primary care. Even if the Hospitals, Patients, Health and Territories Act of 22 July 2009 (HPST) did not really extend the tools for such a policy, it nevertheless introduced a non-binding ambulatory scheme to be set up in all regions. This is probably a first step towards a stronger stick and carrots approach to organising the primary care market and physicians' involvement in specialized care pathways such as the one recently implemented for ESRD in Belgium, concerning general practitioners as well as private nephrologists.

B) Strengthen the link with other services within the DGOS

The regulation process needs to take many more contextual and resource parameters into consideration.

Therefore, the Sub-Directorate for Care-Supply Regulation also has to work with the Performance Sub-Directorate, now in charge of technical operational rules, innovation and the supervision of health facility organisations. A new agency has even been set up to help this Sub-Directorate to achieve its role of providing support to enhance the performance of care facilities: the National Performance Support Agency (ANAP), which should probably act in close cooperation with the ATIH to enhance the ENCC with added knowledge of structure processes and margins.

The Human Resources Sub-Directorate should also be involved in the regulation approach. Knowledge of available human resources, demographic data, Staff training and skills are a key parameter that needs to be taken into account in shaping the regulatory framework. For instance, physicians' ongoing professional education (DPC), a new concept introduced by Article 59 of the HPST Act[19], opens up new opportunities in terms of regulation. It is publicly financed so that training priorities, like PD training, can be set up. Nephrologists "demography" is often cited as a parameter explaining the tendency to

[18] *This second option has largely prevailed at grass roots level.*

[19] *It includes both training and evaluation of professional activities applying HAS methodology.*

develop HDC. Their diminishing number would make it increasingly difficult to monitor home care patients. However, a closer look shows that their number (around 1308 on 1 January 2009) has increased roughly by +3% each year between 2003 and 2008, slightly less than the number of ESRD patients: +4% *(*49*)*. However, the feminization of the profession and the greater interest of the younger generation in transplants should lead to a change in the dialysis activity. A task delegation experiment, inspired by the Canadian example of specialized nurse practitioners, was launched in 2004 *(*48*)*. Even if it has not expanded so far, the new framework for cooperation between health professionals, supervised by the HAS, may well accelerate this process in the coming years.

A new office in charge of strategy supervision set up within the DGOS should also be involved in devising and shaping the regulatory framework.

However, whether the hierarchical silo organisational structure will make this possible is still a matter for concern. From Hatchuel's point of view, the hierarchy is a transgression of the principle of non-separation of knowledge and relationships that should naturally interplay through collective action *(*33*)*. The over-determination of action through a fixed hierarchical relationship is part of its weakness. It makes it hard to have more integrated and developing collective action whereas this appears to be a key to regulatory success. To overcome these hierarchical limits, project managers, without hierarchical power but with a clear and acknowledged role in transversal and collective action coordination should be more clearly identified within the Regulation Sub-Directorate but also at the higher DGOS level.

Twelfth recommendation: strengthen the new integrated approach to regulation inside the DGOS through better identification of project managers

2.1.2 Better use and reshaping of regulation tools

A) Improvement in the use of regulatory tools already in progress…

As noted in the DGOS and CNAMTS national survey *(*20*)*, the Government Decrees of 23 September 2002 concerning the dialysis facility licensing procedure and technical operational rules anticipated the simplification of the French regulatory procedures brought about by the Ordinance of 4 November 2003. Previously, a so-called *"health map"* was piloted directly from the Health Ministry and allowed a limited number of HDC dialysis stations per million of population on the basis of a national index. At the same time each of the 9 dialysis modalities of that period also had to go through a licensing procedure, but without volume limitations for satellite and home care. These quotas for HDC dialyzers led

to limited In-Center service supply. Therefore, some patients requiring HDC had no other choice than to opt for satellite or home care. Available supply prevailed significantly over patient medical needs. It is interesting to note that we are currently faced with the almost opposite situation. However, the new regulation introduced at that time allowed greater freedom to Regional Hospitalisation Agencies (ARH) to plan licensing according to estimated needs. While assessing those needs, most of them defined ambitious satellite and home dialysis goals. PD was expected on average by the ARH to reach an 11% market share in 2011, which it failed to do[20]. One of the reasons for this is linked to the licensing procedure itself. One of its requirements was to offer at least 3 dialysis modalities: HDC, satellite[21] and home dialysis. If this rule should have favoured a more divers supply of dialysis services, one of its major weaknesses was that the health care facilities could contract with other partners to be recognised as a "triple service supply structure". **Table 4** below shows that less than one third of all 2010-2011 licensed facilities actually supply 3 modalities by themselves *(see* Appendix 3 *for related maps)*.

Table 4: Dialysis licensed structures according to FINESS data 2010-2011

In-Centre Haemodialysis (HDC) authorized structures and other Satellite HD or home dialysis (HD/PD) authorizations

(unit = number of legal entities authorized)

HDC			Public sector		For-profit private sector		Non-profit private sector	
HDC only	74	37.2%	56	56.6%	12	16.9%	6	20.7%
HDC + UDM	42	21.1%	18	18.2%	22	31.0%	2	6.9%
HDC + ASHD/Self-HD	5	2.5%	1	1.0%	2	2.8%	2	6.9%
HDC + PD	16	8.0%	10	10.1%	5	7.0%	1	3.4%
HDC + UDM + ASHD/Self-HD	18	9.0%	2	2.0%	12	16.9%	4	13.8%
HDC + UDM + DP	11	5.5%	5	5.1%	5	7.0%	1	3.4%
HDC +ASHD/Self-HD + DP	4	2.0%	2	2.0%	2	2.8%	0	0.0%
HDC + UDM + ASHD/Self-HD + DP	29	14.6%	5	5.1%	11	15.5%	13	44.8%
Total	199	100%	99	100%	71	100%	29	100%

Satellite HD or Home Dialysis (HD/PD) authorized structures without HDC authorization

			Public sector		For-profit private sector		Non-profit private sector	
UDM only	11	28.9%	4	80.0%	4	22.2%	3	20.0%
ASHD only	9	23.7%	0	0.0%	6	33.3%	3	20.0%
PD only	0	0.0%	0	0.0%	0	0.0%	0	0,0%
UDM + ASHD/Self-HD	7	18.4%	1	20.0%	3	16.7%	3	20.0%
UDM + PD	4	10.5%	0	0.0%	1	5.6%	3	20.0%
ASHD/Self-HD + PD	2	5.3%	0	0.0%	2	11.1%	0	0.0%
UDM + ASHD/Self-HD + DP	5	13.2%	0	0.0%	2	11.1%	3	20.0%
TOTAL	38	100%	5	100%	18	100%	15	100%

[20] *Considering the short length of stay in PD (around 2 years) to reach this 11% PD prevalence target would have required a major increase in PD use for incident cases.*
[21] *UDM was not taken into account within the required satellite licence.*

The HPST Act did not bring about much change to this licensing procedure, apart from its new name (SROS-PRS) and its inclusion in the Regional Health Programme (PRS) that has now 3 scheme components: a heath care facilities scheme, a medical and social facilities scheme and, more or less, a primary care scheme. Methodological guidelines have been given to the new Regional Health Agencies (ARS) to build their SROS-PRS ***(***21***)***. It again places emphasis on the need to promote home dialysis (PD or HD) but also satellite care including UDM at a proximate level, which is quite new. However, as noted in the DREES report, for this to happen the operating framework needs to be changed ***(***24***)***. This is precisely what is going on now. Article D. 6124-76 of the Dialysis Decrees 2002 that defines the UDM technical operating conditions is about to undergo major revision. In short, the changes will make it possible for a UDM facility to operate without a nephrologist on site. This follows a HAS recommendation published in January 2010 ***(***30***)***.
Furthermore, at the beginning of 2012, the DGOS with HAS support will launch the ESRD health professionals multidisciplinary meetings experiment involving different facilities in a specific area (different dialysis modalities and renal transplant) to encourage a more integrative approach to care. It was inspired by the multidisciplinary approach implemented in relation to cancer (RCP).
These should be considered as first steps before a larger assessment and possible development of the current dialysis-licensing framework that should take place next year, 10 years after the 2002 Decrees.

B) … There is room for further improvement in the use and shaping of these tools.

Before devising further improvements to existing regulatory tools, it may well be opportune to question the appropriateness of keeping them the way they are. The CNAMTS ***(***14***)*** recently took up the idea launched by the HAS in a 2010 report on surgical intervention environments ***(***32***)*** to create a new status that would allow *"office based surgery"* like in the United States or in other European countries (Belgium and Germany). This interesting but trivial idea deeply challenges the whole of our regulatory framework the keystone of which is the licensing procedure, an "exotic" French planning tool that may be seen, from abroad, as part of an old command-and-control toolbox.
Firstly, there is a false assumption: facilities other than just clinics and hospitals can be licensed to practice health activities provided they receive the relevant prior authorisation. The non-profit associations working in the SHD or home dialysis field illustrate this fact. Nevertheless, there is clearly a hospital-centred perception of this procedure, to the point that the Administrative Court held that a licensed facility should be regarded as a health care establishment when performing such procedures. This has a heavy and

inappropriate impact on the rules governing small facility and probably calls for these rules to be changed, even if small dialysis facilities have coped with them so far[22].

More importantly, it raises the issue of whether the licensing procedure itself should be left as it is or changed[23]. What are the reasons for maintaining the need to apply for a license before providing some health care services? To what extent should it be used? To be concise, and without exploring the full consequences of this postulate on other health care services, there were probably four main reasons for keeping such a system:

1. to structure access to health care facilities;
2. to optimize the location of scarce resources;
3. to limit the spread of costly services;
4. to ensure that high-risk services are safely provided.

Are they still relevant? While exploring the ESRD example, some answers to that question may be provided.

Firstly, if we consider renal transplants, there is no doubt that they require expert skills and a safe environment. Such operations are restricted to the public and non-profit sector for ethical reasons according to European Directives on this subject (for-profit sector is allowed to engage in kidney removal only). Due to the limited resources available and the required expertise, transplants are covered by interregional healthcare organisational schemes (SIOS). This SIOS and the Dialysis scheme are structured separately and not implemented at the same time. This situation probably needs change, especially as the annual ABM reports show huge discrepancies between regions in terms of new inscriptions on registry waiting lists, number of transplants per region (in 2009, 26.1 pmh in Limousin and nearly 58 pmh in Ile-de-France) that are clearly linked to the broader ESRD framework. So the goal of equal access would appear to be a distant goal. The Belgian requirement for in-center dialysis facilities to contract with renal transplant facilities could also be an interesting option to explore, in addition to the multidisciplinary meetings experiment.

However, what changes should be made to HDC, the 2 variants of satellite HD (UDM and assisted or self-HD) and home dialysis? To overcome the restrictions imposed by the 2002 Government Decrees in terms of access to integrated and divers care services, it would appear appropriate to request HDC facilities to supply on their own not only the three levels of care but also the two main variants, i.e. HD and PD. Although this would be a major change compared to the current landscape, it may be worth making such an attempt. It would facilitate a better understanding by In-Centers of the constraints of Satellite and Home Dialysis in respect of which they have a referral function. This could be achieved through various forms of cooperation but such cooperation should be structured

[22] But this is quite different and lighter than the creation of a dedicated status.
[23] **Annexe 3** is an attempt to describe the current jungle of regulatory tools.

within a single legal entity to guarantee shared interests and concerns. Thanks to the REIN and transplants register, we have now a good knowledge of the changes in needs so that it should be possible to overcome both the excessive constraints imposed before 2002 and resolve the OQOS debate. Although there is no volume limit in the current licensing procedure, the limitation of HDC facility licences to a specific area facilitates more cooperative approaches by slowing down the competitive process (search for market share), thus making it easier to optimize dialyzer station use.

What about the satellite and home facilities? If an authorisation procedure should remain in place, considering the strategic goal to develop both renal transplants and satellite and home care, there should be only one licence for the whole range of local dialysis care supply (including satellite and home care, HD and PD). This would be an answer to the epidemiological fact that ASHD and SHD patients are probably the more easily eligible for renal transplants, so that this market share should naturally slow down in the future, if the renal transplantation target is to be reached. Therefore, a unique level of license for more divers “satellite and home dialysis offer profiles” would be helpful to keep a micro-economic financial equilibrium. But should we maintain this authorisation procedure for satellite and home dialysis? What is its added value? This is probably the toughest question. Indeed too opposite principles are at stake: the equity of access to care, on the one hand, and the freedom of settlement of independent activities, on the other hand. However, the goal is more to spread than to contain the local care-supply. If the safety of the operating environment is to be considered, some may correctly argue that other risky activities, such as Dental Surgery, are performed without prior authorisation and compulsory operating rules. Activities that should be promoted rather than limited should follow a third way in terms of licensing procedure. A regional scheme identifying the population needs has an undeniable added value when thinking of equal access to care. This approach has recently been extended to ambulatory care, but without legal constraints for independent practice. Considering all these elements, an adapted authorisation procedure should be enforced. The procedure is currently based on a sort of call for tenders that should rather take place on a continuous flow basis up to the point where the identified implantation needs would be fulfilled.

However, it will be necessary to think and organise also the transition from current dialysis practices to potential more ambulatory ones that may be supervised directly by general practitioners. This is a real challenge for regulators who try to manage the introduction of new costly innovations, but deal less easily with those transition phases. The Article L. 1151-1 of the French Public health Code (CSP) introduced by the HPST Act may be useful to do so. It has been originally adopted to assess and contain high risk and costly innovations before permitting their practice among all facilities licensed for the relevant health activities. New ambulatory approaches to dialysis care could be experimented on a

small basis, under this Article before potential wider implementation. Facilities such as the so-called HAD that offers non-specialized hospital care at home, the visiting nurses organisations (SSIAD) could opportunely be involved in such experimentations.

This leads to the other major room for improvement. There is an obvious need to make operating rules of each license level softer and easier to upgrade. The adoption and publication of a decree is indeed per nature a long process that explains largely why the 2002 Decree did not change in 10 years. More fluid rules and preferably HAS guidelines should help maintaining a safe environment while keeping enough freedom for medical and organisational innovation. These guidelines would be also helpful to stop thinking the safety of ESRD patients in a structure by structure approach instead of considering it as a continuum in a more comprehensive way.

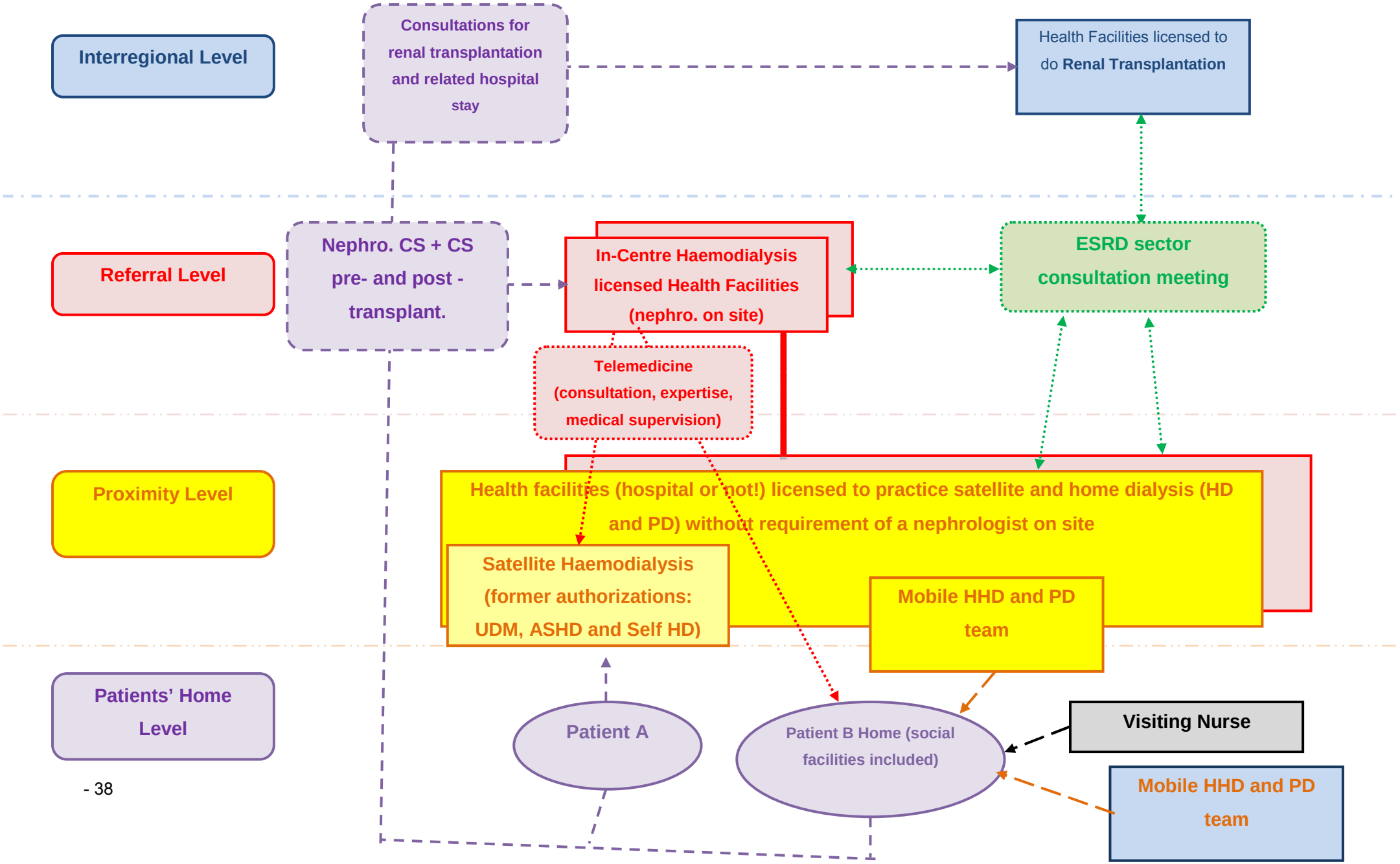
The counterpart will be a necessary enlargement of the evaluation or certification procedures. It will also require enhanced interactions between the different stakeholders of the regulation toolbox to adapt in a reactive way to more frequent guidelines evolutions. However, as shown in **Appendix 4,** there is undoubtedly a need of clarification and better articulation of the existing regulation tools' scope.

Such an evolution should help refocusing the authorisation tool on the accessibility issue, on organisation interactions and on remodelling ESRD health care market place. The Flowchart page 38 describes the organisational ideal type that could be expected from such an integrated approach.

Thirteenth recommendation: refocus the "exotic" French authorisation procedure on ESRD care accessibility, on shaping an integrated ESRD care-supply and on regulating ESRD care market place

Fourteenth: let more space to medical and organisational ESRD innovation through soften but more comprehensive HAS guidelines and through organised experimentations

Scheme Proposal for ESRD Care-Supply



2.2 Health plan versus "ESRD risk management" experience

The DGOS organisation and toolbox improvement cannot *per se* embrace all the complexity of the ESRD health policy. Among the many reasons for that, there is the need to take also into account public health issues that fall within the jurisdiction of the General Directorate for Public Health, but also the National Medical Convention negotiated by the CNAMTS that lays down the rules for independent nephrologist payment etc…
Another core issue is to promote democratic debate, to involve in the decision-making process stakeholders starting with patients but also politicians, elected representatives.
From this perspective, the potential and limits of Health Public Plans **(2.2.1)** will be first analysed before comparing them to what can be learnt from the current innovative ESRD "risk management" approach **(2.2.2)**.

2.2.1 Limits of Health Plans as decision-making process

A) What is interesting with this approach?

The End-Stage Renal Disease has been at the crossroads of not less than three National Health Plans:

- The 2000 Transplant Plan that last until 2003,
- The 2002-2003-2004 Chronic Renal Disease action programmes,
- The 2007-2011 Plan for Improvement of Chronic Diseases Patients' Quality of Life.

Those plans led to interesting achievements. The 2000 Transplant plan identified four priorities for action: to make access to transplantation easier; to reduce regional disparities; to reinforce solidarity and citizens' generosity; to promote research efforts to improve transplantations outcomes. Although some of these goals remain at the forefront of the ESRD agenda, the target of 20 retrievals *pmp* has been met in 2004. This plan sat up a decentralised approach of organ removal and transplantation inspired by the Spain system. The French Transplants Agency (EFG, the former ABM) also launched a comprehensive information system: the *Cristal* registry, thanks to 40 clinical trials technicians (TEC). Besides, 43 Million Francs were invested in 120 retrieval coordinators (40 physicians and 80 nurses), whose funding has been maintained afterwards through two specific systems: the FAG and the CPO annual fixed budget.
The 2002-2003-2004 CRD action programmes mainly listed planned measures of that period, which in itself was quite useful to make sure of their coherence and to make them more visible. Its main achievement was probably the focus on the REIN registry that now allows a panoramic vision of ESRD patient life and care.

The 2007-2011 Plan for chronic diseases patients' QoL is less specific to ESRD but put an interesting light on therapeutic education.

To go further than merely setting out a list of achievements, what can be mentioned as a shared positive feature of those plans is probably the *collective action* that leads to their adoption. Such plans are indeed an opportunity to make the now famous concept of *Health Democracy* real, while discussing around a shared table with representatives of most of the stakeholders involved from patient, physician, and organisation representatives to administrative authorities. These exchanges do help to move from preconceived ideas from different sides to a shared understanding. That is really the epitome of Hatchuel's *collective action* concept: relations and knowledge move simultaneously through a shared action of diagnosis and proposal planning ***(33).***

The main achievement of these Plans is the set up of epidemiological instruments. This is no big surprise considering the lead of the DGS in the decision-making process regarding Public Health Plans that are seen as a major part of its field of competences.

The impact of these plans for patients associations such as Renaloo or the FNAIR, who invest a lot in patients daily life support, should also be considered as a recognition momentum for all the efforts involved.

Besides, it is a way to focus the media attention on a specific issue. The 2000 Transplantation Plan interestingly adopted a communication action: the 22nd of June is now the day dedicated to shared-thinking on organ donation and transplants. This is a way to focus citizens and media attention beyond those plans that cover a limited period of time.

B) Limits of this approach

As explained by Tabuteau ***(59 – 60)***, those Health Plans can be seen as a new way for politicians to invest Health Care Politics and the decision-making process, to think about quality rather than limiting themselves to decide of the broad Health Care framework and the amount of money spent, whereas in Germany or the USA, Health Care Politics is at the heart of most political campaigns[24]. However, if these plans can be a good opportunity for Health Democracy, their decision-making process limit the political debate at a governmental level and do not let much space to the representative democracy itself.

Kouchner as a health Minister launched this trend in 2001 with not less than 22 National plans. Mattei followed with 100 Public Health priorities. The DGS in a recent effort to

[24] *Tabuteau's argument of French complexity to explain the difference is not really relevant: if there are many stakeholders, many type of health care decisions related to security, medicines etc. This situation is not that typical to France. Brown approach of the French healthcare system seen as the product of a more divers theoretical background than just the economic one may better explain a less tense and binary political debate* ***(6).***

clarify the Health Plans landscape identified 35 of them ***(19).*** Both the evolution of the political media scene and the variety of the potential topics can explain this number. But this leads to two major weaknesses of these Health Plans.

The high number of these plans traduces the fact some of them are only communication tools lacking the added value of *Health democracy* and of a shared time spent between Health authorities and stakeholders to confront their views. The up-coming 2012-2017 Second Transplants Plan announced twice on 22 of June 2008 by Mrs BACHELOT and 22 of June 2010 by Mrs BERRA may traduce such fears. Firstly, it illustrates the potential disappointed hopes linked to the difference of time scales between communication and action, the time spent on the waiting list of an announced National Action Plan before its real enforcement. Indeed, in 2008 despite this announcement, and apart from the fact the 2009 year was dedicated to transplants as a national cause, there was no organisation set up to discuss about the content of this future plan. But the current Secretary of State announced the up-coming Plan this year and a goal to diminish the rate of people opposed to post-mortem donation from 30 to 15 %. She also detailed interesting[25] actions seemingly already planned but without the involvement of the Health Authorities concerned except for the ABM.

However, this involvement of Health Authorities within the Health Plans decision-making process as much in terms of agenda as in terms of procedure is probably the major challenge and weakness of the plans. Indeed the publication and political communication constraints often induce the fast enactment of rather loose and little-binding options. There is furthermore usually a specific decision-making process set up for each plan alongside the main framework. It often creates coherence issues: Plan options do not always fit with other political arbitrations taken in a broader approach. Nonetheless, even when there is an attempt to fit within the general framework and even if the project managers of the Plan obtain Health Administration Directions approvals[26], these approvals remains mainly letters of intent. These decisions taken under the timing constraints linked to political communication require new approvals while going through the general health care decision-making process and the fluctuating patterns of political winds. This obligation to go from an administrative decision-making process to another one somehow traduces what Tabuteau pointed out as a preference for implicit legislation and budget decisions by many lobbies, stakeholders, and experts involved within the Health Ministry Administration ***(59).*** It can be added to this assumption, that an external expert Agency like the ABM or the National Institute for Cancer usually facilitates the enforcement of the Plans proposals. Presidential Health priorities (Cancer, Alzheimer …)

[25] *Such as a broader awareness-raising campaign for health professionals, the publication of indicators on activities results of renal retrieval and renal transplants facilities*

[26] *As I personally experimented it when working with the Professor Gil TCHERNIA on the proposals for the Second Rare Diseases Plan*

also help putting more external pressure on the implementation of Health Plans. This fact is well-known by patient associations who seek more and more this presidential support.

Fifteenth recommendation: choose Public Health Plan approach with caution, considering the difficulty to set up these plans in usual decision-making process in the long-term

2.2.2 Lessons learned from the "ESRD risk management" experience

ESRD is now part of the 10 priorities of the so-called National Programs for Risk Management. If risk management is not such a new concept its new framework of implementation offers opportunities for improving the decision-making process and for implementing a more comprehensive ESRD policy.

A) Risk management: what are we talking about?

As explained by Aubert and Polton ***(4)*** the risk management is inspired by the insurance approach that tries to limit the risks covered and doing so to maximize the profits. The CNAMTS, as the French Public Health Insurer adapted this tool to its particular context. It is indeed in a non-profit monopolistic situation and therefore the concept of *managed competition* promoted by Enthoven ***(27)*** or the *managed care* approach linking a payer to chosen providers on the basis of specific targets, do not fit. The CNAMTS therefore adapted the definition of risk management to its specificity to become a "wise purchaser" (although having no provider choice) rather than a "blind payer". It started with individual approaches before exploring more collective goals. The IGAS report on risk management sums it up as a search for efficiency ***(34).*** But in 2005 the CNAMTS identified 5 focuses of work to get these efficiency gains that are worth mentioning:

1. Prevention and information of insured people,
2. Information and support given to Health Professionals (with new visiting delegates that work the same way as drug industry salesmen),
3. Close medical check of patient eligibility for reimbursement,
4. Adaptation of the Health Care Offer to the Needs,
5. Better use of financial incentives.

It contains an obvious regulation component that competes clearly with the DGOS scopes of action, while going a step forward with more emphasize on prevention and information. The IGAS report points out the fact that this risk management, less explored in the 90's by the DGOS, that was busy setting up the PPS framework, has been a major subject for debate during the adoption of the HPST Law. Zittoun would correctly suggest that behind

this fight there was an implicit but strategic *battle for legitimacy* on the use of a set of regulation instruments against the other ***(69).*** Some argued that with the set up of the Regional Health Agencies, this competence should have gone back to the State and Agencies level, and that the Payer should have limited its action to the verification of reimbursements eligibility. But this risk management policy has been a leading strategic goal of the CNAMTS, who increased its risk management staff by more than 960 people while at the same period (2005-2008) cutting its functioning costs by reducing its personnel by more than 5100 people. The Parliament finally adopted a middle way. This risk management policy is now shared both at the national level between the State and the CNAMTS and at the regional level between the local public sickness funds and the ARS. If the Members of Parliament did not clarify the respective fields of action of the CNAMTS and the State, they made this risk management a shared target; meanwhile it probably opens an opportunity for better cooperation.

The ESRD that is one of the 10 topics on which the Risk Management National Programs (RMNP) focus, gives an interesting example of how these RMNP are managed and of the first results achieved.

B) ESRD care: one of 10 priorities on the risk management agenda

In terms of process it should be mentioned first that compared to the Health Plans, the number of selected priorities, ten, is still quite challenging but can be faced simultaneously and more importantly through the use of the general decision-making process. Another reason for that is that it takes place in a long-term perspective, with less short-term political and media pressure, each Health Authority or Administration (ABM, ATIH, HAS, DGOS, DSS, DGS) keeping its usual schedules for action. However, the Minister of Health and the Minister of Finance are involved in the final decisions through the National Steering Committee (CNP) that somehow plays the role of a regulator of the competing regulation authorities. This *managed* administration and payer *competition* channels the struggle for power in a rather efficient way.

For each RMNP, a leading administration has been identified: the Social Security Directorate (DSS) for ESRD. I am currently taking part in this process so my point of view may be biased, but the obligation to think and plan collectively the RMNP, without the presence of external stakeholders at first stage[27], changes the working habits in a more cooperative way. As would suggest Hatchuel, this shared *collective action* of planning an ESRD policy or at least a more coherent set of actions regarding ESRD, changes both our

[27] *But afterwards, these stakeholders were involved the same way as the one applied for Health Plans.*

relations and our knowledge so that the act of planning itself changes. Contrary or in addition to the famous cycle of Daming-Shewhart (Plan, Do, Check, Act) the adaptation process starts right at the beginning even in the *collective action* of planning ***(33)***.

What about the outcomes?

The Most important is probably the fact to have now an alignment in terms of understanding of this notion of best outcomes: the vision moved from over-focusing on PD to a broader understanding of the need for both renal transplantation development and a more diverse range of home or satellite dialysis options. Although each Administration and Authority keeps its own agenda there has also been an incentive to accelerate the moves and to materialise first steps, for instance:

- At the DGOS level: Decree about telemedicine in UDM,
- At the DSS level: Decree allowing visiting nurses to work and be paid when assisting for PD within senior homes,
- At the CNAMTS level: nephrologist capitation payment system for PD, set up of an information campaign about ESRD prevention by the visiting delegates of the CNAMTS towards GPs taking care of diabetes,
- At the ATIH level: cost analysis study of satellite and home ESRD facilities to adapt structures prices,
- At the HAS level: analysis of patient pathways cost-effectiveness, publication of a new ESRD information booklet for patients newly eligible to 100% Health Insurance compensation for chronic renal disease,
- At the CNIPI (Commission in charge of the pedagogic content of medical Fellowship initial training) level: improvement of nephrologists initial training regarding PD.

What is interesting to notice here, as suggested in the DREES report ***(24),*** is that the financial incentives are taken as pieces of a much larger puzzle. Then, the improvement is expected from the alignment of a wide and divers range of measures based on a shared diagnosis, a shared goal, and a shared understanding of the context obstacles that need to be lifted.

Sixteenth recommendation: maintain in the long-term the ESRD *managed regulation* initiated through the risk management current decision-making process

2.3 Agencies involvement: a major role in the implementation and learning process

Once a comprehensive and integrated framework is shaped, the toughest part of the job remains to be done: its implementation and adaptation. The new Regional Health Authorities (ARS) ***(2.3.1)*** and the Biomedicine Agency (ABM) ***(2.3.2)*** should play a key role in this process.

2.3.1 Regional Health Authorities: implementation and feedback keystones

A) A key implementation role

The implementation role of the Regional Health Authorities set up by the HPST Act is indeed a key one. It is all the more the case as now the ARS have more tools in their hands and they include the former URCAM (Regional Union of Local Sickness Funds) that formerly coordinated the risk management policy of the CNAMTS at the regional level. They should therefore both implement their part of the Risk Management National Programs and coordinate their actions with the local funds. As far as ESRD is concerned, one of the big challenges will be indeed the ARS and local funds ability to conceive an awareness and information policy targeting not only individual physicians but also nephrologists working in health facilities and dialysis facilities chief executives. The importance of the nephrologist opinion on PD ***(8)*** and the practice variations observed through the REIN registry[28] argue in favour of such an action. Another scope of action will obviously be the implementation of the SROS-PRS that calls for the abandon of the former ARH command-and-control approach. However, looking at the new ARS organisation charts, evolutions probably still need to be done to link the authorisation procedure to a better micro-economic understanding of the market at stake. Currently jurists and inspectors more concerned by making sure of the application of operating rules are indeed the main operator of this procedure[29].

Besides, as noted by Walshe in her analysis of the NHS Health system, regulatory agencies need to balance independence and accountability ***(66)***. From this perspective, another important evolution that should be noticed is the introduction of a contracting procedure between the State and each ARS that will be part of the ARS Chief Executive

[28] *The IGAS report **(34)** suggests implicating the CNAMTS visiting delegates but their task is probably huge enough with independent physicians so that a complementary team of ARS delegates applying the same action principles would probably be useful.*

[29] *The evolution towards guidelines rather than legal rules suggested in point **2.1.2 B** should facilitate this evolution.*

evaluation. These contracts are based on previously discussed targets, which include the expected evolution of market share percentage for the different ESRD treatment modalities. Those indicators, as pointed out by Jacquelinet ***(39),*** will be more realistic and relevant than the one decided by each ARH on their own within the previous SROS. The REIN registry is indeed a major tool for decision support to analyse different evolution scenarios and the correlated efforts and requirements on both incident and prevalent cases. The simulations will take into account the need to adapt the targets so as to reduce interregional variations of access to ESRD treatments. Likewise, the ARS will sign with ESRD Health facilities Multiannual Objectives and Means Contract (CPOM) that will be part of the evaluation of Public Health Facilities Chief Executive Officer (CEO).

Seventeenth recommendation: make sure of the Regional Health Authorities real accountability for improvement of access to the whole range of ESRD treatments

B) A major warning and feedback role

However, Health Authorities, whether national or regional, should be careful not to rely too much on the idea of having set up a fully comprehensive framework whose implementation should only be assessed through performance indicators. The concept enounced by Edmondson for Companies *competitive imperative of learning* is also valid when dealing with the implementation of a Health policy and in this case of the ESRD Health Policy ***(26).*** She takes the example of General Motors that was probably too confident in its efficient control systems so that it missed big shifts in the market, including customer preference for fuel-efficient cars. Therefore she calls for *execution-as-learning* through the use of up-to-date knowledge, collaborative decision-making and identification of improvement opportunities. That is somehow what has been done while shaping the ESRD Health care policy. An innovative approach has been set up to help central regulation authorities to have operational feedbacks from the field through the ARS. A former survey on ESRD was conducted in 2003 ***(20)*** with the support of the ARH, but what is new this time is that the ARS have been involved in the diagnosis process to identify constraints that should be lifted and to make operational proposals to overcome these problems. The **Appendix 5** shows a summary of these feedbacks. However, as mentioned by Edmonson, there is a need to get feedbacks not only during the planning phase but also while going through its implementation, considering the potential evolution of the operator behaviours, the introduction of new processes, innovation... The key role of the ARS in this *execution-as-learning* is obvious. For this reason, this role should be strengthened by a continuous feedback approach towards central health authorities. This

should rely on the set up of a specific method to do so (an internet Forum for instance) but also, and probably more importantly, on a cultural change to move from a mainly top-down approach to a stronger bottom-up perspective. Besides, ARS at their own level, while implementing the new regional framework of Health Democracy, should also take it as a new opportunity to improve collective action and collective awareness of ESRD challenges.

Eighteenth recommendation: set up a collaborative and learning framework facilitating ARS feedbacks on a continuous-flow basis

2.3.2 The Biomedicine Agency: a key role in the learning and adaptation process

Within this framework the Biomedicine Agency (ABM), whose originality is worth exploring, plays a major role in the adaptation and learning process that could still be reinforced.

A) The Biomedicine Agency: an agency *sui generis*

The Biomedicine Agency's birth took place in 2004. As mentioned in the Parliamentary Bur report ***(3)*** its creation was part of a larger move started in the 80's based on the analysis that a scientific expertise independent of political powers should be strengthened to better understand and prevent "health risks". This agency expertise is largely questioned today considering a lack of transparency, a need to better prevent conflict of interests and to take into account other perspectives (ethical, social, economic) in a more mature Health Democracy. Some also consider that the organisation and articulation of the 18 Health Agencies is not efficient and coherent, although it expresses political priorities. However, the existence of the ABM is not much debated and this is probably linked to its particular roots. It was indeed created through the 2004 Bioethical Law, after the publication of a European Directive on human cells and tissues with the mission to contribute to a well-managed growth of all therapeutics using human elements except blood. It was also created out of former associations such as France Transplant. This original birth and scope for action explains largely the fact that right at the beginning it was not a pure scientific expertise structure, the ethical and social debate being part of its roots. The ABM sat up quite original governance bodies involving in particular scientists, patient representatives, Members of Parliament. However from a Health Democracy perspective, there is probably still room for improvement of this model. First, the participation of Members of Parliament is somehow questionable considering the constitutional separation between Executive and Legislative powers. The Bur report

suggests submitting the annual ABM report already transmitted each year to parliament to further requirements and discussions. Besides, as far as the society involvement is concerned, the American or the German models offers interesting added mechanisms. Indeed all Agencies recommendations (except in case of emergency) are open to comments by anyone interested before finale release to Health Authorities.

But regarding ESRD regulation, it is important to tackle two other main issues. First how far should the ABM take part in ESRD care-supply regulation? As mentioned in the IGAS report on expertise ***(35)*** the emergence of French Health Agencies was based on the concept that health risk evaluation should be separated from "*risk management*"[30], which belongs to the Central Administration's responsibility. However, the border is rather blurred and Health Agencies invest more and more the socio-economic evaluation of different care options. This is the case of the ABM and the HAS who work currently together on the evaluation of ESRD pathways cost-effectiveness. Analysis in which the OFAS (ABM office responsible for health care activities' organization and funding) plays a major role, enlighten Central Health Administration decisions. Nonetheless, they do not take place in the same temporality and framework of constraints. It therefore calls for a subtle equilibrium to manage strategic alignment while maintaining a free and independent expertise so as to avoid frustration both of the experts and of the final decision-maker. Once this difference of paradigms is made clear, there is an obvious added value in ABM and Health Administration collective action and shared information. From this perspective, an interface between the ABM REIN and Cristal registries and Health Administration funding data would probably be worth implementing. It is already the case for the United States Renal Data System.

The second major issue is the scope of themes covered by the ABM. The ABM patchwork of topics does not include the full range of ESRD treatment modalities, despite the responsibility of the ABM for the REIN registry. However, there is an obvious need of ethical debate and independent and permanent expertise[31] regarding this whole ESRD field considering its rapid evolution. That could be part of the ABM mission but another option could be its implication within a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) such as the American one that has no equivalent within the French INSERM Institutes.

B) The ABM and ESRD medical and organisational innovation: recent and potential added value

[30] *With an understanding of risk management mainly oriented towards patients safety and less on efficiency compared with the current definition approach of risk management inspired by the CNAMTS.*

[31] *The HAS and ABM cost-effectiveness is just a part of it.*

If the diffusion to the ARS of data extracted from the REIN registry already shown this ABM expertise added-value, the rapid evolution of ESRD treatments modalities also calls for such an expert follow-up. Indeed as noted by Jacobs ***(40)*** the haemodialysis is a quite recent medical discovery. *The first recovery of a patient undergoing HD for acute renal failure (ARF) was reported in Netherlands by Willem Kolff in 1945, paving the way for a rapidly worldwide expanding treatment of ARF with dialysis. (…) The concept of applying HD to patients with end-stage chronic renal failure (ESRF) was experimented by Alwall in Sweden as far back as 1948.* Then other medical innovations like the AV fistula were invented. *Most promising developments currently in progress, using optimal miniaturisation and nanotechnologies, aim at adding a unit with regulatory "tubular" functions to the filtration "glomerular" process, both being ultimately contained in a single, wearable, implantable device which would thus perform functions closer to that ensured by the normal kidney.* This rapid evolution and these innovations are really challenging from a Heath Care Regulation perspective. As studied by Alter ***(2)***, there is both a complementarity and competitiveness between the logic of innovation and that of organisation. If there is an obvious need for work rationalisation within a health organisation to implement these innovations, the State level also has to adapt accordingly the legal and financial framework. For instance, the DGOS and the ABM recently worked on the introduction of perfusion machines within renal retrieval practices.

Besides, the ABM expertise that is at stake here concerns also ethical evolutions. The new possibility introduced by the 2011 Bioethical Law to practice paired-exchange donations[32] opens new renal transplantations possibilities that should be taken into account when fixing renal transplants targets.

Finally, the ABM expertise would be useful to identify or forecast emerging and innovative organisational practices. For instance, the experimentation of PD promotion even in emergency situation at the University Hospital of Caen ***(44)*** questions the organisation of downstream permanent access to specialized care (PDSES) especially relating to surgery. The ABM is currently focusing on the improvement of surgical PDSES for renal transplants but a more comprehensive approach including PD needs would be also interesting.

Nineteenth recommendation: broaden the Biomedicine Agency scope of action to the full spectrum of ESRD expertise (ethical, epidemiologic, organisational, financial) in order to contribute to the ESRD policy-making in a more comprehensive and challenging way

[32] *It is possible when two Living Related Donors (LRD) are not compatible with their related patient but with the other ones.*

Conclusion

From a starting question on the possibility to improve ESRD patient orientation towards various treatment options through an appropriate pricing policy, some may find that this study has gone too far away. However, while recognising the rarely denied potentialities of an improved pricing-policy tool, one must look at the context within which it takes place. The ESRD context is characterized by an important complexity linked to the diversity of stakeholders, their behaviours and aspirations and the need for a *managed regulation* considering the acute battle for legitimacy of competing regulation authorities. In such an environment it would be pointless to seek patient orientation improvement only through the light of pricing-policy. Somehow price mechanisms over-focus observed in most OECD countries may even result in greater distance from the target. To overcome this challenge there is no ideal framework, no ideal policy but a collective search for a coherent set of actions may be useful to produce positive outcomes. This collective search produces interaction and knowledge improvement. As noticed by Sargut and McGrath in a recent article, "*living with complexity*" calls for adapted behaviours, learning processes considering human beings' cognitive limits ***(55)***. Over-focusing on indicators that are somehow the new idols of policy-makers may be as dangerous as the pricing-policy religion in this respect. It may indeed mask parameters hard to measure or rare events that can be *more significant than average ones* in terms of emerging problems and sometimes potential solutions.

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Appendices

Appendix 1

Report of a DGOS consultation meeting with ESRD stakeholders (9th of September 2011)

Appendix 2

DGOS organization chart

Appendix 3

Maps of dialysis authorized facilities according to FINESS data 2010-2011

Appendix 4

Scope of action of the different regulation tools

Appendix 5

Summary of regional ESRD health care diagnosis and proposals

Appendix 1

REUNION

MINISTERE DU TRAVAIL, DE L'EMPLOI ET DE LA SANTE

SECRETARIAT D'ETAT A LA SANTE

Direction générale de l'offre de soins

RELEVE DE CONCLUSIONS

Intitulé : Réunion sur l'insuffisance rénale chronique terminale (IRCT) **Objet : réunion avec les partenaires**	**Organisateur : DGOS, sous direction de la régulation de l'offre de soins, N Lemaire** **Secrétariat : DGOS, R3, LV**
Lieu : Ministère de la santé	**Date : 9/09/2011**

Liste des présents[33] : C. Bara (FHF), B. Bayle (FEHAP), M. Bensadon (ATIH), S. Billet (DGOS, R1), O. Brisquet (DGOS, R3), I. Bongiovanni (HAS), A. Caillet-Beaudoin (SFT), J. Chanliau (syndicat des néphrologues exerçant en association), C. Couchoud (ABM), G. Couillard (DSS), E. Déso (DSS), P. Gabach (CNAMTS), D. Joly (SFN), C. Jacquelinet (ABM), M. Kessler (syndicat des néphrologues de CHU), H. Logerot (ABM), S. Labatut (CNAMTS), C. Larose (DGOS, R3), G. Le Hénanff (DGOS, R3), N. Lemaire (DGOS, R), JP Ortiz (syndicat des néphrologues libéraux), S. Rousval (FEHAP), C. Rumeau-Pichon (HAS), N. Sanchez (FHF), I. Schapira (DSS), G. Schutz (FHP), A. Townsend (ATIH), L. Valdès (DGOS R3).

Documents mis à disposition lors de la réunion:

- Diaporamas : 1) de la réunion ; 2) de l'état de lieux de l'IRCT (ABM), 3) du point d'étape sur l'évaluation médico-économique des stratégies de prise en charge de l'IRCT en France (HAS) ; 4) des recommandations sur la télémédecine et l'UDM (HAS) ;
- Fiche de synthèse des diagnostics partagés des régions (DGOS/DSS) ;
- Evolution du taux d'incidents des patients en dialyse entre 2005/2009 (REIN) ;
- Indicateurs utilisés pour mesurer la charge en soins IDE en UDM (expérience Rhône-Alpes).

Il s'agit d'une rencontre réunissant l'ensemble des partenaires concernés destinée à :

- partager l'état des lieux sur l'insuffisance rénale chronique terminale (IRCT) ;
- discuter de sujets pouvant donner lieu à des applications rapidement opérationnelles ;
- envisager les perspectives qui pourront faire l'objet d'une discussion lors d'une prochaine réunion en fin d'année.

[33] Par ordre alphabétique.

(I) <u>Le bilan des états des lieux et diagnostics partagés réalisés par les ARS en régions</u>

Cette démarche a été entreprise par les ARS, en concertation avec les partenaires régionaux concernés, dans le cadre de l'élaboration des SROS-PRS[34] et du programme de gestion du risque IRCT. Il faut souligner l'important travail réalisé par le Registre REIN et les Sociétés savantes pour l'élaboration des indicateurs « ARS ».

1-1 Présentations :

- Résultats des états des lieux des régions réalisés à partir des indicateurs ARS, équipe du registre REIN
- Freins et leviers identifiés lors des diagnostics partagés en régions, DGOS, DSS

1-2 Discussion :

Pour mieux appréhender les évolutions, il est demandé à l'ABM de compléter ses documents par 2 tableaux de répartition des patients incidents (orientation « stabilisée », correspondant au 3e mois après le début de leur dialyse) sur les 5 dernières années:

- par modalités
- par âge.

Cependant, le recueil REIN n'était pas exhaustif il y a 5 ans[35]. L'arrivée de nouvelles régions influence les résultats (celles-ci pouvant faire plus ou moins de DP que les régions incluses dès 2005). Il sera donc nécessaire de disposer d'un tableau évolutif sur les 13 régions incluses dans REIN dès 2005.

Greffe :

- M. Kessler : concernant la greffe, le nombre de greffes réalisées à partir de donneurs décédés n'augmente pas, même si le pourcentage de patients vivants avec un greffon fonctionnel s'accroît. Le frein au développement du don d'organe est principalement d'ordre culturel et sociétal.
- JP Ortiz : en Espagne, il y a quelques années, grâce aux campagnes d'information, les chiffres de transplantation (par donneurs décédés) étaient très élevés. Actuellement, les prélèvements ont tendance à baisser (malgré la très forte accidentologie du pays). En effet, les campagnes en faveur du don d'organe sont moins soutenues, d'où une mobilisation moindre de la société.
  Il est, par ailleurs, nécessaire de préserver la spécialité de néphrologie dans son ensemble (greffe, dialyse…). Du fait du nombre croissant de patients greffés, les équipes néphrologiques de transplantation voient leur charge de travail s'accroître pour assurer le suivi de greffe. Il serait souhaitable qu'un suivi partagé de greffe soit effectué (équipes de dialyse/équipe de greffe), permettant de dégager du temps aux équipes de transplantation. La mission des équipes de transplantation doit se centrer sur la greffe/prélèvement et des complications graves « post-greffe ».
- N. Lemaire: Les dons par donneurs vivants peuvent aussi apporter des réponses et il est important de favoriser cette modalité de prise en charge.
- H Logerot : Dans cet objectif, il importe de garantir la neutralité financière des dons pour les donneurs.

Dialyse :

- M. Kessler : Plutôt que de faire une distinction par modalités (HDC, UDM, AD, DP, HDD), il faut se placer du point de vue du patient. Le malade, bien informé sur les modalités existantes, choisit, le plus souvent, une prise en charge proche de son domicile. Il serait donc plus pertinent de distinguer : 1) la prise en charge en centre (celui-ci nécessitant un adossement à une structure de soins MCO), ne constituant donc pas une prise en charge de « proximité »; 2) la prise en charge de proximité, ou « hors centre », constituée par toutes les autres modalités de traitement de dialyse.
- A. Caillet-Beaudoin : les patients souhaitent, au début de leur traitement, être « totalement pris en charge » ; c'est dans un 2e temps, qu'ils optent, s'ils le peuvent, pour des prises en charge plus autonomes.
- M. Kessler : les patients souhaitent toujours de la proximité qu'elle soit assistée ou non.

[34] Il faut noter que le calendrier des SROS-PRS a été « desserré » par le Ministre afin de laisser une plus large place à la concertation avec les acteurs régionaux : la moitié environ des SROS-PRS seront publiés en fin d'année, les autres étant prévus pour le 1e trimestre 2012, à l'exception de l'Ile de France dont le SROS paraîtra mi 2012.

[35] Seules 13 régions étaient incluses en 2005.

- N. Lemaire : les orientations qui ont été données aux ARS (via le guide méthodologique aux ARS élaboré par la DGOS pour la construction des SROS-PRS) privilégient la prise en charge de proximité (UDM de proximité, AD, DP, HDD).
- J. Chanliau : la disparition de la carte sanitaire, la mise en œuvre de la T2A et les SROS III n'ont pas favorisé le hors centre ; il existe un enjeu de qualité de la prise en charge qui dépend aussi des moyens mobilisés.

(II) <u>Les travaux de la HAS relatifs à l'IRC</u>

2-1 : Point d'étape sur l'évaluation médico-économique des stratégies de prise en charge de l'IRCT

2-2 : Les autres travaux :

- **Travaux réalisés par le service d'évaluation des actes professionnels**, sur saisine de la CNAMTS
  - **Dosage de la créatinémie et évaluation du débit de filtration glomérulaire pour l'insuffisance rénale chronique :** le travail a pour objectif de mettre à jour les recommandations de l'ANAES de 2002 sur la formule à utiliser pour estimer le débit de filtration glomérulaire (CG, MDRD ou CKD-Epi).
  - **Performances du rapport albuminurie/créatinurie (ACR)** comparées à celles de l'albuminurie des 24 heures dans le diagnostic de la maladie rénale chronique.

  Un groupe de travail sera réuni pour ces 2 sujets le 26 septembre avec un passage au Collège fin décembre.
- **ALD N°19** : révision du guide, révision du guide médecin et élaboration d'un guide patient avec parcours personnalisé de soins ; calendrier prévisionnel début décembre 2012.

(III) <u>La DP en EHPAD</u>

3-1 : Présentation (DSS)

Le projet de décret vise à permettre la prise en charge sur le risque maladie des actes infirmiers de DP en EHPAD lorsqu'ils sont réalisés par un infirmier libéral (IDEL). Le décret, soumis au Conseil d'Etat en septembre devrait pouvoir être publié en octobre 2011. L'impact de cette mesure sera à évaluer.

3-2 : Discussion :

- Pour l'ensemble des participants, ce projet constitue une avancée importante et attendue.
- S. Rousval : il serait souhaitable de faire passer rapidement le message aux CPAM afin de sécuriser d'ores et déjà la prise en charge des soins d'IDEL. En effet, certaines caisses en attendant la publication du décret, ne prennent plus en charge les soins d'IDEL en DP, alors qu'elles le faisaient antérieurement.
- A. Caillet-Beaudoin : il faudrait étendre cette modalité pour les soins de DP en SSR, USLD.
- N Lemaire : cette question pourra s'envisager dans le cadre de la mise sous T2A des SSR.
- S. Labatut: Le décret permet la prise en charge de l'intervention de l'IDEL en EHPAD. Il permet de clarifier l'intervention de l'IDEL en DP dans son principe, il reste à poursuivre la réflexion pour les autres situations.
- E. Deso : La réflexion doit, en effet, se poursuivre en envisageant l'impact des mesures à proposer.

IV) <u>Les pré-requis pour prendre en compte la lourdeur de prise en charge des malades</u>

4-1 : Présentation des enjeux

La DGOS souhaite dégager des pistes de travail permettant une plus juste appréhension de la lourdeur de la prise en charge au sein de chaque modalité dans l'objectif d'une tarification plus adaptée. Les évolutions récentes de la classification, intégrant, pour les autres activités, des niveaux de sévérité dans les GHM, permettent de prendre davantage en compte la lourdeur des cas traités.

A ce jour, 2 recueils de données sont disponibles, d'où une double saisie pour les professionnels de santé : 1) REIN dont la finalité est celle d'un registre (exhaustivité, recueil annualisé, objectif santé publique) ; 2) le PMSI fournissant des données dont la finalité est médico-économique. L'objectif est d'identifier les critères liés à la lourdeur de la prise en charge, permettant une tarification plus adaptée. Dans cet objectif, des données pourraient être recueillies, de façon simultanée, dans les 2 systèmes d'information en évitant une double saisie.

4-2 : Discussion

- JP. Ortiz : l'identification de « profils de patients » a déjà fait l'objet de travaux qui n'ont pas abouti. En effet, il n'est pas possible de définir de profils types de patients par modalités. Par ailleurs, les 2 outils ont des finalités différentes. Si l'on souhaite mettre en place un recueil fin permettant de prendre en compte pour la tarification, la lourdeur de la prise en charge au sein d'une même modalité, il est nécessaire de concevoir un outil spécifique qui sera complexe à élaborer.
- G. Schutz : une simplification du recueil serait bienvenue. Par ailleurs, la démarche consistant à prendre davantage en compte la lourdeur des prises en charge est pertinente et constitue une voie qu'il faut expertiser. En effet, la lourdeur de la prise en charge (dépendance, comorbidités…) a une réalité au niveau des coûts (charges en personnel : médecin, IDE…).
- M. Kessler : REIN est un outil épidémiologique qui fournit des données a postériori et ne peut donner d'information en temps réel, en particulier, sur la variabilité de l'état médical d'un même patient en fonction des séances. Un recueil de données via le PMSI pourrait le permettre mais suppose de coder à chaque séance, ce qui serait très lourd.
- A. Caillet-Beaudoin : la lourdeur de la prise en charge est effectivement variable pour un même patient dans le temps et dépend surtout de la tolérance de sa séance (exemple : mauvaise tolérance de la dialyse en début de semaine/fin de semaine) et non pas seulement des comorbidités, celles-ci pouvant être stables.
- D. Joly : il existe pour la réanimation des outils de mesure pour estimer le poids de la prise en charge. En adoptant cette approche, un groupe de travail pourrait élaborer un outil permettant de mesurer la charge en soins et la gravité des patients. Il faudrait que l'outil soit simple et opérationnel.
- A. Caillet-Beaudoin : un outil de recueil, d'utilisation simple, a été élaboré dans une structure de la région Rhône-Alpes pour mesurer la charge en soins IDE en UDM/centre et peut être communiqué pour information[36].
- L'ensemble des participants s'accorde sur le fait qu'il est utile de poursuivre la réflexion dans le cadre d'un groupe de travail qui serait chargé d'envisager la faisabilité d'un outil de mesure prenant en compte la lourdeur de la prise en charge. Il serait souhaitable d'associer les sociétés savantes et des représentants paramédicaux.

(V) <u>UDM et télédialyse</u>

5-1 : Recommandations de la HAS et proposition de modification de l'article D6124-76 du Code de santé publique (DGOS)

- N. Lemaire : Il est proposé une modification de la réglementation qui concerne uniquement les conditions techniques de fonctionnement des UDM afin d'y intégrer le fonctionnement par télémédecine. A plus long terme, il sera nécessaire de proposer des aménagements des décrets de 2002 pour prendre en compte les évolutions intervenues dans la prise en charge des patients dialysés.

5-2 : Discussion :

- Les modifications proposées sont approuvées par l'ensemble des participants ainsi que le projet de travaux sur la révision des décrets de 2002.
- N. Lemaire : dans ces conditions, les consultations officielles pour le décret UDM et télémédecine vont donc pouvoir débuter avec, en particulier, un avis du CNOSS avant la fin de l'année.
- B. Bayle : il est important, même si cela ne peut se faire immédiatement, de réviser les décrets de 2002.
- P. Gabach s'interroge sur le contenu de la consultation de télémédecine et sur les moyens de s'assurer de sa réalisation effective pour l'Assurance maladie.
- M. Kessler: il faut noter que le contenu de la consultation sur site, même s'il est connu (interrogatoire, analyse des données biologiques et prescriptions), n'est pas prédéterminé et la téléconsultation n'est pas en soit différente d'une consultation ordinaire.
- D. Joly : la question du contenu de la consultation (sur site ou par télémédecine) relève des sociétés savantes.
- N. Lemaire : il est uniquement nécessaire que la téléconsultation puisse être « tracée » afin d'en vérifier la réalisation, comme c'est le cas pour la consultation sur site (celle-ci étant « attestée » par le patient).

[36] Il est à noter que, suite à ce travail, l'ARS a donné son accord pour une expérimentation de modalités mixtes UDM/centre pour des patients instables.

(VI) <u>Les perspectives</u>

- N. Lemaire : la DGOS souhaiterait définir des orientations générales pour la prise en charge de l'IRCT pour les prochaines années. Le guide méthodologique SROS-PRS élaboré par la DGOS fixe déjà 2 lignes directrices aux ARS : 1) développement du hors centre ; 2) renforcement de la greffe rénale.
    - L'horizon des SROS-PRS, soit 2016, est peut être trop rapproché pour fixer ces objectifs, compte tenu de la mise en œuvre progressive des actions nationales « leviers » (DP en EHPAD, UDM par télémédecine…). Il pourrait être plus pertinent d'envisager l'horizon 2018.
    - Il convient de se donner des objectifs réalistes qui pourront faire l'objet d'une discussion lors de la prochaine réunion.
    - D'ores et déjà, il est proposé une approche globale de la question qui concernerait :
      1) un objectif d'augmentation de la greffe portant sur la proportion de patients vivant avec un greffon fonctionnel ;
      2) un objectif d'augmentation de la dialyse hors centre, portant sur le taux des patients incidents en hors centre/centre, cet indicateur permettant de prendre davantage en compte les changements de pratiques.
- L'ensemble des participants s'accorde sur le fait qu'il est pertinent de déterminer des cibles par patients incidents pour la dialyse.
- JP. Ortiz : il faudrait disposer des données évolutives par région pour cet exercice.
- M. Kessler : il sera difficile de proposer des cibles nationales ; il serait souhaitable de proposer des cibles de progression au niveau de chaque région.
- N. Lemaire : Il est utile que les régions puissent se comparer entre elles. Elles le peuvent grâce à la mise à disposition des indicateurs fournis lors de l'état des lieux.
  Par ailleurs, avoir une cible nationale n'est pas incompatible avec le fait d'avoir une cible déclinée par région. Il faudra partir des situations de chaque région et proposer une cible aux ARS. Dans le cadre du dialogue de gestion Etat/ARS, les cibles font l'objet d'une discussion avec les ARS, puis d'une contractualisation inscrite dans le contrat d'objectifs et de moyens entre l'ARS et le ministère.
- A. Caillet-Beaudoin : il est utile de mieux repérer les patients avant le stade d'IRCT (TFG entre 10/15 ml/minute). La phase « d'avant » la mise sous dialyse est essentielle. Ainsi, pour préparer la DP dans de bonnes conditions et limiter la survenue de dialyse en urgence, il est essentiel de prendre les patients en charge en amont.
- N. Lemaire : il sera difficile de proposer des indicateurs sur tous les sujets. Néanmoins, il serait utile que des informations puissent être données sur cette question lors de la prochaine réunion.

(VII) <u>Les sujets à aborder lors d'une prochaine réunion</u>

- Discussion concernant les grandes orientations pour l'offre cible au niveau national et régional

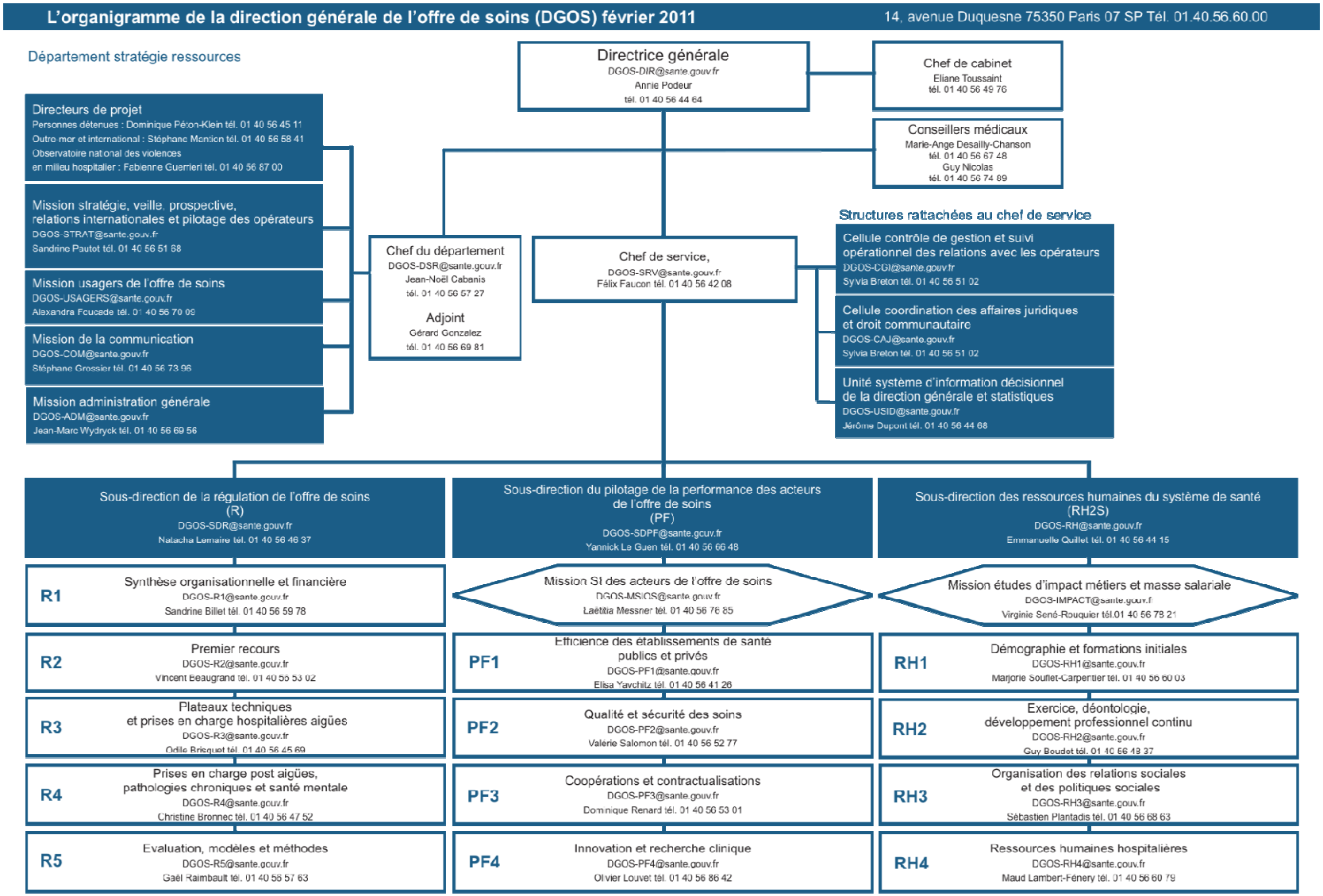
Prochaine réunion le 18 octobre de 14h à 17h
Au ministère de la santé, 14 avenue Duquesne 75007 Paris, salle 7234

Abréviations :
SROS-PRS : Schéma régional d'organisation des soins-programmes régionaux de santé.
DP : dialyse péritonéale
HD : Hémodialyse
HDD : hémodialyse à domicile
HDC : hémodialyse en centre
AD : autodialyse
UDM : unité de dialyse médicalisée
IDE : infirmier diplômé d'état
CPAM : Caisse primaire d'assurance maladie.

Evolution du taux d'incidence sur 13 régions par modalités de dialyse *(Lorraine' 'Rhône-Alpes' 'Bretagne' 'Languedoc Roussillon' 'Champagne-Ardenne' 'Limousin' 'Auvergne' 'Nord-Pas de Calais' 'Provence-Alpes-Côte d Azur' 'Basse Normandie' 'Bourgogne' 'Centre' 'Midi-Pyrénées)*

	HD en centre	HD en UDM	HD hors centre	DP
2005	68,1	2,9	14,2	14,8
2006	68,4	3,6	13,4	14,6
2007	68,2	4,4	13,2	14,2
2008	68,7	5,5	12,9	12,9
2009	68,2	6,7	12,4	12,8

Appendix 2


L'organigramme de la direction générale de l'offre de soins (DGOS) février 2011
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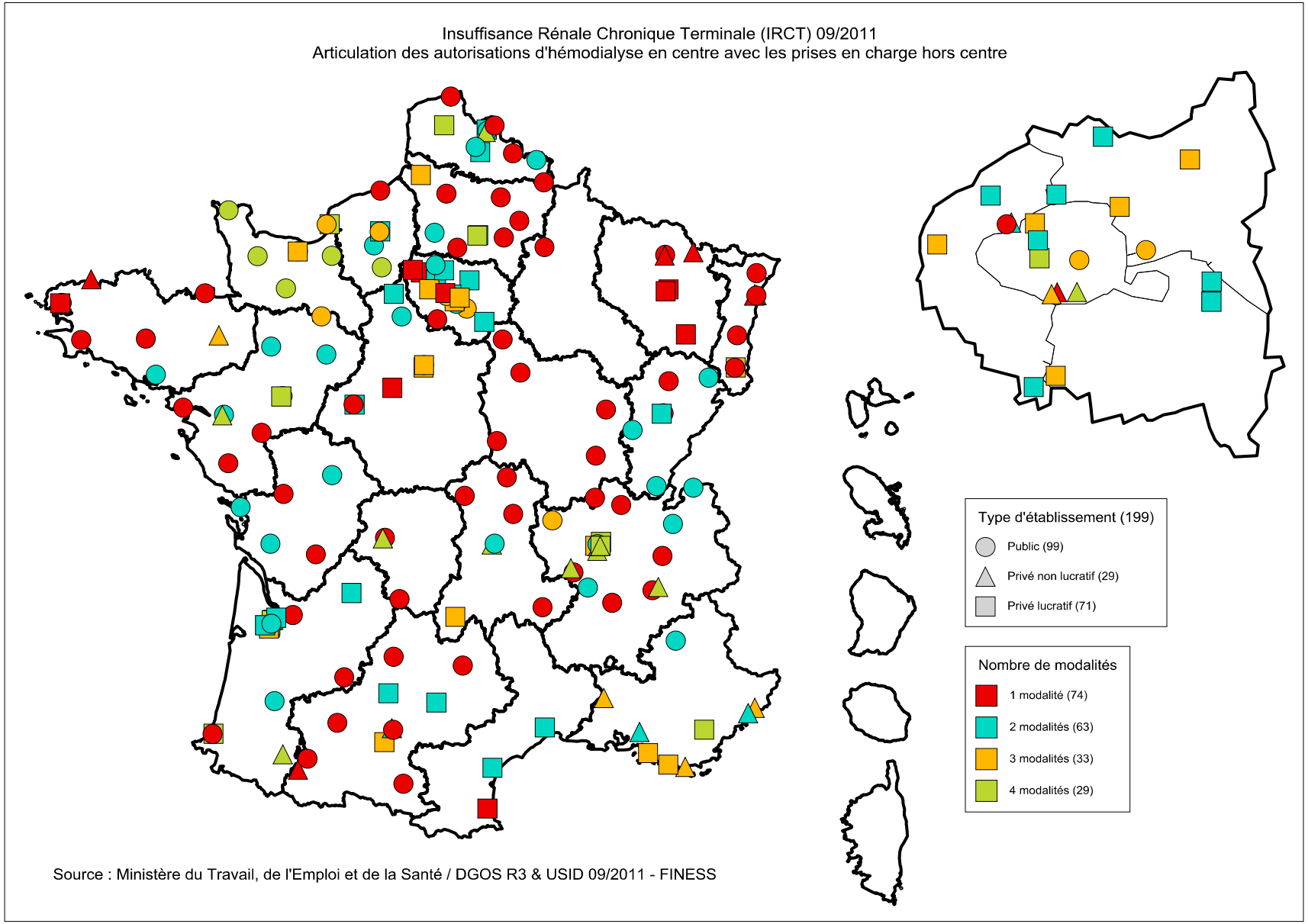
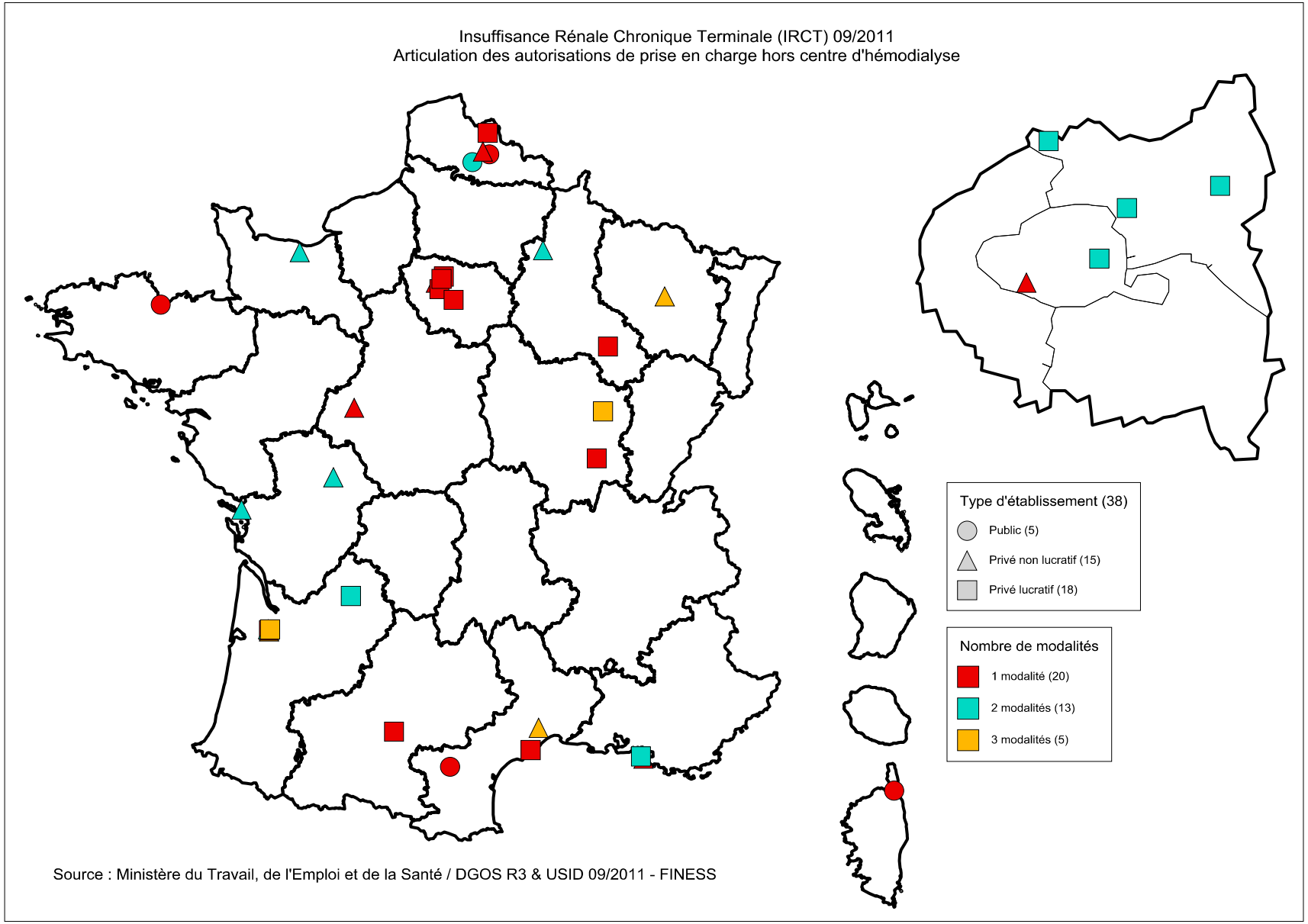
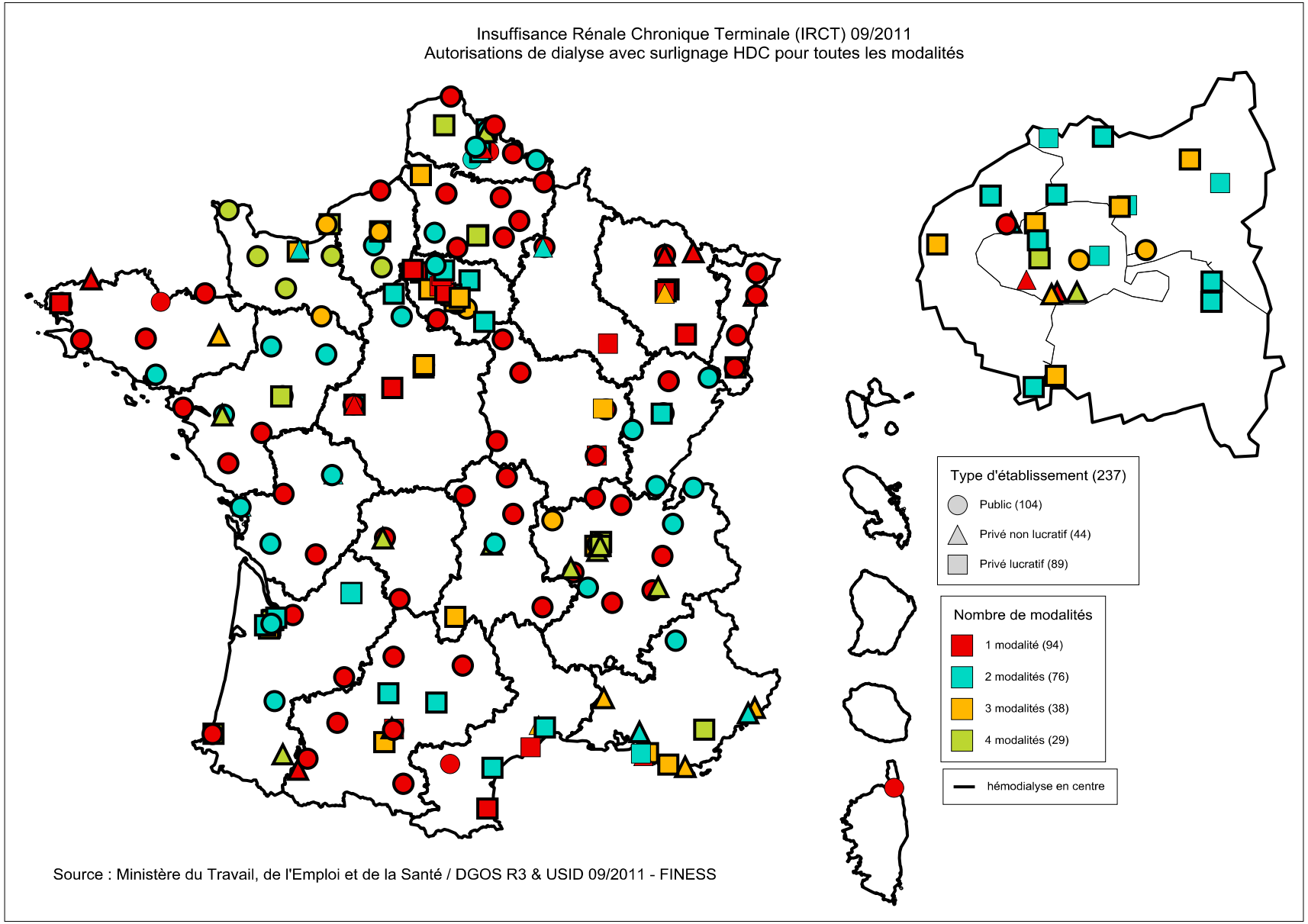
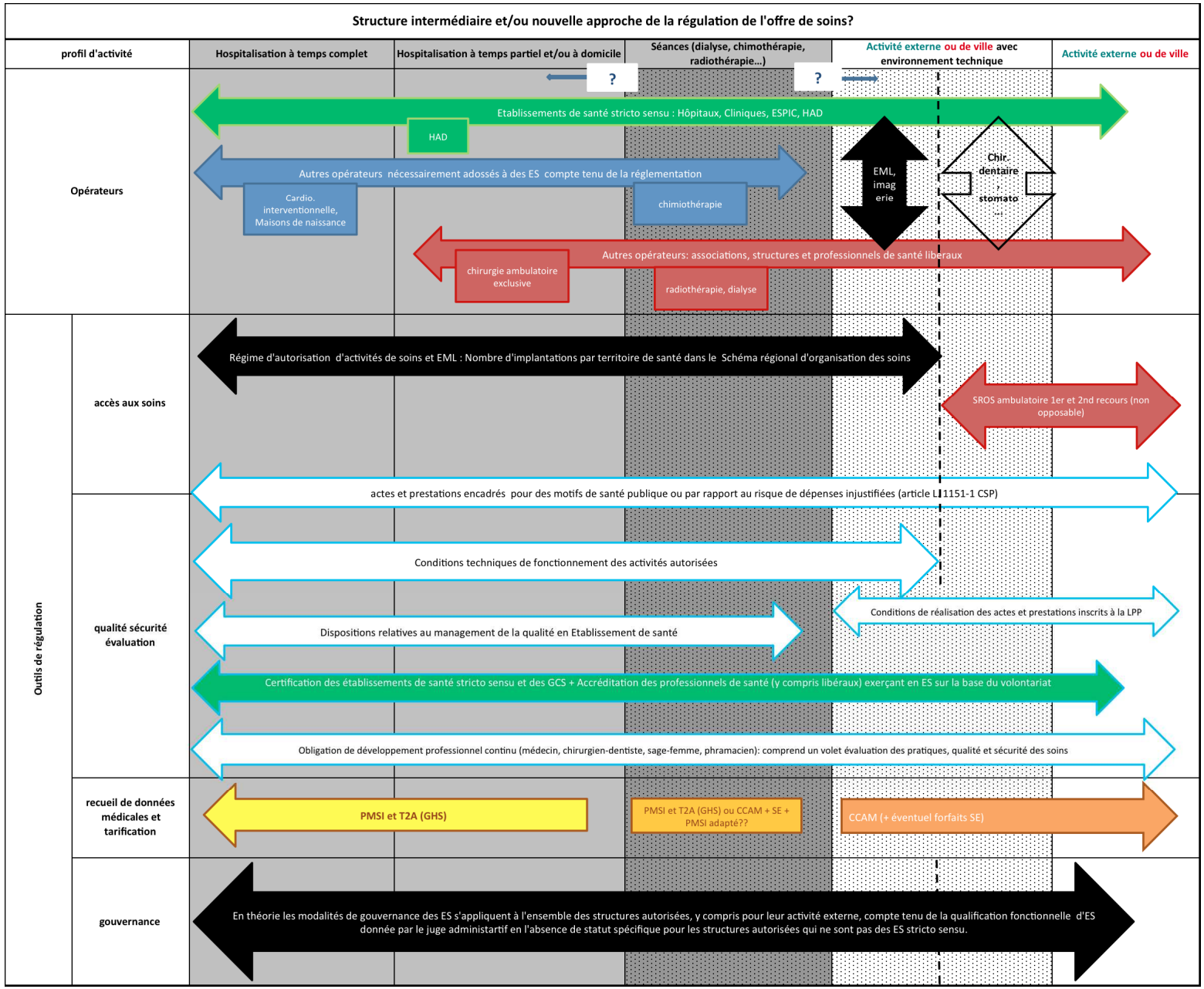
Appendix 3


Insuffisance Rénale Chronique Terminale (IRCT) 09/2011
Articulation des autorisations d'hémodialyse en centre avec les prises en charge hors centre
Type d'établissement (199)
Public (99)
Privé non lucratif (29)
Privé lucratif (71)
Nombre de modalités
1 modalité (74)
2 modalités (63)
3 modalités (33)
4 modalités (29)
Source : Ministère du Travail, de l'Emploi et de la Santé / DGOS R3 & USID 09/2011 - FINESS


Insuffisance Rénale Chronique Terminale (IRCT) 09/2011
Articulation des autorisations de prise en charge hors centre d'hémodialyse
Type d'établissement (38)
Public (5)
Privé non lucratif (15)
Privé lucratif (18)
Nombre de modalités
1 modalité (20)
2 modalités (13)
3 modalités (5)
Source : Ministère du Travail, de l'Emploi et de la Santé / DGOS R3 & USID 09/2011 - FINESS


Insuffisance Rénale Chronique Terminale (IRCT) 09/2011
Autorisations de dialyse avec surlignage HDC pour toutes les modalités
Type d'établissement (237)
Public (104)
Privé non lucratif (44)
Privé lucratif (89)
Nombre de modalités
1 modalité (94)
2 modalités (76)
3 modalités (38)
4 modalités (29)
hémodialyse en centre
Source : Ministère du Travail, de l'Emploi et de la Santé / DGOS R3 & USID 09/2011 - FINESS

Appendix 4


Structure intermédiaire et/ou nouvelle approche de la régulation de l'offre de soins?
profil d'activité
Hospitalisation à temps complet
Hospitalisation à temps partiel et/ou à domicile
Séances (dialyse, chimothérapie, radiothérapie…)
Activité externe ou de ville avec environnement technique
Activité externe ou de ville
?
?
Opérateurs
Etablissements de santé stricto sensu : Hôpitaux, Cliniques, ESPIC, HAD
HAD
Autres opérateurs nécessairement adossés à des ES compte tenu de la réglementation
Cardio. interventionnelle, Maisons de naissance
chimiothérapie
EML, imag erie
Chir. dentaire - stomato -
Autres opérateurs: associations, structures et professionnels de santé libéraux
chirurgie ambulatoire exclusive
radiothérapie, dialyse
Outils de régulation
accès aux soins
Régime d'autorisation d'activités de soins et EML : Nombre d'implantations par territoire de santé dans le Schéma régional d'organisation des soins
SROS ambulatoire 1er et 2nd recours (non opposable)
actes et prestations encadrés pour des motifs de santé publique ou par rapport au risque de dépenses injustifiées (article LI 1151-1 CSP)
qualité sécurité évaluation
Conditions techniques de fonctionnement des activités autorisées
Conditions de réalisation des actes et prestations inscrits à la LPP
Dispositions relatives au management de la qualité en Etablissement de santé
Certification des établissements de santé stricto sensu et des GCS + Accréditation des professionnels de santé (y compris libéraux) exerçant en ES sur la base du volontariat
Obligation de développement professionnel continu (médecin, chirurgien-dentiste, sage-femme, phramacien): comprend un volet évaluation des pratiques, qualité et sécurité des soins
recueil de données médicales et tarification
PMSI et T2A (GHS)
PMSI et T2A (GHS) ou CCAM + SE + PMSI adapté??
CCAM (+ éventuel forfaits SE)
gouvernance
En théorie les modalités de gouvernance des ES s'appliquent à l'ensemble des structures autorisées, y compris pour leur activité externe, compte tenu de la qualification fonctionnelle d'ES donnée par le juge administartif en l'absence de statut spécifique pour les structures autorisées qui ne sont pas des ES stricto sensu.

Appendix 5

BILAN des états des lieux et des diagnostics partagés en région pour l'IRCT		
DIALYSE		
1- Freins		Nombre d'ARS ayant renseigné l'item
1-1 Freins relevant du national		
Réglementaire	statut des soins DP en EHPAD	8
	statut des soins de DP en SSR	3
	obligation de la présence d'un médecin néphrologue dans les UDM pendant les séances	2
Tarifaire	tarification insuffisante de la DP: honoraires médicaux /HDC, avec sous estimation du temps médical de la DP et de ses coûts (consommables)	13
	pas de tarif pour les soins IDE de DP en EHPAD;	11
	pas de tarif pour les soins IDE de DP en SSR	5
	pas de tarif pour l'HDD quotidienne	3
	rémunération des IDEL pour l'HDD	2
	pas de tarif pour les soins IDE de DP en USLD	1
	forfait "D" pour le public inférieur au forfait"D" pour le privé pour les UDM	1
	pas de valorisation pour une expertise annuelle au CHU 1 fois/an (ne rentre plus dans la circulaire frontière pour les hospitalisations de courte durée)	1
Organisationnel	manque de recommandations nationales (référentiels de prise en charge pour efficience optimale)	1
Professionnels : démographie, formation/info des professionnels	insuffisance de formation à la DP et de "culture" DP pour certains néphrologues d'où une répartition des modalités avec sur réprésentation de l'HD: pb d'école	7
	absence d'information standardisée des patients concernant les modalités de dialyse	7
	absence de format pour la consultation d'annonce organisée pour les nouveaux patients en IRCT	6
	conflit d'intérêt des ambulanciers influençant négativement les patients pour des modalités à domicile	4
Public : info public ; ETP	déficit de postes post-internat pour les néphrologues	2
	absence de formalisation des transferts de tâches possibles entre PS (néphrologues et IDE notamment)	2
	programmes nationaux de prévention insuffisants	2
	critères de la loi HPST trop stricts pour les cahiers des charges de l'éducation thérapeutique	1

1-2 Freins relevant du régional		
Organisationnel	absence d'organisation par filières sur le territoire; répartition non harmonieuse de l'offre dans les territoires, fonction des typologies d'offreurs (PLet Pc en centre, associations gérant le hors centre), d'où déficit d'une modalité sur certains territoires (pas d'autoHD, pas de DP voire d'UDM par ex si pas d'asso)	10
	déficit de montée en charge des UDM(ouvertes/autorisées), en particulier, à distance d'un centre	9
	absence de réseau dédié à la prise en charge globale de l'IRC	4
	organisation insuffisante des replis des patients en DP, d'où désincitation à la DP	4
	pb de santé et/ou sociaux des patients limitant les dialyses au domicile: complexite de la prise en charge patients âgés dépendants et coM en DP; pb de précarité (domicile ne permettant pas de soins complexes à domicile)	4
	éparpillement de l'offre / aux besoins de permanence médicale	3
	inadéquation modalites/indications suite au choix des patients:refus des modalités au domicile, désir d'être dialysés en centre (proche du PS habituel)	2
	pb d'approvisionnement en consommables irrégulier (TOM)	1
	pas de partenariat organisé avec IDEL et structures	1
	non-conformité des strutures (d'où fermeture)	1
- Professionnels : démographie, formation/info des professionnels	démographie des néphrologues (peu nombreux et/ou âgés)	13
	absence/insuffisance de formation des IDE à la DP	9
	absence de postes post-internat pour les néphrologues	2
	démographie des IDEL faible sur la région	2
	fragilité des opérateurs urologues (création de KT de DP) et chirurgiens vasculaires (fistules A-V)	2
- Public : info public ; ETP	pas ou insuffisance d'ETP organisée	11
	pas d'info organisée dans le cadre des consultations	10
	dépistage et prévention insuffisants	8

2-Leviers		Nombre d'ARS ayant renseigné l'item
2-1 leviers relevant du national		
Réglementaire	statut soins DP en EHPAD à réformer paiement sur le risque	9
	statut des soins de DP en SSR	3
	statut des soins de DP en USLD	1
Tarifaire	tarif du hors centre plus incitatif, en particulier de la DP	12
	rémunération des néphrologues en DP à revoir	11
	rémunération des IDEL pour la DP (y compris en EHPAD)	11
Organisationnel	usage de la télémédecine (UDM, autoHD)	9
	coopération entre PS; transferts de tâches	6
	recommandations organisationnelles pour efficience optimale de la prise en charge	2
	monitorage de l'activité, via les indicateurs de pilotage	2
Professionnels : démographie, formation/info des professionnels	formation des IDEL à la DP	14
	formation des MG (études médicales) au dépistage de l'IRC et son suivi	6
	formation des néphro à la DP	6
	formalisation des transferts de tâches (néphro/IDE)	2
	incitations démographiques pour les zones déficitaires (néphrologues; IDEL)	1
Public : info public ; ETP	info patients en prédialyse	9
	ETP IRC	8
	Programmes nationaux de prévention	2

2-2 leviers relevant du régional		
	structuration des filières par territoires; travail en collaboration des unités de dialyse d'un territoire donné	8
	PRS prenant particulièrement en compte l'IRC et la nécessité de fédérer un réseau régional sur les problèmes vasculaires au sens large; inscription dans le SROS PRS de cette thématique (prevention, dépistage, PEC, suivi)	3
	création de consultations avancées	3
	analyse des pratiques avec les ES	3
	contractualisation des établissements avec engagements sur la mise en place des diverses modalités, via CPOM ARS/ES	2
	inscription de la télémédecine comme un des objectifs opérationnels du SROS PRS à l'horizon 2012, en particulier pour la PEC de l'IRCT	2
	création d'un parcours de soins du patient en IRCT coordonnant l'ensemble des acteurs, via DMP	2
	transport des patients: limitation des couts	2
	inscription dans le projet médical des établissements d'un volet prévention avec suivi des actions.	1
	fléchage de places en SSR et en EHPAD pour la DP	1
	engagement territorial des unités de dialyse pour une collaboration avec la médecine de ville et les structures médico-sociales	1
- Professionnels : démographie, formation/info des professionnels	formation IDEL à la DP	12
	info/formation des MG sur l'IRCT	5
	promotion des techniques innovantes (hémodialyse quotidienne, dialyseurs simplifiés...)	4
	renforcement de la coopération avec les autres professionnels de santé (cardiologues) pour optimiser les actions de prévention de l'IRCT	3
	création de postes post-internat pour les néphrologues	2
- Public : info public ; Education thérapeutique patient(ETP)	info formalisée de tous les patients sur l'ensemble des modalités de dialyse	13
	ETP	10
	amélioration du dépistage et de la prévention en région/réseaux de prévention ciblée	6
	création d'une plateforme d'information sur les maladies rénales	1

Greffe		
1- Freins		Nombre d'ARS ayant renseigné
1-1 Freins relevant du national		
Réglementaire	ND	0
Tarifaire	financement de l'activité sur donneur vivants insuffisant	2
	financement cœur arreté insuffisant	1
Organisationnel	activité de greffe suspendue pour pb d'organisation bloc, réa post op, d'où surmortalité	2
Professionnels : démographie, formation/info des professionnels	sensibilisation insuffisante des chirurgiens anesthésistes urgentistes, réanimateurs aux prélevements	3
Public : info public ; ETP	information insuffisante du public sur la greffe, greffe donneur vivant au niveau national	3

1-2 Freins relevant du régional		
Organisationnel	déficit IDE de coordination, d'où faible activité de prélèvements, donneurs vivants…	6
	manque de disponibilité des préleveurs et des greffeurs ou des blocs; temps médical et infirmier dédié à la greffe insuffisant	5
	défaut de recensement des sujets en état de mort encéphalique	5
	suivi de greffe non décentralisé ou absence d'organisation du suivi partagé (dossier, télémédecine…)	4
	déficit de néphrologues	4
	insuffisance de relais des campagnes sur le don, la greffe le donneur vivant	3
	pas d'activité ou activité faible donneur vivants	3
	pas ou peu d'activité sur cœur arrété	3
	règles d'attribution des greffons défavorables (région dépendante de 2 inter-régions greffe)	2
	déficit en lits de réanimation d'où baisse des possibilités de prélèvements	1
- Professionnels : démographie, formation/info des professionnels	déficit de néphrologues	5
- Public : info public ; ETP	insuffisance de relais des campagnes sur le don, la greffe le donneur vivant	3

2-Leviers		Nombre d'ARS ayant renseigné
2-1 leviers relevant du national		
Réglementaire	ND	0
Tarifaire	tarif machines à perfuser	2
	création d'un forfait pour le suivi à 1 an des greffés	2
	meilleur financement de l'activité greffe donneur vivant	1
Organisationnel	utilisation de la télémédecine pour le suivi de greffe, outils de suivi	4
	activité sur cœur arreté à développer, machines à perfuser	2
Professionnels :	info/sensibilisation des PS sur la greffe/prélèvement (réa)	2
Public : info public ; ETP	campagnes d'info gd public: greffe donneur vivant et prélèvement	3

2-1 leviers relevant du régional		
- Organisationnel	organisation des filières via des réseaux avec suivi partagé et organisé pour le suivi de greffe	6
	organisation des opérateurs greffe (disponibilité des blocs, chirurgiens…)	5
	meilleur recensement des donneurs potentiels auprès des hôpitaux préleveurs et non-préleveurs	4
	réseau tranversal greffe et suivi dialyse	4
	forte mobilisation du Chu autour de l'activité greffe et prélèvement	3
	réduction des délais d'inscription sur liste d'attente de greffe des patients; inscription sur liste de tous les patients éligibles	3
	organisation fédérative de la greffe et du prélèvement portée par le CHU	2
	développement de la greffe préemptive	2
	réduction des délais d'inscription sur liste d'attente de greffe des patients; inscription sur liste de tous les patients éligibles	3
- Professionnels :	sensibilisation des acteurs pouvant favoriser les prélèvements (réa, urgence…)	3
- Public : info public ; ETP	info patient et ETP pré et post greffe	2

LE HENANFF	Guillaume	22/11/2011

EHMBA

Class of 2010-2011

End-stage renal disease (ESRD)'s care: from belief in adapted market's tools to management of complexity

University partnership: ESCP Europe, LSE, Mailman School of Public Health

***Abstract*:**

Goals: Is it possible (and, if yes, how?) to improve the way in which End-Stage Renal Disease (ESRD) patients are being guided towards the various treatments available by applying a better pricing policy to these treatments? This is the starting point of this study whose purpose is to make operational recommendations on this particular issue.

Method: It relies on an international literature review, cost-effectiveness data and theoretical concepts relevant for this analysis. Those elements are then taken into account to assess the current French pricing-policy.

Results: There is an international scientific and societal consensus on the fact renal transplantation has the best cost-effectiveness to treat ESRD patients. The superiority of Peritoneal Dialysis versus Haemodialysis is much debated but to preserve patient Quality of Life, home and satellite care facilities should be promoted as much as possible, all the more as they cost less than in-Centre dialysis.
The various price mechanisms around the world do not play a major role contrary to the differential and level of prices. A better micro-economic understanding of dialysis facilities and nephrologist margins is needed to adapt accordingly the pricing policy. The promotion of a treatment through pricing-policy induces limitation of choice that raises ethical questions. Besides, while over-focusing on pricing tools, authorities may forget other key parameters to reach their goal, in an ever-changing field.

Conclusion: Thus, to improve ESRD patient orientation towards the most cost-effective treatments according to their respective health status, a more democratic, comprehensive, integrated and learning *collective action* should be implemented. The current ESRD risk management policy, feebacks of both the Regional Health Authorities and the Biomedicine Agency offer new opportunities to manage ESRD complexity.

***Key words*:**

End-Stage Renal Disease – Peritoneal Dialysis – Haemodialysis – Renal Transplantation – Home Care – Pricing-Policy – Cost-effectiveness – Cost-utility - Health Policy – Collective Action – Regulation – Risk Management - Innovation