### **CURRENT OPINION**



## How a Bottom-Up Multi-Stakeholder Initiative Helped Transform the Renal Replacement Therapy Landscape in Spain

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Abstract Healthcare reforms aim to change certain parts of the health system to improve quality of care, access, or financial sustainability. Traditionally, healthcare reform is understood as an action undertaken by a government at a national or local level. However, bottom-up changes can also lead to improvements in the health system. This paper describes the efforts of a coordinated multi-stakeholder advocacy group in Spain to promote a more cost-effective and patient-centred treatment for people receiving renal replacement therapy and assesses the outcomes of their advocacy for health system financing and patient satisfaction. It concludes that bottom-up initiatives do indeed have the power to change health policy and that policy makers should pay attention to their arguments.

Membership of GADDPE, the Spanish Group for Peritoneal Dialysis Development, is accessible in the acknowledgments section.

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### **Key Points for Decision Makers**

A multi-stakeholder group (GADDPE) was set up to initiate and sustain coordinated efforts targeting both policy makers and individual patients and providers to act upon the barriers that led to an unfavourable situation for home-based peritoneal dialysis (PD).

After 5 years, the use of PD has increased significantly throughout the country, as has patients' satisfaction with the information they receive, leading to potentially important savings to the Spanish social and healthcare system.

Raising awareness and gathering the right stakeholders to engage decision makers can be a viable option to initiate profound changes in healthcare provision.

#### 1 Introduction

The burden of chronic diseases, exacerbated by the ageing of European populations and the impact of unhealthy lifestyles, has become a huge threat to the sustainability of European health systems. Spain is no exception, and while many valuable efforts are being undertaken by Spanish regional governments to reduce the impact of chronic diseases on their healthcare systems [1–3], structural factors have made progress rather slow in some treatment areas. One such area is renal-replacement therapy (RRT), which is the most expensive of all chronic disease treatments [4]. Despite strong evidence of the benefits of peritoneal dialysis (PD) for patients and the healthcare system,

uptake of this treatment in Spain had been rather low over the previous 30 years [4]. However, the efforts of a coordinated multi-stakeholder group called GADDPE (acronym for Spanish Support Group for Peritoneal Dialysis Development) have been successful in recent years. We present the factors that contributed to reversing a situation that seemed set in stone only a few years ago and that can serve as a model in other treatment areas or for other countries.

## 2 A Strong Imbalance in Treatments Offered to Renal Patients

While renal transplantation is the treatment of choice in Spain because of its cost-effectiveness and lower mortality compared with alternative RRTs, clinical circumstances mean only a small proportion of patients are eligible [5]. Therefore, alternative therapies are offered, and haemodialysis (HD) has been by far the most widely used RRT in Spain in recent decades [4]. Indeed, unlike PD, HD is available to all patients [6], which has led to unequal access to different RRT therapies across the country.

The prevalence of patients receiving RRT has been growing steadily in Spain, at a rate of 17% between 2001 and 2009. As of 2011, there were 50,871 renal patients [7] (0.1% of the population) who consumed 2.5% of the Spanish healthcare budget [5] and 4% of the specialized care budget [6]. In 2012, there were 51,570 RRT patients [7] at a cost of  $\[ \epsilon \]$ 29,061 per patient per year [8]. A cost analysis carried out in 2010 [9] found that HD accounted for 73–77%, transplantation 17–21%, and PD 6% of the aggregate costs of the Spanish RRT program.

Most (90%) of patients receiving RRT start with HD, and half of these start with emergency treatment [10], usually requiring hospitalization, which incurs additional costs. For 90% of patients who start with HD, this technique becomes their chronic treatment [8].

However, evidence shows that home-based PD is associated with improved quality of life, including amongst older people [11, 12]. HD is 44% more costly than PD, even without accounting for the costs of hospitalization [4].

A 2010 study [13] estimated that increasing the use of PD to treat 30% of patients over 15 years would lead to savings of  $\epsilon$ 500 million and increase survival rates. A report from 2013 [8] further estimated that if 30% of patients receiving dialysis used PD, as in some EU countries, the savings in indirect costs (loss of productivity) related to morbidity would exceed  $\epsilon$ 13.5 million in Spain. Maintaining this percentage until 2020 would save an estimated  $\epsilon$ 21 million because PD allows patients to continue working (50 vs. 22% for HD) [4] and maintain an active lifestyle, which is important because 50% of the patients starting dialysis in Spain are of working age [8].

Finally, a cost-effectiveness analysis of the Spanish RRT program also showed that it would be most cost efficient to increase the number of incident patients using PD [14].

Despite evidence showing the benefits of PD, which can be carried out at home or at work—in contrast to HD, which usually takes place in specialized health centres—patients in Spain have not been routinely offered this option.

## 3 A Bottom-Up Effort to Change the Situation

The provision of PD in Spain was much lower than in some other European countries and varied greatly across Spanish regions, so the GADDPE working group was created in 2009 as a bottom-up attempt to remedy this imbalance. Its aim has been to promote understanding of PD in Spain by gathering a number of stakeholders together, including healthcare professionals, patient associations, and the dialysis industry. Their efforts provided a comprehensive picture of, and barriers to, the use of PD in Spain, and their actions have led to significant improvements in the provision of PD in the course of a few years.

In its 2010 White Paper, GADDPE highlighted that not all patients were able to access PD because of a lack of programs and deployment [6]. In addition, there were tremendous disparities between regions and even within certain districts. The use of PD was generally higher in areas that promoted renal transplantation. The use of homebased PD ranged from 4 to 30% of dialysis patients across Spanish regions [4].

However, since the White Paper was published and GADDPE began their concerted efforts, the number of incident dialysis patients selecting PD has undergone a relative increase of 33.5% from 12.7 to 16.9% over 6 years, reaching 20% in some regions (e.g., Asturias and the Basque Country) [15]. The figures for prevalent PD patients have consequently increased in relative number by 20.5% from 9.6 to 11.6%. Although there is still room for improvement, this shows that, despite a seemingly irreversible situation, the actions of a bottom-up initiative succeeded in helping transform care provision and had a positive impact for both patients and the healthcare system.

#### 4 Structural Barriers

GADDPE collected data, analysed various surveys of key stakeholders, and was able to identify a series of factors that appeared to be hindering the uptake of PD in Spain. The group then developed recommendations for various actors to tackle these factors [6].

The oversupply of HD facilities across the Spanish regions was well-established, and new hospitals were built with oversized HD capacities, which meant hospitals were able to offer HD to all patients. Thus, the incentive for change was small and choice of therapy was based on non-medical criteria related to care provision. This meant that previous attempts to incentivize the use of PD had failed [4, 6].

Another factor was the high percentage of patients with an unplanned RRT start. Despite evidence showing that non-programmed dialysis incurs worse health results as well as higher costs [16], a large number of patients in Spain were starting dialysis as an emergency [10]. When patients and clinicians can plan for RRT, more patients opt for PD (one in three vs. one in 20 for unplanned start patients) [6]. Conversely, PD is rarely selected as treatment for unplanned RRT. Starting RRT with emergency HD also seems to determine whether the patient continues with that technique, either by patient choice or because it is assumed the patient does not require any information to make a decision [8].

Additional hurdles identified by GADDPE included a lack of training for nurses and specialists and lack of appropriate knowledge about PD indications and contraindications. The formal training for nephrologists during their specialization only includes 2 months on PD but 7 months on HD [6]. On another level, nursing resources assigned to home-based PD are insufficient, particularly compared with those for HD [4]. The low awareness from healthcare authorities of all these issues has also influenced the uptake of PD in Spain.

The healthcare structure therefore largely contributed to making HD a treatment of choice for most providers, relegating PD to second choice used only when HD centres were at capacity. A national survey of hospital managers undertaken in 2009 by ALCER, the Spanish Renal Foundation, indicated they were aware of the benefits of PD but perceived organizational issues and a lack of support from specialists, trust in techniques, and skills to be barriers to its use. Nevertheless, nearly half of the respondents were in favour of implementing incentives for PD use, and an overwhelming majority thought the use of home-based PD would increase in coming years [6].

# 5 Gaps in Patient Information and Implementation of Informed Consent

The Spanish law on the autonomy of the patient dates back to 2002 and aims to guarantee informed consent to allow patients to fully take part in decision-making processes affecting their treatment [17]. Despite this, significant gaps were identified in its application in the area of RRT. In fact,

as of 2011 only four of the 17 Spanish regions had models of informed consent for RRT [4].

Both patients and patient associations reported a lack of information to enable informed decisions on RRT and insufficient knowledge about PD [10]. As a result, HD is often chosen because knowledge about PD as an alternative is lacking. According to a national patient survey from 2009, most patients with chronic kidney diseases (CKDs) did not have sufficient knowledge of PD, and older people had even poorer knowledge of the therapy [18]. Although the law states that patient consent should be collected in writing, this seldom happens, and informed consent reports are often too difficult for patients to understand and completed incorrectly. Specialists who provide such information often lack the time to inform patients properly.

## 6 GADDPE's Strategic Action and Achievements

Given the structural barriers described earlier and the gaps in patient information and informed consent, GADDPE focused their efforts on the following four strategic areas and achieved significant results [19]:

- Promoting decision making and informed treatment choice among patients
- Increasing awareness in healthcare authorities of the benefits of PD and encouraging policy initiatives to ensure equity in patient access to RRT modalities, leading to long-term sustainability of RRT
- Improving knowledge of PD among healthcare professionals
- Expanding communication channels to reach the general population and raise awareness about the value and benefits of PD.

## 6.1 Promoting Decision Making and Informed Treatment Choice Among Patients

To foster informed shared decision making among patients, educational processes were put in place for informed RRT choice with patient decision aids (PDAs) in most CKD units. According to The Ottawa Decision Support Framework, PDAs are tools that help people become involved in decision making by making explicit the decision that needs to be made, providing information about the options and outcomes, and by clarifying personal values; they are designed to complement rather than replace counselling from a health practitioner.

In Spain, the previously mentioned law 41/2002 regulates and allows for basic patient autonomy and rights and obligations with regard to clinical information and documentation (BOE 274, 15 November 2002). This law covers

**Table 1** Comparison of the worst-rated aspects of the educational process in the 2009 patients' survey (national) and 2015–2016 survey (GADDPE-led hospitals). Percentage of responses assessing each aspect as "inadequate or very inadequate"

	Dialysis option chosen by respondents	2009 National survey (%)	2015–2016 GADDPE survey (%)
Teaching materials	HD	60.2	14.7
	DP	83.3	1.7
Explanation of advantages and disadvantages	HD	32.3	8.8
	DP	76.7	1.7
Information on all options	HD	66.7	5.6
	DP	70.0	1.7
Detailed information for each option	HD	48.9	6.3
	DP	75.8	1.7
Time dedicated by clinician	HD	34.5	3.1
	DP	66.7	3.2
Clarity of explanations	HD	49.3	3.6
	DP	63.3	3.5
Predisposition of the specialist to inform	HD	38.0	4.1
	DP	57.2	0.0

GADDPE acronym for Spanish Support Group for Peritoneal Dialysis Development, HD haemodialysis, PD peritoneal dialysis

the rights of patients to receive information on and choose among therapeutic alternatives. However, given that a culture of shared decision making and guidelines on how to inform and educate patients on treatment choice were lacking, GADDPE made an effort to educate on the need to involve patients in RRT decision making as well as creating favourable opinions on this desired culture amongst healthcare professionals.

A group of clinicians, nurses, and representatives of ALCER (the major patient association in Spain) collaborated to develop PDAs and a formal structured education process that was then tested in real-life environments and progressively implemented in an increasing number of nephrology units. Patients' choices and the final RRT modality used were recorded during implementation of this process in 26 Spanish hospitals. Analysis of this registry showed a 50:50 split between patients choosing PD or HD plus an increase in preemptive transplantation choice. The use of PDAs, even with an unplanned start to RRT, achieved a high level of concordance between the chosen and final modality [20].

Unfortunately, the GADDPE initiatives have not improved the percentage of patients starting dialysis via emergency treatment; this has remained at 45.6%. However, although HD was still the starting option for most of the educated unplanned patients, their final method after recovering from the acute condition showed a more balanced dialysis distribution that was closer to that of the whole educated group [20].

In addition, informed consent has been made mandatory in Madrid and Andalusia.

A recent study surveying patient satisfaction with the educational process for RRT choice in 13 GADDPE-led hospitals and one dialysis clinic found significant improvement since the beginning of GADDPE's activities in 2009. For example, in 2009, a total of 32% of respondents felt the explanation they received about the advantages and disadvantages of HD was inadequate or very inadequate and 77% felt the same way about the explanation they received about PD [18]. After 6 years, these figures were 9 and 1.7%, respectively, in units with leaders who were members of GADDPE (GADDPE survey carried out in 2015 and 2016 on CKD patient satisfaction with the educational process for RRT choice; unpublished data. Participant hospitals are listed in the 'Acknowledgments' section of this paper.). Overall, patients surveyed in 2015 and 2016 were very satisfied with the education process for RRT choice, with an average score of 8.5 out of 10, and differences between patients who opted for PD and those who chose HD were minimal (unpublished data) (see Table 1). This is in line with the previously mentioned research showing that free choice, assisted by PDAs, leads to an equal distribution of those choosing PD versus HD [20].

## 6.2 Increasing Awareness Among Healthcare Authorities

Given that Spain is a highly regionalized country, some GADDPE members were appointed as regional spokespersons. Since the very beginning, comprehensive

campaigns were undertaken to engage healthcare policy makers from national and regional health authorities and hospital managers across Spain, with more than 70 face-toface meetings. One of the most important tools used for these discussions was the GADDPE White Paper, in which both the main barriers to PD use and the proposals to overcome them were discussed with the different authorities. Additionally, GADDPE members contacted the main political parties in most of the regions using the same rationale. This has led to key achievements such as the approval of proposals promoting equity in patient access to PD (in Madrid, Galicia, Extremadura, Aragon, Canary Islands, and Valencia), a motion from the Senate asking the government to take the necessary steps to promote PD usage for patients with renal insufficiency, the adoption of CKD strategic plans (Balearic Islands, Madrid, Canary Islands, and La Rioja), the inclusion of PD usage as quality indicators in hospitals (Balearic Islands, Valencia, and Castilla and Leon), plus a change in incentives to promote PD in Valencia by including PD indicators in management agreements of health professionals and hospital managers [21].

However, the lack of adequate staffing in CKD and PD units was identified as an important barrier to PD growth, and although some regions have assigned additional resources, the economic crisis has prevented PD units from being adequately staffed across the whole country.

## **6.3** Improving Knowledge of Peritoneal Dialysis Among Healthcare Professionals

Training programs for healthcare professionals about PD and communication skills useful in discussing treatment options with CKD patients have also been adopted as a result of GADDPE efforts (Balearic Islands, Valencia, Castilla and Leon Madrid, Aragon, Catalonia, and Canary Islands). The development of an official PD training program for nephrology fellows was an additional initiative fostered by GADDPE and has been conducted four times thus far.

Unfortunately, GADDPE has not yet been able to increase the length of hands-on PD training for nephrology trainees within hospitals. Nevertheless, the group continues to lobby the National Council of Medical Specialities. However, to raise awareness among health professionals, they developed a number of information leaflets, the PD White Paper and scientific articles were published, and presentations were given by GADDPE members at national and regional scientific and health economics-related congresses. Two national workshops were organized that brought together patients, healthcare authorities, and healthcare professionals.

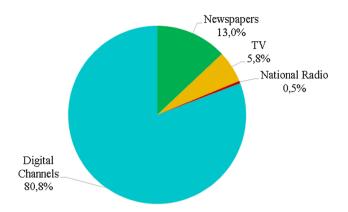


Fig. 1 Distribution of media impacts by channel 2009-2015

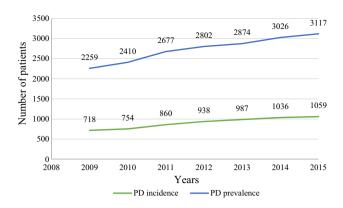
#### **6.4 Expanding Communication Channels**

Last but not least, 6 years of intense activity has resulted in 770 examples of media interaction (including major national daily newspapers, national radio and TV, specialized publications, and digital channels, among others), potentially reaching an audience of 64 million people [22] (see Fig. 1 for distribution of media impacts by channel).

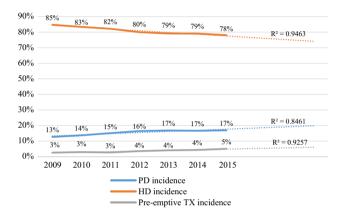
GADDPE has taken advantage of any single opportunity to foster PD awareness through the media, including publishing articles, after every annual registry presentation, patients' testimonies, World Kidney Days, publishing individual hospital outcomes, and so on.

The main claims disseminated by GADDPE to the general population focus on the cost effectiveness of PD, that PD offers greater autonomy and allows patients to maintain working activities, the right of patients to choose their treatments, and the results of implementing education processes, amongst others.

All these initiatives have led to a steady increase in the use of PD since 2009. As of 2015, the latest data available, there were 858 more PD prevalent patients than in 2009, representing a 38% increase. The absolute number of PD incident patients increased by 47.5% in the same period (see Figs. 2 and 3), with the national percentage of incident patients on PD at 17% in 2015 [7]. In GADDPE-led units surveyed in 2015–2016, those engaging in comprehensive patient education have an incident PD proportion of 35% (GADDPE, Survey on CKD patient satisfaction with the educational process for RRT choice; carried out in 2015 and 2016; unpublished data. Participant hospitals are listed in the 'Acknowledgments' section of this paper). This suggests that bottom-up collaborative multi-stakeholder initiatives such as GADDPE can have an important impact on health policy, both from above (by advocating with policy makers and achieving legislative changes) and from below (by educating the choices of individual patients, treating physicians, and provider units).



**Fig. 2** Evolution of peritoneal dialysis incidence and prevalence in number of patients in Spain 2009–2015. *PD* peritoneal dialysis



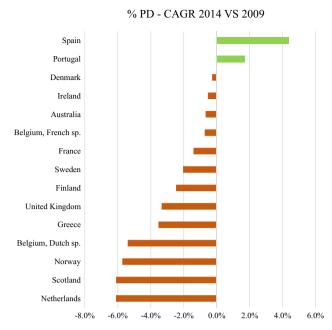
**Fig. 3** Comparative evolution of renal-replacement therapy choices incidence in Spain 2009–2015. *HD* haemodialysis, *PD* peritoneal dialysis, *TX* transplantation

A comparison with neighbouring countries during this period provides perspective on the evolution of PD penetration in Spain. Data from the 'international comparisons' in the 2016 US Renal Data System (USRDS) report [23] indicate that Spain has the highest growth in the European countries of PD prevalent dialysis patients (see Fig. 4).

## 7 The Most Important Learning Moments

The new element in this initiative was that the movement started with patients and healthcare professionals rather than policy makers, which is more usual and socially expected.

The different stakeholders within GADDPE, adding their efforts in a bottom-up initiative, created the momentum to promote a shift towards increased informed patient decision making about RRT choices and cost-effective delivery of RRT.



**Fig. 4** Comparison of the 5-year compound annual growth rate (CAGR) of the percentage of peritoneal dialysis (PD) use in prevalent dialysis patients in the European Countries (2009–2014). Data extracted from the 'international comparisons' section of the 2016 US Renal Data System report

### 8 GADDPE's Future Perspectives

PD is not yet completely established in Spain, and although the use of PD has been increasing since 2009, much of the change involved the modification of processes and behaviours, requiring actions that would overcome inertia. Therefore, GADDPE aims to continue working in the following areas:

- Disseminating knowledge about PD amongst healthcare professionals, patients, authorities, and the general population
- Improving training on PD for professionals
- Leveraging shared decision-making processes at nephrology units to guarantee patients' free choice and implementing mandatory informed consent for RRT choices
- Continuing to emphasize the positive effects of PD, specifically that patients are able to carry on working and thus reducing the risk of poverty and social exclusion
- Increasing the awareness of healthcare professionals and authorities to foster dialysis planning, favouring the selection of more efficient treatment sequences by considering patient care as a continuum.

Finally, GADDPE's aspiration is to continue focusing the energy and enthusiasm of all its members to ensure patients have access to shared decision making as well as the long-term sustainability of RRT in Spain through PD development.

### 9 Conclusions

The Spanish healthcare system, with its oversized HD capacity and lack of dialysis planning, combined with a lack of awareness of the benefits of PD among both healthcare professionals and patients, required action to correct an imbalance in RRT offerings that may negatively affect patients' health outcomes and healthcare costs. Waiting for healthcare reform was unlikely to bring benefits in the short to medium term, so a multi-stakeholder group (GADDPE) was set up to initiate and sustain coordinated efforts to act upon the barriers that led to this unfavourable situation. Its activities targeted both policy makers and individual patients and providers. After 5 years, the use of PD has increased significantly throughout the country, and more so in hospitals whose leaders are members of GADDPE. Patients in these units are now more satisfied with the information they receive than patients were before GADDPE's activities began, and a significant number of informed patients choose PD over HD, leading to potentially important savings to the Spanish social and healthcare systems. This shows that raising awareness and gathering the right stakeholders to engage decision makers can be a viable option to initiate profound changes in healthcare provision.

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List of hospitals that participated in the patient satisfaction survey: Complejo Asistencial Universitario de León; Complexo Hospitalario Universitario A Coruña; Hospital Comarcal de Inca; Hospital Infanta Sofía; Hospital General de Segovia; Hospital General Universitario Gregorio Marañón; Hospital Quirón San Camilo; Hospital San Pedro de Alcántara; Hospital San Rafael de A Coruña; Hospital Universitario Clínico San Carlos; Hospital Universitario de la Paz; Hospital Universitario de la Princesa; Hospital Universitario Ramón y Cajal; Centro de Diálisis Madrid El Pilar.

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