

medical researchers need in order to carry out clinical trials, whether independent or commercial.

Lastly, I would like to touch on the topic of how to obtain resources in order to carry out research. First, we must take into account that research is an investment that costs money. Review or clinical case research is no exception; it also carries a cost. Dr. Praga will agree with me that his and his co-workers' time has a price; data has to be collected, data bases created and filled in, etc. Resources for research are certainly insufficient, but we must ask for them, without becoming discouraged, in order to have the possibility of receiving them, whether from public entities, scientific societies, or even from private companies, as Dr. Praga mentions so rightly. Once the research has been completed, publication is not always the most important step. This is still, perhaps, one of the weakest points of research in Spain: the issuing of patents and the subsequent commercial exploitation of results.

In my humble opinion, nephrologists such as Dr. Praga, who have made important contributions to the understanding and treatment of kidney diseases, and who are and have been references for most of us - and furthermore, who are currently heading Nephrology Departments - should not allow themselves to become discouraged. Rather, the focus should be on analysing the causes of Spanish nephrology's lack of international leadership.

- Praga M. ¿Se está apoyando la investigación clínica independiente en España? *Nefrología* 2009;28(6):575-82.

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Response to comments on the editorial "Independent Clinical Research in Spain"

Nefrología 2009;29(3):271-272.

Dear Editor:

I would like to thank Drs. Lamas, Rodríguez-Puyol and Cruzado for their comments on my editorial.¹⁻³ Is independent clinical research being supported in Spain?⁴ As I mentioned, it was not my intention to do an in-depth study of hospital research in our country, which would be an undertaking quite beyond my capabilities and available time, but rather, to describe the personal experience of a hospital researcher with many years dedicated to the task. I would like to stress that I am surprised by the wide-ranging response provoked by my letter: I have received numerous e-mails from doctors who felt they saw themselves reflected in the editorial and declared that they share the same opinion. On the other hand, a significant percentage of the messages came from doctors outside the practice of nephrology, which shows that our magazine has a wider distribution than we had thought.

Drs. Lamas, Rodríguez-Puyol and Cruzado raise well-deserved points about my letter, and I essentially agree with them. The three authors have all made a career of high-quality research and divulgation of the needs for research and rigour in scientific evaluation, and their opinions are always valuable and represent the highest authority in the sphere of research. However, some of their statements require amendment in turn. The letters by Rodríguez-Puyol and Cruzado stress the effort that Spanish government agencies have put into supporting hospital research. I agree with this point, which I also noted in the editorial. Likewise, today we have financial resources that would have been unthinkable not so long ago. But our need for the provided institutional

support to be effectively reflected in the improvement of the real conditions under which we do research in hospitals is made all the more categorical by these undeniable advances. That is, giving money (which is of course very important) to clinical projects and evaluating research is not enough; rather, mechanisms must be created that would permit clinical projects to be developed and concluded without meaning an excessive effort for doctors. In the editorial, I referred to the huge difference between participating in a clinical treatment study propelled by the industry, in which everything is served on a plate and one can even earn money, and the growing mountain of bureaucratic difficulties that an independent researcher, who receives an official compensation, must face if he or she wishes to finish well. We merely have to count the number of completely independent clinical treatment studies that have been carried out in Spain without the participation of the pharmaceutical industry. As I mentioned in the editorial, in a country such as Spain, which has very complex requirements for authorising a clinical trial, we need official bodies that would do what CROs do to develop studies of the industry and relieve the researcher of a bureaucratic process which at present is nearly unavoidable.

But there are more topics, and therein lies my criticism: I think that very few experienced doctors will deny that the role of the Medical Management in Spanish hospitals has been progressively deteriorating (although there are of course praiseworthy exceptions to this tendency), with the introduction of operating diagrams (clinical management which is neither clinical nor proper management, "quality" departments which have nothing to do with the quality which we can value and recognise, etc.) which grow more autistic and lacking in scientific or moral authority every

day. This is a main topic, which deserves all of our thoughts. In this context, attempting to develop a quality clinical study can be a heroic task. I also commented that in many hospitals, we now have the ideal tools for supporting research, such as research institutes and foundations, but it is necessary to instil in them the spirit of intellectual curiosity that is the basis of research. On this topic, it is necessary that doctors struggle in order for those bodies to truly be effective at facilitating and promoting quality investigation, and for them to not be contaminated by the unfortunate schemas that are so common in hospital management. I know that there are still hospital research foundations that develop a model activity by diagnosing problems within the centre and providing real assistance to research groups. And these foundations and institutes should also serve to fuse basic and clinical research: both Rodríguez-Puyol and Cruzado insist on the need for including both types of research together. I agree completely, and I believe that nowhere in my editorial did I state the contrary. But we must take into account, as I stated above, the particular problems that prospective clinical treatment trials suffer from, which require a specific solution.

And lastly, referring to the dejection that my friend José María Cruzado detects in me, this is not the case; the fact that I launch diatribes like this editorial is proof to the contrary. Nevertheless, although the situation is somewhat better than it was a few years ago, we must go on fighting. Furthermore, as I stated in the editorial, one of the purposes of the same was to stimulate debate on hospital research. I feel that my letter has indeed sparked debate, and therefore, I am satisfied.

1. Lamas S. Investigación y proyectos: algunas matizaciones. *Nefrología* 2009;29(2):79-80.
2. Rodríguez Puyol D. Carta sobre la investigación clínica independiente en España. *Nefrología* 2009;29(2):80-1.

3. Cruzado JM. Investigación Clínica Independiente en España *Nefrología* 2009;29(2).
4. Praga M. ¿Se está apoyando la investigación clínica independiente en España? *Nefrología* 2009;28(6):575-82.

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Comment on "a discussion on quality"

Nefrología 2009;29(3):272-273.

Dear Editor:

In a recent letter titled "A discussion on quality"¹ the author states that "in order to demonstrate the virtues of the quality indicators, some of the articles use very weak baseline data".^{2,3} We feel that this hypothesis could easily be refuted with objective data. We will compare variables from the clinical results of the observational study titled *Dialysis Outcomes and Practice Pattern Study* (DOPPS),⁴ which included 575 patients from 20 different centres in Spain, with the baseline results of our study (313 patients from four centres)²: mean haemoglobin 10.8 vs. 11.7 ± 1.4g/dl, phosphorus 5.5 vs. 5.3 ± 1.6mg/dl, Kt/Vsp 1.31 vs. 1.37 ± 0.29, ferritin 288 vs. 370 ± 290mg/ml and percentage of autologous arteriovenous fistulas 81 vs. 79.9 (DOPPS vs. our own study)² (the standard deviation for the DOPPS study is not mentioned because it does not appear in the publication). After seeing the results from both studies, we can state that variables from the clinical results of the DOPPS study could be considered worse than, or at best similar to, those presented by the patients in our study. The conclusion that we reach is not

different when we analyse the European population (excluding Spain), which is also represented in the DOPPS study. The comparison with the study carried out by Plantinga et al. is more complex due to the form in which the results are expressed, but in general, although these results are worse than the Spanish and European results, they are similar to those from the rest of the population of the United States. Comparisons of variables from clinical results in centres should be carried out with representative samples from the general population, and not with samples representing select centres. The author does not mention what studies the cited studies are compared with. As Fink et al. describe, the variability of results from centre to centre is well-demonstrated (they call this phenomenon the "centre effect").⁵ We heartily agree with the other statements expressed in the letter. Meanwhile, we confirm the limitations of our study (which were not mentioned by the writer of the letter) which were listed in the original publication.

1. Pons R. Una reflexión sobre calidad. *Nefrología* 2009;29(1):81-2.
2. Parra E, Ramos R, Betriu A, Paniagua J, Belart M, Martínez T. Effect of a quality improvement strategy on several haemodialysis outcomes. *Nephrol Dial Transplant* 2008;23(9):2943-7.
3. Plantinga LC, Jaar BG, Fink NE, et al. Frequency of patient-physician contact in chronic kidney disease care and achievement of clinical performance targets. *Int J Qual Health Care* 2005;17:115-21.
4. Cruz JM, Piera L, Bragg-Gresham L, Feldman H, Port FK. Resultados del estudio internacional de hemodiálisis DOPPS en Europa y España. *Nefrología* 2003;28(5):437-43.
5. Fink JC, Zhan M, Blahut SA, Soucie M, McClellan WM. Measuring the efficacy of a quality improvement program in dialysis adequacy with changes in center effects. *J Am Soc Nephrol* 2002;13:2338-44.