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A) COMMENTS ON PUBLISHED ARTICLES

Independent Clinical Research in Spain

Nefrología 2009;29**(3)**:270-271.

Dear Editor:

It was with great interest that I read Dr. Manuel Praga's editorial on clinical research in Spain.[1] Firstly, I would like to comment that it is undeniable that Dr. Praga is a great researcher in the field of Nephrology, whether or not he has received financing for his projects. His research works have undoubtedly contributed to improving knowledge about physiopathology and the treatment of kidney diseases. However, probably due to the intense admiration that I feel for Dr. Praga, his heartfelt editorial made me somewhat uncomfortable. In fact, it transmits a certain sense of neglect and even discouragement after years dedicated to the study of nephrology in a university hospital.

The Spanish health system, as far as medical personnel are concerned (at least in university hospitals) is based on high staff numbers with low individual salaries which reflect the standard required of professionals. Such as it is, this model works well, at least on the level of providing health care, and that is why it is still in force with the collusion of medical associations and unions. Perhaps in the last few years this model fails more than usual due to the fact that salary differences between doctors with temporary contracts and full staff members have grown larger. This phenomenon produces two enormously negative effects: first, it discourages future leaders in the medical services and it ingrains, even more if possible, some lax attitudes among certain senior doctors, who fortunately are few. Furthermore, there are no differences in salary whether you work in a provincial hospital or with complex pathologies in a university hospital (in which in order to become a staff physician, you must spend several years in the purgatory of traineeships or disposable contracts once you have finished with your specialty). A troubling consequence resulting from the above is that a growing number of brilliant residents choose to undergo their specialist training in small hospitals.

The reality is that this situation, which has been described and permitted by all for years, has led to co-existence within the medical services of university hospitals with a wide range of professional profiles. At this point, I would like to debunk a fallacy which I consider to be one of the most toxic to our health care system: the doctor who does research provides no assistance, or at least less assistance than a doctor who does not do research. Wrong, wrong, wrong. The situation is actually the opposite: the doctor who does research in a Spanish public hospital tends to provide more assistance than the doctor who does not. For that reason, we must applaud such initiatives as the *Programa de Incentivación de la Actividad Investigadora* (Research Activity Incentive Programme). I am certain that future will order things as they should be, but in the meantime we must persuade hospital directors that in order to provide good assistance we must carry out good research. This will require recognition of research activity as a merit and a *sine qua non* condition for advancing one's professional career. Also, the policies for hiring and assigning positions (beginning with the Chief of Medicine) in university hospitals must take into account candidates' research potential. In short, quality assistance can and must always be provided, in any hospital. However, a university hospital must also generate knowledge (which in the end is capital), and to do so we must carry out research.

Participation in commercial clinical trials is necessary. However, not all of these clinical trials are the same. Some exist for strictly commercial reasons and to create customer loyalty. But there are also phase II-III trials or registry trials. These are not as easy to obtain, because they require leadership. Participation in these trials must be one of our objectives. In the first place, they are an excellent source of resources for our institution. Secondly, they can help us to finance our own research structures. And lastly, participation in this type of trial leads to the improvement of our daily clinical practice. Then there is independent clinical research, which was recently subjected to regulation to avoid hidden clinical research or studies with ethical problems. Although I understand Dr. Praga's comments on this topic, I feel that we should recognise the effort made by our health authorities to encourage independent clinical research. Firstly, through the calls for independent clinical research projects, where the application process is genuinely simple and where we can list financial budget items for all of those factors that worry Dr. Praga: insurance, data collection notebook, monitoring, medication under study, etc. Secondly, and more importantly, by creating transversal research structures, such as the CAIBER consortiums, that specifically lend resources to hospitals where research is done on all aspects

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"

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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