

A) COMMENTS ON PUBLISHED ARTICLES

Research and projects: some clarification

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Dear Editor,

I have greatly enjoyed reading Dr. Praga's editorial regarding independent clinical research.¹ Aside from being written with clarity and grace, it includes a serious analysis of the multiple ailments that the "independent" clinical researcher suffers from in our country. Although I have been away from the hospital environment for some time now,² I have not stopped appreciating and admiring the service, teaching and research activities that are carried out daily in Spanish hospitals. However, some of the affirmations/reflections found in the editorial have provoked me into sharing my comments. First of all, I believe that Dr. Praga effectively demonstrates that the brilliant clinical research in our country is not efficiently supported thus not providing a trajectory of successful projects. Without a doubt, I agree with him that the achievement of good scientific research *per se* without good publications is poor evaluation criteria

The problem, however, does not reside in "glorifying" the project but in correctly evaluating its development and final results. In Spain, evaluation is frequently carried out «*ex ante*»; that is, in the moment that a new project is applied for, and, in theory, a good part of its viability depends on the curricular trajectory of the applicant. Thus, if Dr. Praga applied for funding from an agency with sound evaluation systems, he would have a good chance of obtaining it. On the other hand, the evaluation should also be carried out «*ex post*», a trend that is progressively being incorporated into certain funding agencies. An additional perversion derives from the argument proposed in

the editorial: the conceptual separation between research and project. Research projects in hospitals (basic or clinical) should serve to make the intellectual life of the departments more dynamic and integrate different areas of the hospital, besides financing the personnel and materials to carry out the projects. Therefore, projects should always be carried out, as clearly defined by the editor, with rigorous follow-up and evaluation of the results. A second aspect that I would like to emphasise is the permanent divorce between clinical and basic research, a loss that would be significantly reduced not only if the basic researchers in the hospitals were to consider the clinical researchers, but also if the clinical researchers, reasonably motivated, dedicated time and effort to get close to the laboratory. This leads me to comment on his thoughts concerning the programme to intensify research proposed by the Carlos III Health Institute (ISCIII). Although my laboratory has been funded only on rare occasions by this organization, and thus I can speak with certain independence, it is only fair to recognize its effort in the last few years to carry out rigorous evaluations and to try to improve the research environment in hospitals. The "protected time" initiative for clinicians with research interest is not copied from basic research but is inspired by the American system where hospitals with this profile are partially or totally freed from their health-care responsibilities in order to focus on the development of their projects. This initiative, although still needing much improvement according to that proposed by Dr. Praga, implies that the system is, at least, taking it into account.

However, the true revolution will not arrive until the curricular researcher does not suppose an implicit commercial benefit. As Dr. Praga notes, the assessment of the professional development of hospitals in the public

sector system of many Autonomous Communities suffers from obsolete criteria whatever the perspective. Returning to the subject of independent clinical research, there is no doubt that case-by-case review and meta-analysis are powerful tools for good clinical research. However, they do not allow for the establishment of causal evidence in the majority of cases and thus it is necessary to resort to clinical trials with intervention phases and other approximations. The same thing happens in the laboratory and, basically, at the back of function loss or gain strategies, only an asymptotic approximation to the truth is obtained. That said, this independent clinical research is not only praiseworthy but necessary to allow, among other things, the consideration of more ambitious projects than those with which it should be a part. We will not forget the primary consideration of research is that, like medicine, it should be of good quality regardless of being basic or clinical.

As an example, I would like to point out the minimum advances in the treatment of glomerular diseases during the last 30 years and, moreover, it is likely that the future will come from the knowledge of an abstruse and complex pathway discovered in a fly, the Notch pathway.³ I wonder how many Spanish nephrologists know about and think about this pathway. The same nephrologists who within 10 years will present communications about the drugs based on its regulation. Would it not be interesting if some of them started right now to integrate it in the realm of their worries and if they would actively participate in the understanding of their role in glomerular pathology? I will conclude with a comment for my much appreciated and admired clinical researcher. A hundred and fifty years ago, Darwin put the human species where it belonged, and at the speed at which we are living, it does not seem

that his moral genome has reached such high evolutionary levels. Dr. Praga says that “research is carried out for the love of truth... for our profession and for our patients”. Beyond getting into an irresolvable discussion about the existence or not of authentic altruism, there is little real motivation for our species beyond glory, power, sex and money. Although I am willing to get excited about the possibility that Dr. Praga forms an exception, it would be a good thing if the scientific policy managers would take into account these ideas and, above all, the proposals of the editorial, to slowly transform the reality of research in the majority of Spanish hospitals.

1. Praga M. ¿Se está apoyando la investigación clínica independiente en España?. *Nefrología* 2009;28 (6):575-82.
2. Lamas S. Los nefrólogos que elegimos en el laboratorio. *Nefrología* 2002;22:106-7.
3. Niranjana T, Bielez B, Gruenwald A, Ponda MP, Kopp JB, Thomas DB, et al. The Notch pathway in podocytes plays a role in the development of glomerular disease. *Nat Med* 2008;14:290-8.

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A paper on independent clinical research in Spain

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Dear Editor,

I have read Dr. Manuel Praga's¹ Terente's article about independent clinical research in Spain with great respect and admiration. I share many of his ideas, especially when he claims that quality research in hospitals will not be possible until there is real material recognition

rather than mere moral support of the activity carried out. Unfortunately, the politically influenced persons who make the decisions regarding the management of personnel in the hospital environment systematically forget this premise, making the development of any type of quality research in this area very difficult.

Nonetheless, in spite of my respect and admiration for Dr. Praga, I would like to put a different point of view, not necessarily to the contrary of his about some of the topics that he covers. In particular, I would like to make a few brief references about the evaluation process, the role of Official Agencies concerning Clinical Research and the systematically evoked dichotomy between clinical and basic research.

The evaluation of a research project is a complex process. In general, it is based on a combined analysis of the scientific quality of the applicant group and of the project. At the same time, the research groups are usually evaluated with mixed criteria, depending on their capacity to obtain competitive funding and on their level of scientific productivity. It is true, as Dr. Praga notes, that certain programmes, or certain assessors, attribute excessive relative importance to some of these areas, creating a biased evaluation. The examples given make reference to highly productive groups without competitive funding and to groups with great amounts of competitive funding and low productivity that can be evaluated as “bad” and “good” respectively in some of these evaluation processes. Although it is true that this happens at times, the managers of the evaluation process as well as the very assessors themselves are absolutely convinced that a quality research group is defined by a reasonable balance between planning capacity, including obtaining resources, and scientific productivity. This is what normally happens bearing in mind that there are always exceptions. Although in reality, in the last few years, groups with abundant funding and little scientific production are evaluated, almost automatically, in a negative

manner, while those with high scientific productivity, although they have no funding, are usually evaluated in a positive manner.

I would like to note here that as pointed out in the last cited hypothetical figure: it is the groups with high scientific productivity without funding in the hospital setting. It is true that these groups exist, as Dr. Praga clearly is aware but it is also completely true that they are an exception. Some of these groups have even been systematically funded by private companies with commercial interests leading to a scientific productivity that is not always based on their own ideas.

While even considering this possibility, there are still certain totally independent research groups of high quality, without funding, in the hospital setting. These groups, with an effort and dedication, could have obtained economic support from the Public Research Agencies which would have helped their research efforts.

The Public Agencies that evaluate and fund research have made huge efforts in the last few years to give proper attention to clinical research in the hospital setting. Three examples are enough. The ANEP, the Spanish *Agencia Nacional de Evaluación y Prospectiva* has remodelled its evaluation areas, creating a specific area of Clinical Medicine where not only the Coordinator but also the workers are hospital doctors. The Carlos III Health Institute, in its general project funding programme, includes a specific area of Epidemiology and an area of the Evaluation of Health-related Technologies in order to foster specific hospital research of a strong clinical character.

These areas, which group together a large number of projects are as successful as others in obtaining funding, are funded with success rates that are similar to others.

Finally, many research projects allow for the inclusion of atypical funding concepts which are very different from the classic