Ethics in research: the black sheep

In this editorial I shall touch on some aspects which are often perceived as potential sources of bias when interpreting the outcome of clinical research: the relationships between researchers, sponsors and the presentation of the clinical results.

When conducting clinical research most of the parties involved have as a main objective to prove that the techniques or the product under evaluation possibly works better than the others. The correct approach would be to investigate whether a new technique or product works as good as, better or worse than others reputed to work well in a specific application. The difference, which looks subtle, is actually fundamental since it predisposes the mental approach of the investigators.

Let's hypothesise some different scenarios: *Scenario 1* is dealing with a completely independent study aimed at showing that a new technique is effective in a certain application. The researchers are convinced that their unique technique is the best to solve a specific clinical problem. Even if the correct study design is used (unfortunately still uncommon), I often read conclusions not reflecting the actual results of the studies. These articles are not commonly encountered in *EJOI*, but this is because *EJOI* Editors try to put a filter of objectivity to these over-enthusiastic studies. The final outcome of the manuscript (whether it is accepted or not in *EJOI*) depends on the authors' personality: some understand the issue and are grateful for it, some accept the corrections in order to have the study published, whereas some become literally furious, writing vehement letters explaining how excellent they are as researchers and how good their technique is and usually end up withdrawing the submitted manuscript.

Scenario 2: A manufacturer wishes to evaluate a new product, being strongly convinced that the product is useful and effective. How to prove this to a large audience? One way is by conducting clinical research. Often an 'influential' researcher is approached to do some clinical research. Now the issue starts to become more complicated. For instance the more 'influential' the researcher, the more research could cost. Another problem is that a few researchers make clear at the start that the more money there is invested, the better the product will work. Other issues then come into play. For instance, what is to be done if the new product is working as good as or even less so than the control therapy? What will happen regarding possible future funding if the sponsoring entity is not very pleased with the outcome of the research? In other words, who owns and manages the data? And who decides to publish or **not** to publish these data?

Scenario 3: A serious manufacturer wishes to know whether the newly developed product is suitable to be launched on the market and is performing as good or even better than the currently available product. *In vitro* and animal studies were very promising. A serious and truly independent research group is committed to perform the clinical research and it is agreed beforehand that results will be published independently from the outcome of the trial which will be designed and conducted according the current best methodological standards.

We all should know the correct way to proceed: we should always use the best study design with the most meaningful outcome measures, assessed, whenever possible, by truly blinded outcome assessors, without excluding failures and complications under the 'etiquette' of protocol deviations. We should be aware and honest when considering the limits of our study and we should **always** publish the results independently from the outcome of the study. Fantastic, but does this happen only in 'Wonderland'? It should

not, it should be an ethical rule jointly adopted by all parties involved.

EJOI wishes to be a 'Wonderland' in this sense. We try our best to be objective, to push authors to be objective in their articles; we are ready to correct and to learn from our mistakes and we shall publish whatever is reliable without hiding 'inconvenient' results since some poor patients may risk to receive some 'inconvenient' therapies because the truth was not published. Now it can also happen that some sponsors, who committed to a clinical trial saying that they were genuinely keen to know about the real effectiveness of their product, may be disappointed by the preliminary clinical results of their products and suddenly decide not to honour the financial agreements with the researchers (for instance see the trial published in the previous issue of *EJOI* on the adjunctive use of light-activated [LAD] therapy in the treatment of peri-implantitis). This can happen of course and it is part of the game but it should also be made known so readers can better judge whether it is the better option to treat patients for instance using a LAD therapy device like FotoSan or not. Unfortunately, the largest trial ever published on the adjunctive use of LAD therapy failed to show any effectiveness of this treatment modality. Now what should the investigators do in such an unpleasant but possible situation? Publish or not to publish? They must publish of course even though this would cost them their own salary, but it will preserve their own integrity, which is a highly valuable feature in most of the professions and in particular in those dealing with patient health.

What is the moral of the story then? The moral is that research can be done in many different ways. It is unavoidable that mistakes will occur, but if we really want to know how things are we should keep our integrity. All of us (editors, researchers, sponsors and readers) must always try to do our utmost, being humble, open-minded and moreover resisting evil temptations that can corrupt the entire process. We could live in Heaven if all of us do the right things, the choice is entirely ours.

Happy critical reading in Wonderland
Marco