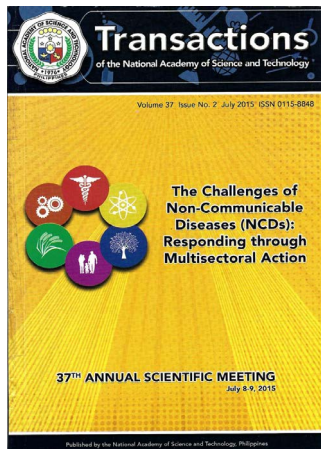


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The Role of Stem Cell Therapy in the Treatment of Non-Communicable Diseases

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THE ROLE OF STEM CELL THERAPY IN THE TREATMENT OF NON-COMMUNICABLE DISEASES

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Introduction to stem cells: What are they, and how do they work?

A stem cell is an undifferentiated cell of a multicellular organism that is capable of giving rise to indefinitely more cells of the same type, and from which certain other kinds of cells arise by differentiation. The human body is made up of organ systems defined by specific functions—for example we have the digestive system which functions to get nourishment from food and excrete unneeded waste. The circulatory system makes up the highways of blood vessels throughout the body distributing the nourishment from the gastrointestinal system. Oxygen from the pulmonary system also travel to different tissues via the blood vessels. These specialized organ systems have specialized cells which have undergone differentiation in order to do their job. Before becoming differentiated, these cells were undifferentiated and were called stem cells. Even as adults, we all have what is called “stem cell niches” throughout our body, with cells capable of dividing and under proper stimulation, differentiate into specialized tissues.

Adult stem cells have been identified in many organs and tissues, including brain, bone marrow, peripheral blood, blood vessels, skeletal muscle, skin, and in all other tissue types. There are two kinds of stem cells: The hematopoietic stem cell (HSC), which differentiates into mature blood and immune cells and the mesenchymal or stromal stem cell (MSC), which differentiate into all other cells outside the blood. MSCs can come from adults or from umbilical cords of newly born infants. Note that both HSC and MSC (even those coming from umbilical cords) are non-embryonic and do not come from human embryos. All studies on MSCs presented in this talk will be on somatic or non-embryonic stem cells.

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The Role of Hematopoietic Stem Cells in the Treatment of Non-Communicable Diseases (NCDs)

The role of hematopoietic stem cells in the treatment of Non-communicable diseases, especially blood cancers, is well established and non-controversial. The bone marrow and peripheral blood are the most accessible organ sources of both hematopoietic and mesenchymal stem cells and science has developed to the point that these organs can even be stimulated to produce more stem cells than normal. Technology has also developed to the point where stem cells in the bone marrow or peripheral blood can be identified and isolated and transplanted to another person whose own bone marrow has failed. This process is called Allogeneic Hematopoietic Stem Cell Transplantation.

Harvested stem cells from the bone marrow can also be returned to its original owner after his bone marrow is cleansed from its sick cells, usually by high dose chemotherapy. This process is called Autologous Hematopoietic Stem Cell Transplant. In this process, the patient literally rescues himself from death by bone marrow failure by using his own stem cells that fully repopulate his marrow within 2 to 3 weeks. Hematopoietic Stem Cell Transplantation has been used to treat hundreds of blood cancers and disorders for over 50 years now. More recently, newer indications including Germ Cell Tumors, and Multiple Sclerosis, and other Non-communicable diseases like Rheumatoid Arthritis are coming to light. These are the accepted and non controversial uses of Stem Cell Therapy.

The first successful transplant was performed by Dr. E. Donnall Thomas in Cooperstown, N.Y., in the late 1950s. The transplant involved identical twins, one of whom had leukemia. Because identical twins share the same genetic make-up, transplants between twins avoid the problems associated with non-twin transplants, such as graft-vs.-host disease or GVHD. GVHD occurs when the transplanted cells (the graft) attack the patient (the host) as they would a foreign object or infection. In 1975, Thomas moved his research to Fred Hutchinson Cancer Research Center, where much of the developmental work on bone-marrow and blood stem-cell transplantation has been done. He received the Nobel Prize in physiology or medicine in 1990, along with Dr. Joseph E. Murray, who pioneered kidney transplantation. Since that time, over a million hematopoietic stem cell transplants have been performed, saving hundreds of thousands of lives.

Today, more than 50,000 patients are transplanted each year all over the world. The Worldwide Network for Blood and Marrow Transplantation is a tremendous example of worldwide cooperation and sharing of health data involving more than 70 countries grouped into 19 member organizations. Because of this cooperative spirit among scientists, and clinicians, disease free survival rates of patients with transplantable blood diseases now reach more than 90%.

In the Philippines, the first marrow transplant was done in 1990 by Dra Honorata G. Baylon. As of 2008, only 21 transplants had been performed, limited mainly by the prohibitive cost of the procedure and the out-of-pocket nature of our healthcare system. The blue line in the bottom of this graph 1 represents the Philippines progress over 20 years of transplantation. From the first bone marrow transplant in 1990, to 2011, less than 30 transplants had been done in our country, a number comparable to that of Vietnam, which started later than we did. Note that if we arrange the nations to the right of Figure 1 according to population burden, the Philippines, (population of 98.4 million) would be high up in this the list, third only to India (852 M) and Pakistan (182M). In the past five years, at least five Filipino hematologists have gone to Germany, Taiwan, Australia and the United States specifically to train on performing HSCT. As of today a little less than 150 HSCTs have been done in our country and in July 2015, the Philippine Society of Blood and Marrow Transplant was organized, headed by the top two transplanters in the nation (Dr Baylon and Dr Francis Lopez). We are optimistic that this group of collaborative transplanters will usher in the era of blood and marrow transplantation as standard of care for all whose lives it can save.

The role of Mesenchymal Stem Cells in NICD Treatment

Mesenchymal stem cell therapies are much newer than their haematopoietic counterpart, broader in scope and holds promise for so many more patients with chronic, degenerative and debilitating illnesses, and for these reasons, are much more controversial.

Like the Italian film which starred Americans entitled “The Good, The Bad, and The Ugly”, a 1966 Spaghetti Western movie about three cowboys competing to find buried treasure of Confederate gold amidst the violence of the American Civil War, Stem Cell therapy also has its share of good, bad and ugly aspects. At the time of the movie’s early showing, there was general public disapproval of such Spaghetti Western genre, and it initially received mixed response. Today, it is considered as one of the best Western movies ever made. I use it as an example of anything new and different, even if good, being susceptible to criticism and negative reviews in its inception. There is also the good, the bad and the ugly about Mesenchymal Stem Cell Therapy.

Mesenchymal Stem Cell transplants are now being done for the treatment of refractory and difficult to treat Multiple Sclerosis- a chronic, debilitating neurologic illness affecting thousands of young lives all over the world. It has also put into prolonged remission patients with stage 4 cancer which would otherwise be incurable. Skin grafting for burn patients and corneal grafting for patients with certain eye disorders have been done for many years now, improving the lives of patients afflicted with these diseases. These are the good things happening with Stem Cell Therapy for non-communicable illnesses.

The “bad” and the “ugly” have to do with profiteering from and application of stem cell therapy by those who promise cancer cure or return to youth to vulnerable patients and their families. These practices by and large have now stopped, thanks to the Philippine FDA directives to stop the sale of untested and unproven “stem cell therapies”, and DOH Administrative Order 2013-0012 which contained the rules and regulations governing the accreditation of health facilities engaging in human stem cell and cell-based or cellular therapies in the Philippines. This mandated that all stem cell treatment be done only in DOH accredited health facilities. As of April 2015, The Medical City, Asian Hospital and Makati Medical Center are the only hospitals visited by the DOH and whose stem cell labs have been certified as coming up to world standard with regards the creation of stem cells to be used in the treatment of human disease.

The Philippines was, or is, not alone in this controversial situation. The Scientific Journal NATURE, in January 2014, published an article on Italy's Stamina Foundation whose files were leaked to the press and allegedly contained proof of serious flaws and omissions in the protocol used by the Foundation in the manufacture of its stem cells.

The Journal on Stem Cell Research Therapy itself published early this year 2015 an article accusing the promotion and provision of autologous stem cell therapies in Australia as "untested, unproven, and unethical"--words familiar to us in this country two years ago when we had our version of this controversy being played out among our own physicians, regulators, politicians, journalists and general public.

Why is mesenchymal stem cell therapy (MSCT) so controversial, while its hematopoietic counterpart not? For one thing, Mesenchymal SCT is almost 20 years younger than Hematopoietic SCT, as it began in the Massachusetts Institute of Technology only in 1974. It was here that two brothers, both victims of severe burns, gave up a small patch of undamaged skin to the MIT lab, which cultured the skin cells, allowed it to grow into a graft which was then implanted over their damaged skin. Also, unlike the detailed pathway of differentiation of the hematopoietic stem cell, knowledge on the pathway of differentiation of the mesenchymal stem cell is less certain and detailed.

In Medicine, as in many other versions of reality, whenever there is a balance of opposing forces, we have what we call equipoise. Typically, for example, a patient with high cholesterol levels in his blood may be informed by his doctor that his cholesterol may be lowered by exercising three times a week for 90 minutes each time, or by conscientious avoidance of food with high cholesterol, or by doing a combination of both. The patient, however, abhors exercise, and the doctor has noticed that in his practice, half of his patients taking cholesterol lowering drugs develop such side effects as painful muscles and rising liver enzymes. SO what is the patient to do? One technique that has proven to result in good health outcomes and decisions when there is equipoise is the use of Evidence Based Medicine.

Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values. By best research evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic, the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.

By clinical expertise we mean the ability of the healthcare team to use clinical skills and past experience to identify each patient's unique health state and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations.

By patient values we mean the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient. When these three elements are integrated, clinicians and patients form a diagnostic and therapeutic alliance which optimizes clinical outcomes and quality of life.

Current Scientific Data on Mesenchymal Stem Cell Therapies

Research into the role of mesenchymal SCT in healthcare is in equipoise. On one hand is the more traditional position of conducting randomized controlled trials for free for enrolled subjects; on the other hand is the position allowing compassionate use of this new therapy on an individual basis with the patient paying for his own stem cell treatment.

As scientists, our task is to carefully study the current scientific data, the current local data and practice, and The Filipino patient values and needs.

Table 1 summarizes different clinical trials done and published between 2010 to 2014. The diseases treated were all end stage, meaning the patients recruited were very sick and debilitated despite receiving standard treatments. These patients had poor functional status because of their illnesses. Note that compared to larger randomized controlled or Phase III trials where hundreds or thousands of patients are enrolled, these studies were all Phase I or II, meaning they either had no control group or control groups were not randomly chosen, and their subjects numbered from less than 20 to at most 87 patients.

All studies showed clinical benefit to their patients, and no adverse events were reported, and all of these studies concluded that bigger trials were necessary in order to come up with more robust conclusions and to achieve a greater understanding on how MSC transplantation works to treat non communicable diseases.

Cancer scientists, of course, are never far behind in doing cutting edge research as they search for that elusive cancer cure. A therapeutic cancer vaccine called Sipuleucel-T, uses autologous active cellular immunotherapy, and has shown evidence of efficacy in reducing the risk of death among men with metastatic castration resistant prostate cancer or stage IV prostate cancer where hormonal treatment no longer works

Five hundred twelve (512) patients were randomly assigned to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of three infusions. Results showed that in the sipuleucel-T group, there was a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). Immune responses to the immunizing antigen were observed in patients who received sipuleucel-T. Adverse events that were more frequently reported in the sipuleucel-T group than in the placebo group included chills, fever, and headache. Today Provenge is the only cellular immunotherapy using the patient's own cells approved by the US FDA in the treatment of any cancer.

Local Experience on Stem Cell Research

What about our local experience? What kinds of trials have been done, if any? As expected, our local data is mostly anecdotal. At the Medical City, 2 patients with SLE, 2 patients with chronic liver disease, and 1 with osteoarthritis have undergone treatment for their severe diseases similar to those done in the global trials presented earlier. No adverse events have been noted, again like all the studies presented earlier. Though observation period is still short, none of these patients have developed worsening of disease. All have at least stabilized, some have improved.

The largest experience in this same Institution is in the treatment of advanced cancers. To date over 200 patients with different kinds of advanced cancer have been given dendritic cell vaccines created from their own cancer antigens. This unpublished retrospective study analyzed the effect of dendritic cell therapy on the overall survival of patients with locally advanced or metastatic breast cancer. Results showed that the survival of the group of 26 patients that received dendritic cell vaccine together with standard chemotherapy surviving significantly longer than the 36 patients in the control group that received standard chemotherapy only. This study removed much of the skepticism regarding the value of personalized cancer vaccine in prolonging the life of patients with advanced cancer, and encouraged the pursuit of a prospective trial on the use of this treatment method in cancers with dismal outcomes when using standard treatment.

Another study done at The Medical City involved 5 children, ages 5 to 9, with Autism Spectrum Disorder. Mesenchymal stem cells from the bone marrow were harvested and given intravenously and intraspinally over 6 months. Outcomes measured was primarily safety and secondarily changes in behaviour and scores in standardized Childhood Autism Rating Scale and results showed minimal adverse events which were all easily reversible. The patients appeared to exhibit less aberrant and more appropriate behaviour after therapy. These two small local studies have been presented in posters in the National Cancer Research Institute Annual Scientific Meeting in Liverpool, England (2014) and in the International Society for Cellular Therapy in Las Vegas, USA (2015). Both received interest and encouragement from viewers and researchers on stem cell therapy from all over the world.

The Patient Perspective

While scientists continue to gather scientific proof on the risks and benefits of mesenchymal stem cell therapy, and while local stakeholders, politicians, regulatory authorities and physicians clarify when to use science and when to use compassion, the patients wait at the sidelines. When making difficult decisions in clinical practice, I ask my patient, "What is it that you want?" I asked the same question of 4 patients with present or past history of non-communicable diseases and 2 healthy adults. I asked them for their perspective as a present or future patient on this issue, as I prepared to give this talk. I explained to them both sides of this equipoise and asked them "If you were a patient, would you approve or disapprove of your doctors' giving you the option to undergo (or not) expensive treatment which may (or may not) be beneficial to you?" In answering, I asked them to please assume minimal or no harm or risk has been noted from Stem Cell Therapies.

All respondents were in my circle of friends. GJB is my cousin, He was diagnosed with locally advanced Colon Cancer in 2013. He refused chemotherapy after surgery, is alive and well and works as a member of the Board of Directors of Landbank of the Philippines. RBJ is my sister. She is the Head of the Overseas Workers Welfare Administration. Her husband had Stage IV lung cancer early this year. He chose NO treatment and passed away in 3 months after being given palliative care at home for 2 weeks. TJH is my other sister who is a Professorial Lecturer in the School Of Economics in UP Diliman. She is a health economist and worked with the World Bank for over 20 years before coming back home. She has no chronic disease. ePatient Dave I met at the Society for Participatory Medicine list serve group. He is a 7 year survivor of Stage IV cancer of the kidneys and is an advocate of Patient empowerment and participation in healthcare. His treatment was immunotherapy with interleukin 2, which few people in the world know about. SKC is my brother-in-law. He is an academician of the National Academy of Engineering and is the world expert in human-computer interaction. He has Celiac disease. RJB is my cousin. He had thyroid carcinoma 35 years ago and was cured after undergoing what was then considered aggressive treatment. He is a retired demographer and an intellectual. All of them responded to my request for the patient or caregiver perspective. I have summarized their answers in the following paragraphs. Their common answers had to do with going through a transparent and informed consent process with protection from ulterior motives, with being given compassion and respect by their healthcare

team, with issues of affordability and being able to afford expensive treatment. I have used direct quotations from their responses in order to avoid giving biased statements.

These are their points of view...

On the topic of Informed Consent...

- “I always want to know what my options are. I listen to their (doctors’) advice, and then I explore online, and I try to talk to other patients, whose views might be different. I am *always* aware that the current literature may be wrong and might be contradicted next month. Or next year, or in ten years.
- I don't expect certainty (from our *current* evidence, nor from my doctors), and (importantly) I take responsibility for my decisions. I would not feel angry or cheated if something doesn't work - I only feel angry if someone hides facts from me or tries to convince me something is true when *they* don't know what they're talking about.
- I am a full believer in informed consent. As a patient I would want to know expected costs and benefits of this and all other alternatives, plus the probability of each outcome occurring (if known from scientific studies), and the strength of the scientific evidence. I would want my physician to make me feel like I am welcome to ask as many questions as I want, as often as I want, and to be given the time to absorb all the information given, then ask more questions. Sometimes it's the small details that matter very much to the patient, though they may seem petty or irrelevant to the physician.

On the topic of Transparency and Protection from Ulterior Motives:

- In approaching this problem, I am mindful of the preciousness of time. Evidence-based medicine is a very good thing, but it's of necessity slow and pursuing a result on an institutional time scale. But for a patient with a lethal disease, that result may not matter, because it comes too late. But this desperation for something that might work makes the patient vulnerable to chasing unrealistic alternatives or manipulation by other actors. In your stem cell example, there is a potentially very profitable business selling this procedure *independent* of its efficacy.

- (We need) protection from ulterior motives. Having the patient choose an experimental treatment could be affected by conflicts of interest. There are first pharmaceutical manufacturers or doctors that benefit commercially. Then there are researchers who need subjects. These interests need to be revealed to the patient. Perhaps there needs to be an ombudsman or patient's advocate who sorts these out from a neutral position.”
- I think the matter of 'expensive' treatments is more an issue for those that can afford. For the poor, that is a non- issue and a non- option right off. Still, it would be good to be in the know. Deliberately withholding information or deluding a patient with wrong information to suit one's selfish and profitable ends, on the other hand, is a big no- no in my book.”
- “No, I don't think I would have resented you or any doctor bringing up the possibility of stem cell treatment...”
- Full disclosure is always a good thing. Then again, much depends on how a doctor does this. If he/she can explain the options with clarity, patience and some amount or semblance of compassion, then I say "why not?"

Regarding Compassion and Respect from their healthcare team:

- I realize that not all patients may want all this information, but whatever is available should be ‘translatable’ (not dumbed down) to a language that is familiar to the patient. I don't believe that the physician should make decisions about what information to give the patient on the basis of affordability, except in the rare cases where this may cause serious psychological distress to the detriment of the patient's ability to cooperate with the management of his illness. In brief, this judgment should be motivated principally by the fullest respect for the humanity and sovereignty of the patient.
- As a demographer, looking at large numbers, I tend to favor an emphasis on clinical trials, which provide the greatest good for the greatest number over time. But still you have to provide for individuals, and some version of compassionate use is not necessarily inconsistent.”

- Compassionate availability. I think some procedures that show promise, but as of yet are under-verified, should be available to patients

Regarding the question of who pays for treatment, these were mentioned:

- "For profit" use of unproven therapies I think is easy to rule out, though not necessarily easy to control. There has to be an alternative, such as provision of experimental therapies, on a compassionate basis, in a non-profit setting at cost (or cost plus if necessary).
- Whether there should be any subsidy for the treatment from, say, health insurance plans should depend on the promise. Insurance companies often take an extreme view of what is "experimental" medicine, counting as experimental, medicines that have had successful stage 3 trials and journal articles showing results. I suggest there should be a scale of promise for a procedure or medicine set outside the insurance company, and this should determine how much payment is born by the patient vs the insurance company.
- I don't believe that there is a universal rule that any patient should receive any treatment for free, whether on moral or ethical grounds, regardless of whether or not the treatment is part of a clinical trial. I just spent the last semester teaching my economics students about principles of equity as applied to health care, and the approach to equity and fairness - as taught by economists at least - is much more complicated than this. Other considerations would be the values of fairness that the specific society holds (these can differ a lot from one society to another), the alternative uses of the funds including possible uses for other social needs outside of health, the extent to which the benefits of the treatment will be enjoyed by the patient and his family alone versus the expected externalities (as in the case of treatment and prevention of communicable diseases), etc. Medical research is generally considered to carry large external benefits to society, and hence tends to weigh positively in favor of some social subsidy. But even here alternative uses, expected benefits, expected costs, etc should be considered. There's no point offering the treatment for free if the study itself (or some other important study) may be compromised if funds eventually run low.

As it turns out, not every patient wants to be cured, nor even extend life beyond its natural length. Here is an alternative view from one cancer patient.

- “I guess one difference between the doctor and the patient is our view of life. The doctor due to his/her oath is pledged to maintain life, while the patient may under certain circumstances actually pray for death or pray that the Lord's will be done. I think it is faith that tells us that the next life will be better than this one, so my most frequent prayer is that the Lord's will be done on earth as it is in heaven and that He have mercy on me, a sinner. In other words, I don't fear death. If the Lord keeps me alive, it my duty to find out what he wants me to do for Him and our people and try my best to do whatever it is, even as I continue to enjoy this life. If He decides my time is up, I would go with him willingly hoping he would have mercy on me.”

Some made my job easier by giving summary answers and suggestions:

- “Another obvious item is the need for public education and awareness. Government is the appropriate way to do this but not very good at it. One needs advocates, private organizations and foundations to argue for patients and at the same time provide them with better information about appropriate alternatives.”
- “As I always tell my students – there is no one correct answer. Just a matter of good values and good judgment on the one hand, good, objective scientific evaluation on the other and the hope that the decision maker(s) embody the best of these characteristics. So there you have it, an Evidence Based Medicine approach to the question: What is the Role of Stem Cells in the Treatment of Non-Communicable diseases”

Summary and conclusion

Adult, somatic, non-embryonic stem cells have an important role in the therapy of Non-Communicable diseases. Hematopoietic stem cells or HSCs have been around since the 1950s have been used in treatment of NCDs over a million times, and have saved hundreds and thousands of lives since then. Mesenchymal stem cells or MSCs have been used to generate new organs and tissues to replace defective ones since the 1970s.

While HCS transplantation is now standard of care for blood diseases in most countries, the Philippines lags behind in this area mainly because of the cost of this treatment and until recently because of the lack of any organized approach to the development of the use of this treatment method for Filipino patients

Mesenchymal stem cell transplantation is a new, expensive yet promising, and therefore controversial treatment procedure for non-communicable diseases. Scientific studies on this procedure exist but these involve few patients and are non randomized. Locally, MSC have been given on compassionate basis and data gathering is anecdotal at best.

Patients are interested in finding out and understanding what mesenchymal therapy can do for their quality of life, but cost is prohibitive and they have no time to wait for the results of randomized trials which typically take 20 years before pharmaceutical treatments are FDA approved. What is more, big pharmaceutical companies which usually sponsor drug trials stay away from doing research and development studies on MSC therapy because these have no single end product that they can someday package and sell in the open market.

Recommendations

We should continue to allow compassionate use of stem cell therapy in specialized DOH accredited Medical Centers provided patients undergo a transparent and open informed consent process, and allow their anonymized data to be used in retrospective trials. The conduct of proof of principle prospective (Phase II or III) trials in these same accredited Centers should be encouraged, provided their Protocols are in accordance with International Standards on the Conduct of such Clinical Trials, approved by their local Ethics Board, and conducted on patients with illness which are otherwise incurable with no chance of having a meaningful and productive life or which has a median survival of less than 5 years. These prospective trials can be small (15 to 30 subjects with appropriate control groups) and preferably sponsored by government Research Agencies. These studies should also be published and contribute to global knowledge on the risks and benefits of this controversial yet promising treatment of Non-Communicable diseases

We should exert extra effort to reach out and collaborate with research centers in big university hospitals abroad, send our patients to them if they have open trials, or invite them to share their knowledge and skills with local scientists. A specific suggestion is we do a study on the Role Of Dendritic Cell Vaccine on the Overall Survival of such diseases as Glioblastoma Multiforme or Liver Cancer in patients with Liver cirrhosis—diseases where 50 % of patients die within a year, 90% within 3 years. Government and non-government organizations should finance studies like this, and those who conduct it should be transparent and share their data with their patients. Anonymized data should also be shared across different accredited institutions to facilitate growth of data base so this method of treatment can be used by more who need it.

Finally, we should let patients help. They have the most at stake here. Their time, their money, their lives. Listen to them and ask them their perspective always.

Conclusion

In the end, we all need each other, regardless of where we are and what perspective we have in this controversial treatment of non-communicable diseases. Let us harness our Bayanihan spirit. This Filipino trait of communal unity and cooperation will take us from here, where progress is slow and finger pointing abounds, to there, where the best possible quality of life, regardless of circumstance and as the patient himself defines it, exists. May the culture of Science and Research, admixed with compassion and mutual respect, continue to guide us all to a better tomorrow.

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