



**Roundtable Discussion Forum on  
Use of Natural Substances and Processes as Adjuvants  
To Standard Treatment of Cancer  
Liu Institute, University of British Columbia, Vancouver  
Tuesday, June 24, 2008**

**Summary by Dr. Arun Chockalingam, Chair, Research Advisory Council, Michael Smith Foundation for Health Research; and Professor, Simon Fraser University**

As a good academician, let me make my disclaimer upfront. I have no special expertise in cancer or even a cogent knowledge of cancer and how it works. I am a cardiovascular epidemiologist by training. I participated in the roundtable conference in my capacity as Health Research Advisory Council Chair of the Michael Smith Foundation, Simon Fraser University professor as well as global health expert.

When Dr. Sunil Chacko, Research Director and Mr. Praveen Shrivastava, Founder of Malony Foundation, spoke with me some 3 months ago and expressed how passionate they are to bring the natural health products to the forefront, I was quite enamored. Mr. Shrivastava's personal experience with Malony, his late wife who passed away due to breast cancer in 2007, and to extend the same comfort she received during her last years to millions of people suffering from cancer is quite moving and his effort, heart warming.

Thanks to Praveen Shrivastava, Dr. Chacko, Surabhi Shrivastava, Trustee and the Malony Foundation, the roundtable conference was organized, briefing background paper was prepared and supplied, and an eclectic group of experts who all have a common interest and are coming from different backgrounds gathered at the University of British Columbia. It is quite an achievement to bring in so many great minds to a forum like this. Congratulations to all those involved in organizing today's event and the Malony Foundation. To capture the energy and brilliance in the room during 7 hours of discussion, the following is my best attempt, together with Malony Foundation, to synthesize the day's discussion and achievement.

### Opening

Dr. Chacko moderated the day's presentations and discussions. The day began with personal testimony from Mr. Shrivastava, Founder of the Malony Foundation, that set the stage. Also Dr. Chacko encapsulated Malony Foundation's spirit and the roundtable conference, "From Tragedy to Determination."

Dr. Alison Buchan, Senior Associate Dean, Faculty of Medicine of the University of British Columbia (UBC) delivered opening remarks, citing from her personal experiences with breast cancer in her family members, that conventional medical treatment is often uncomfortable. Furthermore, it does not yield intended effect on 50% of patients, and this requires tailoring the treatment to individual needs and more investigation on care management. Thus, she expressed her interest at the outset itself on the outcome of today's roundtable discussion.

We as human beings live with food and water. Sometimes, the same food could be harmful depending on the state of health we are in. We then resort to medicine to cure the ill effects. So, food and medicine are two essentials for living, as well as very lucrative areas from an economic standpoint. Both food and pharma are major industries. Dr. Chacko gave some interesting statistics on these two industries.

Malony's life experience after diagnosis with breast cancer and her positive attitude to overcome the pain and the family support she received from Praveen and their children were remarkable. The biological state of her bone density after chemotherapy and its reversal to regenerated bones after a few months of treatment by Carctol is a fascinating story that well-deserves to be more carefully looked into and taken up to the next level -- medical investigation on the compound.

Carctol is the combination of 8 herbal ingredients with believed medicinal properties, created by Dr. Nandlal Tiwari, an Indian medical practitioner of Ayurvedic medicine, ancient medical practice of India. Dr. Tiwari from Jaipur, India was a physician of Malony, treating her with Carctol as a complementary medicine to her modern medical treatment, chemotherapy and injection of Herceptin at the BC Cancer Agency in Vancouver, Canada.

Dr. Tiwari, participating in the roundtable discussion via web-video conference from India, gave an account of how he created Carctol utilizing ingredients from 8 different natural herbs found in the jungles of Assam. He has been a practicing Ayurvedic physician for 30 years and with some excellent results on some patients, he said. He admitted that not all cancer patients attained remission, and that he was seeing remission in about 30-40% of patients when Carctol was used alone. He also indicated that Carctol in combination with modern allopathic medicine yielded excellent results. He attributed the failure of Carctol in some patients to poor timing. Many patients came to him at a terminal stage. If they came early, the chance of treatment and survival could have been better. That points to the value of early diagnosis and towards prevention.

Dr. Tiwari, in a philosophical mode, made a plea to the audience that "since Carctol is working, why not use it as an adjuvant." He pointed out that a physician from the UK, Dr. Rosy Daniel, who visited him and learnt about Carctol is administering it to her patients, with the approval and reimbursement of the UK National Health Service, and more than 800 have been treated resulting in positive outcomes. He himself has administered Carctol in over 10,000 patients in India and found satisfactory to excellent results. The population of India is over 1.1 billion people.

During discussions, it became apparent that to enable it to become universally used, well-designed clinical trials and rigorous documentary evidence are possible and required. Questions and advice were presented through active participation: by Dr. Jean Paul Collet of the UBC Centre for Healthcare Innovation on its scientific publication, by Paula Brown of BCIT on regulatory requirements and its efforts, by Dr. Amanda Hoogbruin of the Kwantlen University College on documentation of side-effect and complication, by Lauren Evanow of Arthrex Arthroscopy Ltd. on ready-availability of raw ingredient, by Dr. Emma Guns of the Prostate Centre at Vancouver General Hospital on cost, by Dr. Julius Halascheck-Wiener of the Genome Sciences Centre at BC Cancer Agency on Malony's other alternative treatment besides Carctol and changes at the molecular level due to adjuvants, by Dr. Suzanne Slocum, Canadian Institute of Health Research fellow at UBC on the issue of measurement, such as psycho-socio outcome and bio-outcome and also need to establish study infrastructure on this, and by Dr. Carolyn Gotay the Canadian Cancer Society Chair at UBC on immuno-functioning among many.

According to Dr. Tiwari, Carctol expands the lifespan of cancer victims and also provides a better quality of life. This fact was reinforced by the life of Malony Shrivastava.

When asked about any published materials on Carctol, including its components, Dr. Chacko showed a binder full of publications on the components of Carctol and indicated that toxicology studies had been conducted in the UK and India. From Dr. Tiwari's anecdotal experience, Dr. Tiwari said that he had not found any serious side effects due to Carctol in his 30 years of practice. In Malony's case, according to Praveen, the cost of one month supply of Carctol was \$70. There have been no immune function studies done to date.

Following the break, Dr. Chacko presented a comprehensive presentation on the state of natural health products and clinical trials, and the fact that we need to recognize the issues and bring the evidence to capture the interest of patient groups, professional societies, donors, philanthropists, financing agencies and investors. His attention to cost control at each stage presented notable analysis. Phase IV-focused approach for natural products might be the most scientifically and financially feasible, combining the current issue of increasing need for post-marketing surveillance of approved pharmaceutical therapeutics and science gap revealed by food substance products. He also showed the successful example of TB drug, when he was a Rockefeller Foundation health science advisor 1998-2000, using small studies on fluoroquinolones including Moxifloxacin, and getting the interest of the Rockefeller and Gates Foundations to create the Global Alliance on TB R&D and raise \$200 million for formal clinical trials, that have been underway for some years, and Moxifloxacin is near approval as an addition to standard TB treatment. He called on the group to enable clinical studies on Carctol.

#### Excellent Discussions ensured.

Dr. Hal Gunn, CEO of InspireHealth, commented on the different ways of thinking and different ways of doing research. In cancer management, there is no disconnect between prevention and treatment. Strong patient interest in complementary treatment is presenting the new paradigm today and patients are demanding it to be included in standard cancer patient care. As a physician of cancer care, Dr. Gunn pointed out how important it is to honor treatment choice for patients. The choice often becomes, for patients battling cancer, source of immune system functions.

Dr. Collet mentioned the importance of data because of treatment sensitivities of cancer patients. He drew excellent analogy for the focal point of this roundtable discussion based on his clinical research experience on Chinese medicine with InspireHealth. Beijing Cancer Institute, he characterized as "supplier of the knowledge," that introduced him to 58 Chinese medicines, and one received NHPD approval in 2 years. It is, therefore, very possible to conduct this trial, randomization, individualization, and he advised to be creative and innovative in designing the research, such as the trials themselves, but also system-centered process, way of delivery, quality of practice among many.

On the vital issues of intellectual property right protection, Dr. Collet, Ms. Brown, Dr. Chacko commented. For this type of research, alternate mode and different pathway to protection are possible such as the World Intellectual Property Organization (WIPO).

Carole Robert from the BDA Foundation, Montreal, made an impressive presentation of her foundation's work to identify botanical drugs primarily in Africa. She made distinction between

nutraceuticals and natural health products. Her product introduction has utilized WHO's Medicinal Plant Cultivation Protocol, recently created designation in 2003, and been playing the role of quality control that helps growers in Africa. BDA is engaged on three levels: educational programs, agricultural & food data collection practice training, and medicinal plants farming and marketing.

Jim Dao, Chairman and CEO of Genyous Biomed International Inc. brought the group's attention to the importance of identifying botanical active principles, recognizing the botanical drug guideline of the FDA. He pointed out the need to adhere to this guideline, and warns that the slippery downhill may cause the collapse of the entire industry. Dr. Chacko commented on this as a common interest area for all those engaged in researching the traditional medicinal herbal knowledge from all corners of the world.

Paula Brown gave an account of regulatory issues surrounding natural health products and her experience with the intricacies of compliance requirements of each step before product is introduced to the market. Comparing between Canada, US, Australia, Japan and others, Canada is uniquely positioned in terms of regulatory system: unlike US system, natural products can be a subcategory of therapeutics, and thus she pointed out that Canada has the best framework to pursue this type of work, provided that it needs to have pre-marketing approval.

Mr. Shrivastava mentioned the pain killer cost that BC Palliative Care incurs, \$1 million per month on pain killers, and challenged the audience that why not spend \$200,000 on its research effort that can save \$2 million.

The roundtable discussion was also attended by Mr. Adrian Dix, British Columbia Provincial Member of the Legislative Assembly, and Health Critic. Having received signed petitions by tens of thousands of people on the recent C51 bill debate, he is acutely aware of the passion and extent of public interest in complementary and alternative medicine. He commented on academic rigor to be maintained throughout research, and that gives the public confidence. The public needs to be protected and the public has to have access. Quality of life of cancer patients is undefinable in terms of cost. Managing chronic condition of type I diabetes himself, he is personally interested to see the outcome of this roundtable and the development forward. He made excellent remarks stressing the value of research weight brought to bear by the efforts of the Malony Foundation.

Dr. Buchan called for the provincial strategy on health research to effectively channel incoming resources. Dr. Chacko echoed this call indicating the "offer to collaborate."

### Body and Mind

A moving video of Malony Shrivastava spoke to this point of mind and body. Dr. Hal Gunn expressed that once spirituality is involved, clinically remarkable things happen to patients and we should bring body and mind to clinical management. Maureen Edwardson, a mind body therapist, echoed the fact that for better results, patients' full involvement through both body and mind is critical. The neurobiological effects are there and must be captured through effective research. Dr. Amandah Hoogbruin, a practicing nurse, faculty, and an energy healer, asked in what ways the body-mind control practice, healing, stress relief can be incorporated into conventional medical treatment so that the importance of the practice can be quantified or measured. It is an important question, and answers and possibilities are many that need to be

worked out, one of which could be collaboration between CAM researchers, practitioners, and neuroscience researchers.

Dr. Gotay discussed a nutrition-based compound for prevention from her experience in Hawaii. On pain control management, visualization techniques have been established. Such techniques have not been integrated with the current medical practice. Quality of Life: Patient-reported outcomes are key areas to look at. In fact, FDA relies on patients' reported outcomes to approve new drugs. Pain thermometers are an example that was also brought to attention earlier by Dr. Chacko's presentation.

Dr. Collet showed the spectrum of research objectives and players, clinical/industry/regulators and primarily, patients. He brought up an interesting point for consideration: usefulness of finding active compounds needs to be debated in Chinese medicine because all compounds are used in combination. He reiterated the patient-centric practice. He talked about a strategy to evaluate CAM. He compared the observational studies versus clinical trials and indicated the limitations in each of them, and suggested trials using external validity. The TCM evaluation strategy works in a reverse mode starting from phase IV (post-marketing) to phase I (safety in humans). He concluded that research is needed for credibility, recognition, and development. For CAM, safety is the number 1 priority. Collaborative approach is the must.

Jim Dao said that he is looking for collaboration. He indicated that Cancer tops the causes of people's fears. The DVD testimony of Malony can alleviate that fear. His presentation included striking statistics – despite multibillion annual spending on cancer research, since 1950, US cancer mortality rates have declined by only 5%, and this highlights how far away we still are from finding effective treatment. He spoke about his invention of Scanning Electron Microscopy (SEM), and stressed on MFMT (multifunctional, multitargeted) therapy. Placebo (mind) is the number 1 drug. Explaining that 95% of new drugs fail, Jim Dao spoke about Aneustat, that he said has anti-inflammatory, anti-viral, anti-oxidative and immune modulating properties and is set to begin phase I trials. He said that the missing piece is translational research, the link between science and engineering. He proposed a new paradigm for clinical trials, involving trusted 3<sup>rd</sup> party mega trials, databases, tissue/serum repository. He called for maximization of the synergistic effects of drug combinations, for optimization of personalized medicine for patients and long-term safety monitoring.

Julie McMillan who is responsible for the Canadian Breast Cancer Foundation's CAM research portfolio, discussed their partnership with Inspire Health. A database on integrated worldwide research on CAM, research updates produced monthly for the patients (cancer survivors in BC), Hug Squads, support from family and friends. She discussed the navigational map for those diagnosed with breast cancer. She stated that the healing process should include – stress management and relaxation.

Prateek Juneja, graduate student at UBC and researcher at the Institute of Functional Medicine, discussed a detailed account of green tea, morphology to clinical studies. The effects of green tea, including anticancer and antioxidant were discussed. In Japan, one successful green tea beverage now has \$400 million annual sales, showing the enormous public interest on natural health substance is very high around the world. A comparative experiment he conducted on hot dog versus tea revealed clear contrast on secondary carcinogenic effect found in hot dog that was just like that of cigarette smoking, sparked an interesting conversation. Tea can help prevent coronary heart disease cancer and diabetes mellitus.

## Recommendations and Next Steps

There were many great suggestions throughout, and particularly during the closing session. I have summarized and highlighted discussion points. Then, Praveen Shivastava, the host of the roundtable, initiated discussion on how to put today's efforts together with future direction. The exchange of concrete and great ideas on the next step followed, to move forward in collaboration with Malony Foundation:

- Dr. Cynthia Hamilton, Assistant Research Director at Vancouver Coastal Health Research Institute (VCHRI) suggested and expressed willingness to support to create “Center of Excellence on Complementary and Alternative Medicine Research”. For different medical research disciplines, there are operations of such specialized centers currently located at her VCHRI. Realizing that complementary cancer management was not a predominant paradigm in the past 50 years, albeit playing vital role in reality, it is very important to focus all participants' effort for common purpose and work together with “honorable interaction” and “synergistic working relationship.”
- Dr. Collet cautioned any direction toward creating excessive infrastructure, but suggested to utilize the existing clinical research infrastructure with new focus collaboratively.
- Dr. Chacko mentioned the great example of AFMnet, Canadian Agriculture, Foods and Materials Network to be a model. In many ways, it is a virtual network supported by physical secretariat, but effective in terms of communicating and exchanging research outcomes, commercialization of products, advocacy and support. This efficient network model conforms to Dr. Collet's point, yet is organized in a focused way that enables to push the agenda forward with coordination.
- Dr. Gotay mentioned neuro-biological outcome has to be captured to point to the new research. She also suggested e-mail exchange as “a tiny next step” for some sort of forum to start. In expressing her support for this initiative, she elucidated the possible utilization of grant for the emerging team from Michael Smith Foundation and other organizations.
- Dr. Hal Gunn, referring to Dr. Chacko's previous experience on starting with small studies on TB drug, called for the similar clinical research model to apply to Carctol. He voiced support for establishing a Center of Research Excellence on CAM with emphasis on value of patients-clinicians dialogue. Feedback on what they found helpful are very valuable, and needs to be captured and channeled to research since many practitioners are isolated.
- Maureen Edwardson echoed Dr. Gunn's point on feedback system among practitioners and researchers across various discipline.
- Ireh Iyioha, lawyer, recommended to look into the legal framework of emerging field of CAM as more scientific details are being revealed.
- Jim Dao captured the result of the day as informative and productive that produced concrete suggestions and next steps. He concluded his remarks with “All of us are looking forward to collaboration”.

## Recommendations and Conclusion

Vote of Confidence on:

- **Chinese/Indian/African/Latin American natural medicine is 1000s of years old – opportunity of the day is to use science to assess efficacy, safety and effectiveness.**
- **There was agreement for a Centre of Excellence for CAM (in BC) to be established. It would network existing and new researchers on CAM and foster connectivity.**

This expression of confidence successfully concluded the roundtable conference, hosted, organized and coordinated by the Malony Foundation.

