David S. Michaud, PhD
Principal Investigator
Consumer and Clinical Radiation Protection Bureau
Healthy Environments and Consumer Safety Branch
Health Canada
Wind.turbine.health.stuy@hc-sc.gc.ca
Fax: 613-941-1734

Comments and queries on the Health Canada Proposal to Assess Wind Turbine Noise and Health

For the record I would like to state that I live on Amherst Island and Algonquin Power holds a contract for a 75Mw IWT installation on the island. This translates to up to 37 50-story tall industrial wind turbines on an island with a landmass the size of 110 square km.

I will also state that I am a senior manager in the health care industry. I have been involved in therapeutic research and development for 29 years. My various positions across the industry have included senior management roles in a large number of therapeutic development programs. My work has involved diverse therapeutic areas, including Rheumatology, Dermatology, Respiratory, Psychiatry, Oncology, Cardiology/Circulatory, Endocrinology, and Medical Imaging. I earned my graduate degree in Epidemiology at the London School of Hygiene and Tropical Medicine in the UK. I have been actively involved in scientific projects in Canada, the US, the EU, and Australia.

I have the following comments/queries/concerns about your proposed study, given the limited information currently available to the general public.

Initial Medical/Clinical Question

The *Health Impacts and Exposure to Wind Turbine Noise: Research Design and Noise Exposure Assessment* document provides the following research objectives:

- To investigate the prevalence of health effects or health indicators among a sample of Canadians exposed to WTN using both self-reported and objective health measures.
- To apply statistical modeling in order to derive exposure response relationships for WTN levels as well as self-reported and objective health measures.
- To address the uncertainty that currently exists with respect to low frequency noise from WTs as a potential contributing factor to adverse community reaction.

The three points above raise the following questions /concerns:

- What is the precise question being asked and ultimately assessed? Is it that we want to know if there is a dose response (proximity/noise relationship with reported deleterious outcomes?)

- How precise is the definition of exposure?
- How precise is the standardization of exposure assessment?
- How reliable is it?
- How reproducible is it?
- Is the measure you will take truly the quantitative marker that will elicit human response?
- Has the proposed exposure measure been assessed in a pilot study to see how feasible it is? If it is sensitive? If it is reproducible? In other words are you using validated instruments? If not, why not?

The presence of an Industrial Wind Turbine (IWT) in one's immediate surroundings could result in CNS signs and symptoms. Those who do not want them in their vicinity may be even more susceptible. These concerns are compounded by the fact that the downstream health outcomes may not be observed, reported, even measurable until months to years after the IWT placements. In this regards, I am talking about issues such as anxiety, depression, sleep dysfunction, headaches, concentration, learning and school performance, and others. As such, precisely quantifiable measures are not the only players here. I think some key question clusters need to be looked at:

- Behavior
- Mood
- Medical care
- Use of medications and the reason for their use, frequency of use, etc.

Outcomes

- How will you assess causality, as environmental exposures are tough to bring down to the subject level.
- Why measure just cortisol? If the HPA axis is suppressed or activated, perhaps a repeated battery of biochemical markers might be more informative? Cortisol has a lot of background noise. Will your test be sensitive enough to overcome that and see the exposure-emergent changes in serum cortisol as marked by hair deposition? Doubt it.
- What about glycosylated hemoglobin, C-reactive protein, INR, thyroxine, other general markers of metabolic state?
- Will you assess QoL with multiple instruments; Sleep is an easy pick as one can use Epstein but what about overall health status? SF-36 and HMQ both have dimensions that might be useful. I know the developers of the SF-36 in the USA at Quality Metric (QM) quite well, and a customized SF-36 instrument might be quite easily created for this application.
- Further, and just as valuable, QM has a hundreds of thousands of 'normals' in their database, and under various exposure states that could be helpful as historical controls for your study
- Will other measures be used to assess quality from the patient perspective? For instance some iteration of a QALY, magnitude estimation of overall effect, or Time Trade Off approach? What would someone trade to not live near the turbines?

Health Status/ Health Outcomes/Quality of Life

As you know, any health questionnaire is required to undergo rigorous validation (see attached reference on recent FDA/HC Guidance in reference to developing PROs). Validation requires:

- sensitivity evaluation
- construct validity
- criterion validity
- face validity
- content validity

In other words you will require proof that the questionnaire you choose to assess the effects that these turbines create, results in data that is reliable, durable, reproducible and ultimately can be generalizable/predictable. This normally requires a pilot study to refine questions and research answers for responder understanding, etc. Will this be performed on your proposed questionnaire? If so, can members of the public see the instrument to be used and its validation plan? I'd like to see it.

Pilot Study

I see in the Q & A document that you are planning a pilot study, however this study seems to be very limited in scope. In order to evaluate/validate your questionnaire, your field processes, your data management team, etc, you will need to perform a somewhat comprehensive pilot study. In fact, when I do label comprehension studies, I always start with questionnaire focus groups, re-edit the questionnaire, then go to the pilot, re-edit, then prepare for prime time. Is this what you plan?

Duration of Study

Will the study include a long-term follow-up component? The kinds of conditions that may evolve with ongoing exposure may initially be subtle and have long latent times, especially observations associated with learning disabilities due to lack of sleep or other behavioral or psychometric effects due to environmental signals such as exposure to shadow flicker and nocturnal aviation light flicker. Your proposed study needs to reflect both acute and long-term exposures.

Populations

Defacto or dejure? Will you stratify by population characteristics such as:

- demographics
- education level
- age
- income
- occupation, etc.

All these groups have different views of even the acceptability of turbines from social, financial, environmental and health angles and no two people totally agree. Not only will their age, knowledge of the issue, politics, etc. come into play but so will their comorbidities. Those hard of hearing, those shut ins, those with baseline depression/anxiety, those with children in school, even those who moved to a region for peace and contentment after a hard life in the city will respond differently to a questionnaire than a 5th-generation farmer who sees turbines as an additional income stream.

The study needs to assess children in some manner as they are very sensitive to sleep issues, are likely to be outside a lot and be exposed to both sound and flicker and provide researchers with a measurable outcome of cognition, i.e. school performance. Further, nervous kids being stimulated in some unknown manner at home or at school may sleep poorly and begin to act out behavioral issues as well. I'd include children down to 12; 12 year olds can express themselves quite well…. or maybe you can create a pediatric version of the questionnaire. There is some indication in the grey literature that Autistic children are particularly sensitive to the noise / shadow flicker generated by industrial wind turbines.

Controls

What controls will be used? Can you really find a control who is not somehow biased in regards to WTs? How about using matched cases from an area nowhere near turbines, some nearer (within visual range but outside audible and flicker range), and then the more concentrated data in a concentric focus by distance, say within 10 km right in to the turbine, which is what I assume you'll do. To assess distance to response this way should give a nice response curve if there is in fact any effect. This "dose-response" needs to assess a variety of incomes and the effects are unlikely to all be linear in nature so you'll need a lot of distance points.

Data Management and Statistics

- How did you arrive at 2000 respondents for your sample size?
- Did you do a sample size calculation based on the variance of some known effects of turbine noise on sleep? I suggest an interim analysis using a two-stage approach (O'Brian-Fleming? very conservative) to re-estimate sample size part way through the study, and/or as a futility analyses to make sure you don't have an issue in regards to recruitment. That way there is little alpha spend if you plan to perform hypothesis testing.
- Is the data secure and inaccessible to all but a few people as its being sequestered?
- Is the data being double entered?
- What is the QC plan for the datasets?
- Will the data entry folk/statistical reviewers be blinded? If not, why not?
- Do you have or plan to create a rigorous Statistical Analysis Plan (SAP). I'd (the Canadian public) like to see it.

- Will the study assess households or individuals? Some individuals in a household may have health effects that another stronger member of the family does not have. Then it becomes consensus decision which is rife with group dynamic issues.
- How will you handle missing data? What if you do not get a 75% responder rate?
- Will the populations be drawn from the same populations generally? Are they going to be entirely comparable? Will you need to stratify by region?
- Will you assess for confounding, noise, bias, interactions?
- Will you obtain the following information:
    - Turbine size / height / model / length of the blades – turbines range from 80 meters to 150 meters in height.
    - Distance from home to turbine.
    - Number of turbines within a 5 kilometer radius of a home.
    - Citing of turbines within a 5 kilometer radius of a home, a fan or linear array

Access to Data

The *Health Impacts and Exposure to Wind Turbine Noise: Research Design and Noise Exposure Assessment* document states, "Environmental sound level measurements, including low frequency noise, will be conducted inside and outside a sub-sample of homes in order to validate parameters ensuring accurate sound level modeling." How will they adjust for multiple turbines?

- How will the researchers access data when it is speculated that many wind power companies have put in place gag orders with those who have signed on for turbines requiring the signatories silence on turbine related health or other issues.
- It is a confirmed fact that wind companies have purchased the homes of some individuals who suffered adverse health effects and wished to move away. A condition of the purchase and sale was apparently a gag order requiring the signatories silence on turbine related issues. How do you plan on contacting these individuals as they are clearly a very important segment of the study population.
- As an aside, why would such a restriction be required if there were no potential for health-related controversy?
- How will you sample people who have no computer or internet access; some rural folks still don't have computers, and others may not have internet access. Again, some users are pretty unsophisticated and may not be able to find or complete the questionnaire.
- What about loners and tough-to-get-to people (there are lots of those in the country) … how will you get to them?

Ethics – Points for Consideration

- Given this information could impact whether these respondents get wind turbines and how close such turbines may be legislated to be located near them, there is a potential for the respondents data resulting in personal help or harm. How will you control for this bias, both negative and positive?

- How will you address the very contentious issue involving Personal Health Information (PHI) about which the world is now very concerned e.g. PIPEDA. Will all data be delinked from personal identity once in the database?
- Will you require an independent ethics review of your program/protocol in Canada (say at a learned and independent institution).
- Should there be an independent public Study Monitoring and Review Board with a Working Charter to ensure that the study is conforming to its protocol, and to help make any changes along the way in an unbiased manner. Every protocol undergoes changes of some kind. I'd say 5 independent experts could do the job.
- Conflict of interest statements should signed by all researchers who have a strong view pro or con. This is essentially the same procedure as jury selection.
- Will the payments to a potentially needy farmer (resulting from hosting a wind turbine on their land) be considered subtle coercion? I know in the health care business it certainly would be and this very important issue cannot be minimized ethically. It's coercive and it's also a clear power relationship issue.

Burden on Community/Individual

One aspect of the study is the extent to which some individuals, not through any fault or action on their own, are being burdened with these industrial plants. This appears to represent an unequal social burden of risk. This is called **Distributive Justice** and power companies engaged in building industrial wind turbines break this basic ethical principle every time they develop a wind farm in a divided community; as well as several others such as **Non-maleficence** and the **Precautionary Principle**.

This becomes a public health care issue in so far as depression, anxiety, and despair in some individuals largely reflects an unequal power relationship between the wind generation companies/government and some members of the communities that they absorb**.** I think this requires a broader net than just assessing wind turbine ***noise*** as the sole important potentially health-related exposure, but requires a battery of fairly specific psychometric evaluations to estimate this feeling of helplessness, and, further on, the extent to which it colors their views on their overall health.

Overall individual Quality of Life is no less important than clear evidence of sleep deprivation or CNS effects due to strobe effects. However, from an ethnographic perspective, QoL should also focus on the health and well-being of individual communities as it's going to be harder to make generalizable claims for individuals from the study you are posing. In aiming for this, I think your group could focus on couching some of the findings in terms of Benefit/Risk and possibly Utility/Risk. Will there be an overall risk/benefit assessment??... one that addresses the level of life satisfaction and happiness that is lost in those near the installations who did not want them, versus the economic benefit for those who do want them and who will directly monetarily benefit from the presence of these units.

Finally. I feel quite strongly, and I suspect this will come to a court of law sooner than later, that those individuals who are not hosting turbines who have neighbors with

turbines have long realized, and continue to realize that they are not being compensated for their loss of privacy, peace and the ability to enjoy their land in the manner they expected when they purchased it without the IWTs. Unhindered freedom to enjoy one's full bundle of freedom and rights is associated with property Common Law.

Focus of Study

I believe the focus on noise may be too narrow as the recent literature suggests an equally important component to health status and QoL by shadow flicker.

Literature of Interest

The *Health Impacts and Exposure to Wind Turbine Noise: Research Design and Noise Exposure Assessment* document's References could benefit from the review of the following:

1. Environmental Review Tribunal, Case Nos.: 10-121/10-122 Erickson v. Director, Ministry of the Environment, Dated this 18th day of July, 2011 by Jerry V. DeMarco, Panel Chair and Paul Muldoon, Vice-Chair, www.ert.gov.on.ca/english/decisions/index.htm; p. 207; emphasis added)
The wording of part of the judgement follows: "While the Appellants were not successful in their appeals, the Tribunal notes that their involvement and that of the Respondents, has served to advance the state of the debate about wind turbines and human health. This case has successfully shown that the debate should not be simplified to one about whether wind turbines can cause harm to humans. The evidence presented to the Tribunal demonstrates that they can, if facilities are placed too close to residents. The debate has now evolved to one of degree."

2. Wind turbine noise seems to affect health adversely; an independent review of evidence is neededHanning and Evans, *BMJ* 2012;344:e1527 (Published 8 March 2012)

3. Wind farms, communities and ecosystems: Special issue of Bulletin of Science, Technology & Society*Bulletin of Science, Technology & Society*, October 2011, 31(5)

- Occupational Health and Industrial Wind Turbines: A Case Study — Rand, Ambrose, and Krogh
- Mitigating the Acoustic Impacts of Modern Technologies: Acoustic, Health, and Psychosocial Factors Informing Wind Farm Placement — Shepherd and Billington
- Literature Reviews on Wind Turbines and Health: Are They Enough? — Horner, Jeffery, and Krogh
- Wind Turbines Make Waves: Why Some Residents Near Wind Turbines Become Ill — Havas and Colling

4. Evaluating the impact of wind turbine noise on health-related quality of lifeShepherd, McBride, Welch, Dirks, and Hill, *Noise & Health*, September-October 2011, 13:54,333-9

5. Wind turbine noise and health: Special issue*Bulletin of Science, Technology &*

Society, August 2011, 31(4)

- Wind Turbine Noise — Harrison
- The Problems With "Noise Numbers" for Wind Farm Noise Assessment — Thorne
- The Noise From Wind Turbines: Potential Adverse Impacts on Children's Well-Being — Bronzaft
- Infrasound From Wind Turbines Could Affect Humans — Salt and Kaltenbach
- Properly Interpreting the Epidemiologic Evidence About the Health Effects of Industrial Wind Turbines on Nearby Residents — Phillips
- Toward a Case Definition of Adverse Health Effects in the Environs of Industrial Wind Turbines: Facilitating a Clinical Diagnosis — McMurtry
- Industrial Wind Turbine Development and Loss of Social Justice? — Krogh
- WindVOiCe, a Self-Reporting Survey: Adverse Health Effects, Industrial Wind Turbines, and the Need for Vigilance Monitoring — Krogh, Gillis, Kouwen, and Aramini
- Public Health Ethics, Legitimacy, and the Challenges of Industrial Wind Turbines: The Case of Ontario, Canada — Shain

6. Responses of the ear to low frequency sounds, infrasound and wind turbinesSalt and Hullar, *Hearing Research*, 2010 Sep 1;268(1-2):12-21

7. Nissenbaum, M, Aramini J , Hanning C. (2011, July) Adverse health effects of industrial wind turbines: a preliminary report, 10th International Congress on Noise as a Public Health Problem (ICBEN) 2011, London, UK. Retrieved from http://www.windvigilance.com/about-adverse-health-effects/resource-centre

All for now. Good luck. I hope the scientific community will have a chance to vet the report as I know a lot of people are now lined up to get some rigorous, reproducible, definitive data on the health aspects of IWTs to evaluate and act upon.

Kind Regards,

Mike Vanzieleghem
Canadian citizen

cc :

Honorable Leona Aglukkaq
Minister of Health
Health Canada
leona.aglukkaq@parl.gc.ca

Ms. Glenda Yeates
Deputy Minister
Health Canada
glenda.yeates@hc-sc.gc.ca

Ms. Hilary Geller
Assistant Deputy Minister
Health Canada
hilary.geller@hc-sc.gc.ca

Ms Beth Pieterson,
Director General
Health Canada
Beth.Pieterson@hc-sc.gc.ca

Dalton McGuinty, Premier
Legislative Building
Queen's Park
Toronto, ON
M7A 1A1
dmcguinty.mpp@liberal.ola.org

Tim Hudak
Room 381, Main Legislative Building
Queen's Park
Toronto, Ontario M7A 1A8
tim.hudakco@pc.ola.org

Andrea Horwath
Room 113, Main Legislative Building
Queen's Park
Toronto, Ontario M7A 1A5
ahorwath-qp@ndp.on.ca

MPP France Gelinas – Health Critic
Room 186, Main Legislative Building, Queen's Park
Toronto, Ontario M7A 1A4
fgelinas-qp@ndp.on.ca

#1 An item of relevance re: HC five-year mandate for science (2009)

Excerpt from "Towards a Strategic Science Plan"

Health Canada
HC Pub.: 091123
Cat.: H164-113/2009
ISBN: 978-1-100-50399-8

4E Quality of Life and Patient-Reported Outcomes

The area of health products and quality of life focuses on improving the quality of life for Canadians through access to safe, effective, and high-grade health products. These health products consist of natural health products, foods, prescription drugs (including restorative and regenerative medicine), medical devices, and over-the-counter products. The quality of life of patients is an important consideration when developing and regulating new therapeutic products, as it is something that is highly valued. For example, many Parkinson's patients are trading off the risk of drug complications to uphold their quality of life. Veterinary therapeutic products also fit into this category, as it can be argued that vet products that make pets and agricultural animals healthier also contribute to human well-being.

ED note: While it is recognied we are not dealing with a health care product re: Wind Turbines, the assessment of risk exposure remains a similar paradigm, and thereby follows a similar set of guidances. QoL and PROs are critical elements to exposure assessment.

Item #2 Excerpt from the FDA Guidance on Development of PROs (2009)

Guidance for Industry

Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, rm. 2201
Silver Spring, MD 20993-0002
Tel: 301-796-3400; Fax: 301-847-8714; E-mail: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
or
Office of Communication, Outreach, and Development, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Tel: 800-835-4709 or 301-827-1800; E-mail: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm
or
Office of Communication, Education, and Radiation Programs
Division of Small Manufacturers, International, and Consumer Assistance, HFZ-220
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Rockville, MD 20850-4307
DSMICA E-mail: dsmica@cdrh.fda.gov
DSMICA Fax: 301-443-8818
(Tel) Manufacturers Assistance: 800-638-2041 or 301-443-6597
(Tel) International Staff: 301-827-3993
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
December 2009

III. EVALUATION OF A PRO INSTRUMENT

The evaluation of a PRO instrument to support claims in medical product labeling includes the following considerations:

- The population enrolled in the clinical trial
- The clinical trial objectives and design
- The PRO instrument's conceptual framework
- The PRO instrument's ***measurement properties***

Because the purpose of a PRO measure is to capture the patient's experience, an instrument will not be a credible measure without evidence of its usefulness from the target population of patients. Sponsors should provide documented evidence of patient input during instrument development and of the instrument's performance in the specific application in which it is used (i.e., population, condition). An existing instrument can support a labeling claim if it can be shown to reliably measure the claimed concept in the patient population enrolled in the clinical trial.

Characteristics of PRO instruments that are reviewed by the FDA include the following:

- Concepts being measured
- Number of ***items***
- Conceptual framework of the instrument
- Medical condition for intended use
- Population for intended use
- Data collection method
- Administration mode
- Response options
- ***Recall period***
- Scoring
- Weighting of items or ***domains***
- Format
- Respondent burden
- Translation or cultural adaptation availability

ED note: Same comment as previously made. The ethical, scientific, and practical paradigms of health assessment remain, although we are not dealing with a medical or health care product when we are dealing with these large environmental exposures such as Wind Turbines.