APPENDIX F
Review of Potential Effects of Hydraulic Fracturing on Human Health in Western Newfoundland

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Kevin Keough, PhD FCAHS ICD.D
Professor Emeritus
Department of Biochemistry
Memorial University of Newfoundland

A universal and abiding concern that has been associated with large-scale industrial hydraulic fracturing has been about the potential for the industry to have a negative effect on the health of people who live in its vicinity. Many of the submissions that were received by the Panel raised the issue of potential impact on human health (www.nlhfrp.ca/; Storey, 2015). The Panel has considered this issue carefully and it has sourced a number of relevant documents on the issue in addition to materials that were submitted to the Panel. It has also sought advice from public health and toxicology experts, especially on the contents of this appendix for the Panel's report.

Any decision with regard to allowing for a large-scale hydraulic fracturing industry must depend upon the balance of risks and benefits as seen by citizens and governments. This appendix will discuss risk and benefits to human health that might come from such an industry, and situate them within a regional context. The discussion will draw examples for the region around Port au Port Bay which is the basis for the hypothetical development scenario that has been expanded upon in Section 9 of the Panel Report.

An estimate of how a hydraulic fracturing industry might have effects on human health will, of necessity, have to be implied from information determined elsewhere. This appendix will discuss possible impacts on health in light of historical findings based in other places, and provide some examples of recent findings in other locations that might be interpreted with regard to the Port au Port Bay region. While it is important to note that information from other places can lead to some idea of local effects, it will ultimately be the characteristics of the local region and its people that will determine the impact of a development on human health.

Studies in other locations have found that there are a number of factors such as the state of the physical and social environment, access to good health care, income and social status that have an influence on a person's health. This appendix will discuss the possible health impacts of a hydraulic fracturing industry from a health determinant perspective.

WHAT AFFECTS YOUR HEALTH?

After considerable study public and population health experts from around the world have agreed that there is a group of factors that have major impacts on health. These are referred to as the Determinants of Health. Health Canada and the Public Health Agency of Canada recognize twelve determinants of health.

- Income and Social Status
- Education and Literacy
- Social Environments
- Personal Health Practices and Coping Skills
- Biology and Genetic Endowment
- Gender
- Social Support Networks
- Employment/Working Conditions
- Physical Environments
- Healthy Child Development
- Health Services
- Culture

Many of the determinants might be affected by the presence of a large-scale hydraulic fracturing industry, some to a greater extent than others. This appendix will deal with determinants that might be of greatest weight and importance should a large scale hydraulic fracturing industry proceed.

There is general agreement among experts that socioeconomic factors contribute about half of the impact on a person's health, with genetics, physical environment and health services contributing the balance. Figures 1 and 2 below (see May and May, 2015) provide estimations of the influence of the various determinants on the health of people in North America.

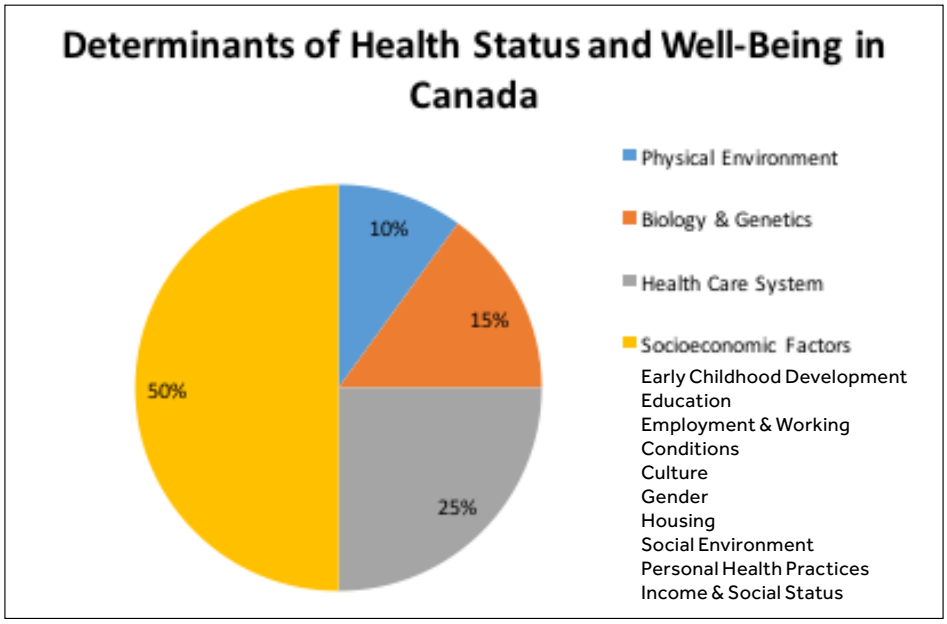

Figure 1. Determinants of health status and well-being in Canada. Source: May and May, 2015, (adapted from Keon and Pépin 2009).

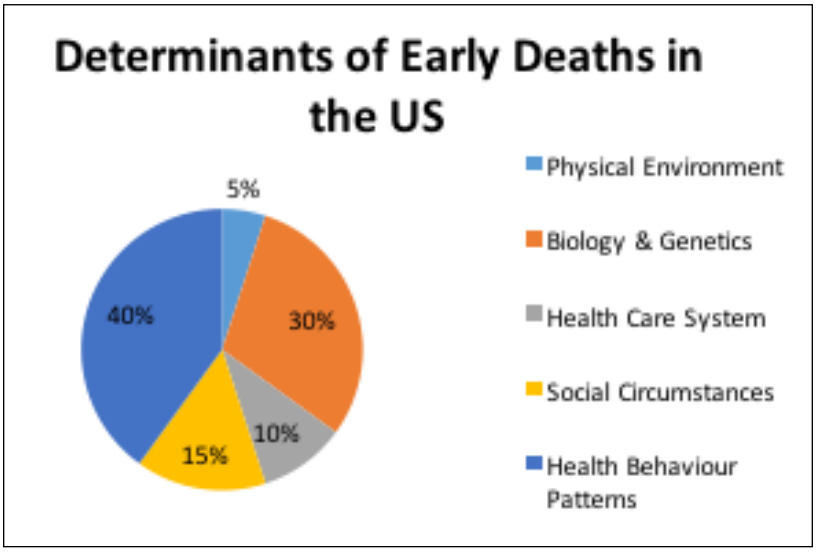

Figure 2. Determinants of early deaths in the US. Source: May and May, 2015; (McGinnis, Williams-Russo and Knickman 2002).

Potential Degradation in Health

The development and expansion of a large-scale hydraulic fracturing industry, as envisioned in Section 9 could lead to degradation in some aspects of the physical and social environments. It is in these areas where citizens have expressed a high degree of concern. There is a substantial literature consisting of research studies, commentaries and opinions that has indicated that in various other jurisdictions there might be associations between the presence of a hydraulic fracturing industry and adverse environmental health effects in the population. Information on studies and commentaries can be found in many sources, for example, Atherton et al. (2014); Chief Medical Officer of Health,

New Brunswick (2012); Council of Canadian Academies (2014); Department of Health, New York State (2014);Hays and Shonkoff (2015); Intrinsik Environmental Sciences Inc. (2015); Long et al. (2015); Maryland Institute for Applied Environmental Health (2014); Public Health England (2014); UK Task Force on Shale Gas (2015); Werner et al. (2015). As noted, studies from other locations can point to potential factors that might adversely affect health, but the risks that are associated with those potential effects will be dependent on a variety of local conditions and practices. In a section below we will attempt to extrapolate some information from other locations to give some tentative estimates of local health risks, but it is important to keep in mind that the estimates are uncertain because the necessary local information is not known. The higher quality studies do suggest that there is a need for vigilance, good regulations, proper practice and effective monitoring to minimize potential health risks if a hydraulic fracturing industry proceeds.

Potential Beneficial Effects on Health

Factors considered to have a large impact on health are health services (the health care system), and the direct and indirect effects of income. Many years of study have shown that there is a direct relationship between personal or family income and health status (see May and May, 2015). The full impact of income cannot be easily assessed because it also has an indirect effect on a number of the other determinants such as social circumstances, education, employment, early childhood development, housing and personal health practices. Therefore, income has a disproportionately large influence on health (see May and May 2015 for a more extensive discussion of the effect of income or wealth on health status). Employment income generally leads to better long term health outcomes than income from social support systems. The issue of income inequality emerges in many studies as being an important influencer of health (e.g., May and May, 2015; Commission on the Social Determinants of Health, World Health Organization (2008); de Oliveira (2009); Luo et al. (2006); Robert Wood Johnson Foundation (2011)). One perspective on the effect of income and income disparity on health or illness is provided in Figure 3 below that shows the amount of diabetes in different income groups in the Canadian population. It can be seen that Canadians in the lowest income range were 2.8 as likely to have diabetes as those in the highest income bracket.

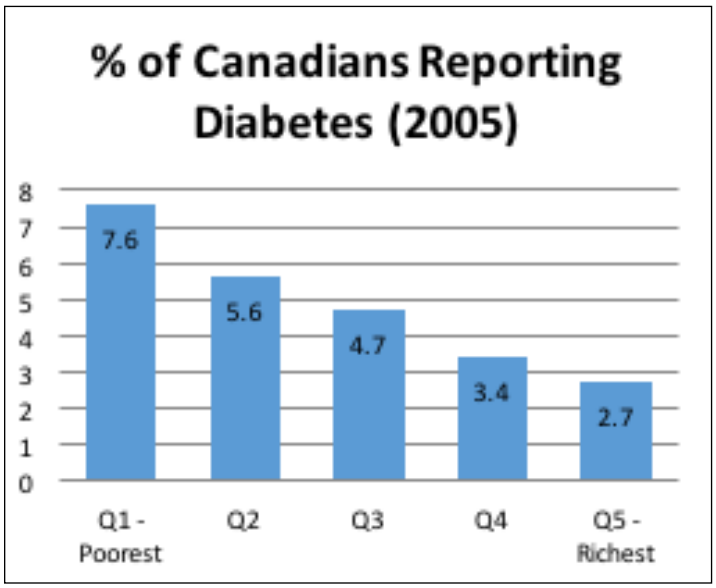

Figure 3. Prevalence of diabetes by income quintile. Source: Reproduced from Keon and Pépin, 2009.

In addition to the direct influence on health status associated with increased income for individuals or families there can be an indirect health benefit arising from income accruing to communities and the Province in the form of royalties and taxes. Communities and the Province would be in a position to make additional investments in services that are health promoting, such as improved health care, better educational opportunities, or other socially and health enriching opportunities.

INDICATORS OF HEALTH IN THE REGION

It is well to appreciate the current state of health in the Port au Port region where a hydraulic fracturing industry might be undertaken. Impacts, both positive and negative, would be most immediately felt by people around the Bay and surrounding area. This section will describe health and population characteristics for Local Area 37 as presented in the Community Accounts of Newfoundland and Labrador. Local area 37, Stephenville-Port au Port, includes Black Duck, Cold Brook, Fox Island River-Point au Mal, Gallants, Georges Lake, Kippens, Mattis Point, Noels Pond, Port au Port East, Spruce Brook, Stephenville, Stephenville Crossing and the Port au Port Peninsula. The information, summarized from the Newfoundland and Labrador Community Accounts (nl.communityaccounts.ca), includes the latest available indicators from 2011 and 2014.

Demographic and Financial Data

Before addressing direct health indicators it is worthwhile noting some significant socioeconomic indicators because they reflect directly or indirectly on health status. The population of the local area was 15,920 in 2011, the number having declined by 0.4% in the previous five years while the population of the Province increased by 1.8%. In local area 37 the percentage of the population who are over 65 years of age increased by 80% (from 10% to 18% of the total population) over the previous 15 years, presumably due to aging of the long-term residents plus in-migration in the older age group. The ratio of people over 65 to those between ages 15 and 64 has also increased by 80%, indicating that the "working age" population has remained relatively steady while the over 65 group has gone up. The employment insurance rate is 36% which ranks 15th highest out of 79 local areas in the Province. The rate of income support benefits, at 17.8%, and percentage of low income families, at 21.4%, place the Stephenville-Port au Port area among the most dependent on such supplements (3rd from the bottom of all local areas in both cases). Those who have a high school diploma or higher level of education make up about 70% of the population between 18 and 64 while those with a bachelor's degree or higher account for about 10%. These proportions place the local area in the top third with respect to level of education out of all local areas of the Province.

Health Status Data

Only 53% of the people in the local area rate themselves as having excellent or very good overall health status and about 20% rank themselves as having quite a bit of or extreme life stress. Both these levels are among the lower estimates of health status in the Province (60th of 79 and 57th of 61, respectively). On the other hand, 93% of people indicate that they are very satisfied or satisfied with life in general, placing local area 37 in the 10th highest position among all local areas with respect to the population's sense of well-being. The latter finding seems somewhat anomalous with respect to some of the other observations, and it might suggest that there are some special characteristics of the population that are not captured in the indicators noted above.

There are no striking differences in the incidences of the more common illnesses among the population of local area 37 in comparison to those in other parts of the province (Newfoundland and Labrador Community Accounts; May and May, 2015). In a few cases the incidences appear to be low, which might reflect special population characteristics, or they might just be due to random measurement effects in small populations over short time frames. The latter influence seems more likely.

Hospital usages for treatments of various conditions in local area 37 are not substantially different from most other parts of the Province (see table below). The data are for 2013 but they reflect similar patterns over the past decade or more.

Table 1. Hospital usage for Stephenville-Port au Port (S/PAP) and the Province in 2013.

	TOTAL NUMBER OF PATIENTS IN HOSPITAL		AVERAGE DAYS IN HOSPITALS	
Condition	**S/PaP**	**Province**	**S/PaP**	**Province**
Total admissions	2125	55,600	9.8	8.2
Circulatory system	245	6535	10.2	10.2
Digestive system	175	5550	8.7	6.5
Respiratory system	165	5005	9.0	8.9
Genitourinary system	140	3330	7.8	6.0
Injury and poisoning	140	3715	10.2	9.8
Cancer	155	3925	10.9	9.2
Mental disorders	250	3165	*Not available*	

Some of the low estimates of self-assessed health and the high level of stress noted in the surveys appear to be at odds with sickness as seen in the morbidity rates as reflected in hospital utilization rates. The former indicate a more distressed population and one might expect this to be reflected in increased hospitalization rates to some extent. The morbidity and hospitalization rates, however, show little difference from the rates in other parts of the Province. The apparent discrepancy might have arisen because of effects of small samples. But it is equally, possibly more, likely that the discrepancies are due to self-assessed health status being more highly influenced by overall mental health status than are the morbidity data.

On the other hand, there is some concordance between the low self-assessed health status in the local area and high dependency on income assistance (employment insurance, income support benefits) plus the relatively high proportion of low income families.

The fairly high sense of well-being in the population might be positively influenced by state-supported income supplementation, and access to some benefits of a rural or semi-rural environment that allow for supplementation of income plus positive social and family factors not measured readily by the indicators.

Health of Children

Children, especially those in the perinatal and early childhood stages of life, are most vulnerable to the negative and positive influences in their environments. Therefore, some comments on characteristics of this subpopulation in local area 37 are in order. The total birth rate in local area 37 in 2013 was 7.2 live births per thousand people. This was 11 % below the previous year in the region and was 18 % below the provincial total birth rate. These differences likely reflect the high number of older adults who are no longer in the child bearing age.

Additional perinatal data was not available for the Stephenville-Port au Port local area. Some information on perinatal parameters has been provided for the Western Health Region for the period 2010-2012 by the Newfoundland and Labrador Centre for Health Information: (nlchi.nl.ca/images/PDFs/Live%20Birth%20Trends%20%202006-2010%20Dec%205%202011.pdf). There were 204 live births in that period with a mean birth weight of 3.4 Kg. The percentage of infants per year who were small for gestational age (the smallest 10% at any given gestational age) was 4.2%. The incidence of low birth weight (birth weight of <2.5 kg, usually at full term) was < 5% per year was not substantially different from that of the Province as a whole, which was 5.9% in 2013. The rate of premature birth was <5% per year in the period recorded, and the number of babies with one or more congenital birth defects was also < 5% of the total per year.

Being born prematurely or at full term but with a low birth weight can be associated with adverse effects in utero. Sometimes these conditions are associated with slower development in the early life stages of these children, and in

some cases some negative health effects persist throughout life. Most children in these categories, however, seem to "catch up", and it is not easy to show dependencies into later life.

General Observations

While there are no specific higher incidences of physical illnesses in the Stephenville-Port au Port area over those in the rest of the Province, the self-assessed health indicators and the high level of reported stress suggest that health status is not as robust in the region as it is in the rest of the Province. The economic indicators suggest that an increase in the economy and, more specifically, increases in income and reduction in income disparities would have the potential for positive impact on the health of the population. Such an effect would be expected to be most positive in early childhood, and lead to better long-term life outcomes.

POTENTIAL POSITIVE EFFECTS OF OIL AND GAS DEVELOPMENT ON HEALTH – POTENTIAL BENEFITS

Many studies have found associations between health status and factors such as income, education level, social status, and state of employment (May and May 2015). One can infer from these studies that if unconventional oil and gas development were to proceed in local area 37 and a significant amount of income were to accrue to individuals and communities in the region, that there would be ensuing benefits to the health of the population. May and May (2015) provides a more detailed analysis of the information from studies that have shown relationships between health and income, and it places these findings in the context of Newfoundland, and particularly, the Stephenville-Port au Port area.

As can be seen in Figure 3, there is a 2.8-fold higher likelihood of having diabetes if a person is in the lowest income group in comparison to those in the highest income group. These types of relationships have been found in other jurisdictions for a number of health conditions (see, e.g., Commission on the Social Determinants of Health, World Health Organization (2008); de Oliveira (2009); Luo et al. (2006); Robert Wood Johnson Foundation (2011)). In other locations positive associations have also been found between income, and self-assessed health and general sense of well-being. These relationships are described in May and May 2015 and the references therein. Although such studies are not available for Newfoundland and Labrador there is no reason to expect the Province to be different from the many other areas that have been studied and yielded similar results for different diseases. Income disparities have also been found to influence population health negatively (e.g., May and May, 2015; Commission on the Social Determinants of Health, World Health Organization (2008);De Oliveira (2009); Luo et al. (2006); Robert Wood Johnson Foundation (2011)). This has been a relatively consistent observation – that those in the lower income ranges have the most adverse health conditions, but they are the groups that can most likely be positively influenced by increases in income. The demographic and financial data that are summarized above for Stephenville-Port au Port indicate that earned income is generally low, and various sources of state-provided assistance are in place that help raise overall family incomes.

There is reason to expect that increases in employment income and associated family income could facilitate improvement in health status. There is also reason to expect that availability of additional revenue for communities would lead to increased public services that include health care and other health-promoting activities. An example of such an activity might be the provision of more enriching environments and experiences for young children.

To ensure that potential health benefits are realized from resource development there must be an expectation and assurance that from the onset there would be a significant number of local people employed, especially in highly-skilled, better paying jobs. That would imply that an effort must be undertaken in skills training. In addition, revenue must flow to the communities affected over the full term of the industry so that communities can provide services that lead to a better quality of life and that predispose to increasing health status.

A simple example of how this effect could be felt by individuals and families might be drawn from the early childhood subpopulation. Stress on mothers from dealing with provision for children in the face of low income can negatively influence fetal development and birth outcomes. Alleviating financial stress could improve birth outcomes, and provide for a better start in life. In a similar vein, an increase in disposable family income could enable the provision of enriched environments such as the quality of nutrition and positive childhood experiences that will lead to healthier development, to the benefit of the children and that of society.

Should additional income derived from development flow to local area 37 it is anticipated that there will be medium to longer term positive effects on health. It is relevant that in the local area there is a high dependency on employment insurance and social assistance and that there is a high proportion of low income families. Those in the lower income brackets are more likely to gain greater health benefits over time from income increases. From the perspective of health benefit it is important that income does flow to that group. Those same people are also likely to be the most vulnerable to negative effects of development. Provision must be made to mitigate against these negative outcomes. Revenue flowing to communities could lead to direct positive health benefits. For example, increased community or government revenue might be used to improve water and sewer facilities that would directly and indirectly improve health. Provision of childhood enrichment services and better educational facilities as a result of more community revenue will have a positive influence on health status.

However, the potential for development of the hydraulic fracturing industry to enable positive health effects as discussed above will be realized only if income and wealth generation is incremental to, and not displacing, income and wealth from some existing industry, such as fishing or tourism.

POTENTIAL NEGATIVE EFFECTS OF DEVELOPMENT – POTENTIAL RISKS

Citizens have expressed a high degree of concern about potential negative effects on health that might be associated with a large-scale hydraulic fracturing industry. There is a substantial body of published papers, opinions and commentaries that have addressed the risks potentially associated with the industry. Much of this literature has been discussed in documents from other advisory bodies and in many review papers (e.g., Atherton et al. (2014); Chief Medical Officer of Health, New Brunswick (2012); Council of Canadian Academies (2014); Department of Health, New York State (2014);Hays and Shonkoff (2015); Intrinsik Environmental Sciences Inc. (2015); Long et al. (2015); Maryland Institute for Applied Environmental Health (2014); Public Health England (2014); UK Task Force on Shale Gas (2015); Werner et al. (2015)). Many studies have suggested that there might be negative health effects, whereas a smaller number have not found such evidence. As noted by Council of Canadian Academies (2014) and in Werner et al. (2015) there are relatively few papers that have directly measured health status in populations in direct correlation with hydraulic fracturing and associated potential toxicants.

One should not invoke the paucity of direct evidence for effects at this time as being evidence for a lack of effect. The implications from other studies indicate that this area should be approached with caution.

Risk and Benefit

The risk or benefit associated with a situation is defined by two factors. The first factor is the magnitude or consequence of an effect, that is, the impact of the activity or its outcome, and the second is the likelihood or probability of that situation or activity occurring. Risk or benefit is estimated as a combination of those two parameters. In formal risk assessment these relationships are defined and measured, although in some cases neither parameter can be measured precisely. For most citizens the two factors are inherently acknowledged but their specific relationships are not formally assessed. As we think about potential adverse effects, it is worthwhile keeping in mind that we often learn about the magnitude of toxic effects in humans from adverse events that have occurred through occupational hazards or accidents where there have been high levels of exposure to toxic materials.

Environmental exposures are usually lower than those found in those former situations, but they can occur over long periods. We do not always know much about exposure to very low doses over a long period or about the effects of exposures to multiple toxicants. Risk assessors deal with these issues with caution in the absence of specific data. Often, the human toxic dose of a material is not known. We can learn about toxic effects through studies on cells and animals, but neither of these approaches fully reflect the human situation. Usually when risk assessors are trying to estimate human toxic doses based on animal studies they will divide the lowest toxic dose in an animal by at least 10 in setting a cautionary toxic level for humans. If toxic doses are established using isolated cells, even more cautious lower doses are recommended for human exposures. This is all to say that we need to be circumspect in assessing risk from environmental exposure to potential toxic materials, and not be led to be overly cautious or overly cavalier about potential effects.

While some estimation of risk and benefit can be made in advance of a project by carrying out a health impact assessment, the actual levels will depend on the local physical, social and operational situations. Thus, baseline and ongoing monitoring will be essential in any development allowing for updating of risk and benefit levels followed by appropriate adjustments in regulations and operations.

Toxicants

Much of the discussion concerning potential negative effects of hydraulic fracturing arises because of concern that agents in the fracturing fluids and additional materials that are released underground can have toxic effects on animals and people. While steps are taken to contain these fluids for subsequent treatment and disposal, people express concern about spills, leaks or emissions that might contaminant water and air. Potentially toxic substances could be released through accidents during transport or during containment of input and output fluids (so-called flowback and produced fluids). Many of these potential toxicants have been listed in prior publications, but ultimately the full scope of the materials will be process and site specific. As the hydraulic fracturing industry has matured, regulators have required, and more responsible operators have taken steps to reduce use of more toxic materials and to improve containment, treatment, and transportation, and thereby to reduce both the magnitude and probability of adverse effects.

In considering the influence of a toxicant it is important to consider a number of factors:

- how toxic is the material per unit of weight;
- what amount of material (dose) has been delivered to the affected person;
- at what time in life has the toxicant been present;
- how long has there been exposure to toxic material (also determines dose);
- is the toxic material present by itself or in the presence of other toxic or anti-toxic materials; and,
- is the individual regularly exposed to other drugs or toxins (e.g., from smoking)?

Only the first of these questions can be answered with data from other sources. The remaining questions will only be fully answered through rigorous monitoring of the local situation.

Appropriate treatment and disposal of waste fluids are necessary to protect health and the environment. Ensuring that this is done safely and effectively will be a significant charge for the industry and the regulator.

As we consider the effects of environmental toxins on health we need to recognize that the magnitude of their effects are often small in comparison to effects due to other conditions over which individuals have personal control such as smoking, diet, behaviour and other social factors.

Formal Studies

The majority of the studies on the potential impact of the hydraulic fracturing industry have suggested that there are or will be negative impacts on human health, although a small proportion have found no substantial effect from the agents under consideration. Sorting out opinion, inference, and fact in the multitude of studies is not easy. As noted above Werner et al. (2015) and PSE Health Energy (2015) have attempted to deal with this issue.

Various types of studies have been done. Toxicological studies in animals that have shown cause and effect relationships have led to implied effects in humans. Measurements of various toxicants and possible toxicants in air and water in the vicinities of unconventional oil and gas wells or near conventional wells have been used to invoke potential adverse effects on human health. Studies that correlate the presence of potential toxicants with negative influences on human health have also been undertaken. Because it is difficult to establish the dose in an environmental exposure and to assess the impact of exposure to multiple contaminants, some studies have used the distance from an exposure or the number of nearby exposure sources as proxies to estimate these effects in human studies. All of these studies require that a host of proper baseline or control conditions be examined or accounted for so that the outcomes of the studies are valid.

Werner et al. (2015) used a systematic methodology with a structured set of selection criteria that are based on the quality of the science and the pertinence to unconventional oil and gas development to arrive at the conclusion that fewer than 10 papers were highly relevant to the issue. This finding is in keeping with the observation of the Council of Canadian Academies (CCA) that there was a dearth of highly relevant publications on the health effects of hydraulic fracturing and associated industrial activity.

Peer Review

The best available method used by scientific and medical communities to increase the reliability and validity of research reports and studies is to ensure that independent experts review the way in which the studies are done and comment on the validity of the conclusions drawn. That process is not without its own flaws occasionally, but it is the best way the scientific community and society have to ensure the validity of findings and the rigor of their interpretation. It is used by all the best scientific and medical publications and by bodies such as the Council of Canadian Academies.

It is important to avoid giving credence to biased or poorly-designed or poorly-conducted studies because of the great impact the outcomes and conclusions can have on policy and human health. Studies that have not been subjected to independent peer review should be regarded with suspicion. Even peer reviewed studies might have had flaws in design or interpretation that the reviewers did not see. Studies that look at similar questions will have different results depending on the study design and other aspects of the research. There are many confounding factors in studies of the influence of environmental toxicants on people. Most studies have not accounted for all the confounding factors. Peer reviewers will sometimes require that the shortcomings be acknowledged in a publication, and that can alert a reader to confounding factors that have not been taken into account. Unfortunately, not all reviewers are themselves free from bias.

Peer-reviewed studies are not all free from bias or errors, so output requires ongoing critical review. The ultimate test of reliability of any study is whether it and its findings can be replicated in a separate study carried out by different independent investigators. It is acknowledged that this presents substantial difficulties for citizens who are not experts as they try to make sense of what can sometimes appear to be conflicting conclusions and recommendations.

Bias or inadequate design or other errors in studies will often be recognized and corrected only in retrospect. A common approach used in clinical medicine and public and environmental health is to assemble groups of experts to draw some consensus perspective on the issues. But the field of hydraulic fracturing is relatively new, and the body of scientific work that is highly relevant and of high value is as yet small, as noted by the CCA and Werner et al. (2015). Governments and citizens need to seek advice from trusted unbiased experts on how to interpret the ongoing production of scientific information.

Study Design

It is difficult to answer all questions for exposures to individual and combined toxic materials under controlled circumstances, let alone in field circumstances. As noted, some researchers have employed distance from a wellsite or drilling pad or the density of wells around an individual's residence as a proxy for dealing with the issues of dose and combinations of potential agents. The assumption is that those living closer to a source of a toxic substance will receive a higher dose over the same period of exposure than those who live farther from the source.

Some studies have been reported that have relied on recall of data by subjects. Such studies can be suspect in that experts are aware of substantial recall bias among subjects on the one hand, and very poor memories on the other (e.g., Raphael, 1987).

It is well to remember that, to date, studies have shown possible associations (or lack of associations) between potential toxicants and adverse health effects. Definitive cause and effect relationships have seldom been shown, as they usually require more expensive and longer term studies than have been undertaken to date. Cause and effect has been strongly implied from some studies in occupational exposures and in animal studies, but the results need to be extrapolated carefully to other situations such as various lower-level environmental exposures. In the longer term, one expects that some of these cause and effect issues might get resolved by studying the same group of people over a substantial period of time, through what are termed longitudinal cohort studies.

An additional consideration necessary to assess the information contained in many of the studies arises from the propensity to report or to comment upon findings in terms of relative or percentage changes. Without knowing what the actual measures are, it is difficult to interpret such statements in terms of real day to day impact. Better studies will contain the actual measurements.

Some Recent Studies – What They Might Imply for Stephenville-Port au Port

It could be helpful to our understanding of potential impacts of fracking if a few recent findings in other jurisdictions were to be extrapolated to the Stephenville-Port au Port area. It is emphasized that a high degree of caution is necessary in doing this because the nature of hazards and the impacts of fracking activities will be dependent on the geographical location and the processes used. For example, the shale formations are different in western Newfoundland from most of the other North American formations. The hydrocarbons expected from the shales are different. In Pennsylvania mostly "dry" gas (mostly methane with some other higher hydrocarbons) is recovered. In the Green Point Shale the expectation is for oil with a small amount of gas components. The atmospheric conditions will differ from place to place. Processes employed in hydraulic fracturing have been evolving towards better, less risky operations over the last decade. With those caveats we will extrapolate some recent results to the Stephenville-Port au Port area so that the reader might have a rough appreciation of what these results might imply for the local population.

In a well-cited study on birth outcomes near natural gas developments in rural Colorado, McKenzie et al. (2014) found negative effects of proximity to gas wells on congenital heart defects and neural tube defects. McKenzie et al. used large state databases to do a retrospective examination over the period of 1996-2009 of the proximity of mothers' homes to natural gas wells and birth outcomes. The authors compared births to mothers who lived within 10 miles of one or more wells to those who lived more than 10 miles from a well. They found that there was an increased occurrence of congenital heart defects and neural tube defects when there was a density of 125 gas wells within one mile of the mother's home in comparison to those who lived over 10 miles from any wells. The prevalences (number over the time studied) were increased by 30% for congenital heart defects and 100% for neural tube defects in comparison to those over 10 miles from wells. The actual numbers went from one birth out of 74 being a case with a congenital heart defect when the mother had no wells within 10 miles to one birth in 55 when there was a density of 125 gas wells within a mile. The Stephenville-Port au Port area has a rate of congenital heart defects of about 1.7 per

year, and that would increase to 2.25 per year for a group of mothers living with 125 gas wells within one mile. A similar extrapolation of neural tube defects would lead to the estimate for the local area of one case of neural tube defects per 20 years in normal circumstances to one case per 10 years under the high exposure conditions. There were no significant differences in the prevalences of cleft palate.

The same study found two unexpected positive influences of fracking: the number of preterm (premature) births was lower for the group closest to wells in comparison to those furthest away, and the average birth weights were higher among the most exposed group. These unexpected findings were statistically significant as were the effects on birth abnormalities noted above. The decrease in the occurrence of prematurity (10%) was large enough to warrant further study. The increase in average birth weight was not likely clinically significant, up to 24 grams on the basis of an expected average birth weight of 3.5 Kg. Of course, it cannot be discounted that the small change in birth weight is indicative of some as yet unknown effect in a subset of the population. At this point it is hard to give good explanations for these unexpected findings, other than they might be quirks of the population, or there might have been failure to account for all confounding factors in the study design, even though a strong effort was made to account for such factors.

In another recent study based on administrative data in Pennsylvania, Stacey et al. (2015) also investigated perinatal outcomes in southwestern Pennsylvania where there have been substantial unconventional natural gas operations. Those authors also examined the perinatal effects with respect to the density of wells near the mothers' homes. They found that the rate of prematurity did not vary with proximity to gas wells. In contrast to McKenzie et al. (2014) these authors found a small decrease in birth weights of babies born to mothers who lived closest to wells. Again it is difficult to ascertain the clinical significance of the small difference in average birth weights (about 120 grams with respect to an average overall birth weight of 3.3 Kg. As noted above, there might be some unknown influence on the broader population or a subset of the population that accounts for the lower birth weight. If the lower birth weights were more prevalent among babies at the lower end of the weight distribution there could be more substantial effects that last into later life. Further information would be needed to examine this possibility. There was a proximity (proxy for dose) dependent relationship for newborns in the group that were classified as small for gestational age. When mothers had been in the most exposed group, the incidence of babies who were small for gestational age was 6.5%, whereas the rate was 4.8% for least exposed mothers. That change was not only statistically significant, but it might have clinical significance in the population. The incidence of small for gestational age infants in local area 37 is not known. Assuming that it is the same as for the Western Health Region of 4.2%, and that the effect found in Pennsylvania applies to the Stephenville-Port au Port area the rate of "small for gestational age" babies would be expected to rise to 5.7%. That would translate to about one additional baby being born with low birthweight each year if the exposures were equivalent to those in Pennsylvania.

Estimates have been made by McKenzie et al. (2012) for environmental risks of many volatile compounds that might be released into the air through fracturing and well operations based on data from sites in Colorado. Consider the case of benzene which is well-documented as a human carcinogen. The authors found that if one lived within 0.5 miles of a well site the cancer risk from exposure to benzene was calculated to be 60% higher than if one lived more than 0.5 miles from a well. The actual likelihood of getting cancer from benzene exposure for those living over 0.5 miles from a well was calculated to be 5.4 in a million and a 60% increase raises the actual likelihood to 8.7 in a million. For the population of local area 37 that would mean an extra number of cancer cases of about 1 in every 50 years. This number is not meant to try to minimize risks but to highlight the need to examine all data in detail, and particularly to be careful about interpreting changes that are given as percentages. There are many other potential volatile contaminants that might come into play, and need to be considered also. But all need to be regarded with proper scrutiny and perspective.

One must also consider that physical and social factors vary from region to region and jurisdiction to jurisdiction, and extrapolation between different areas needs to be done cautiously. For example, the family, social, financial and health care support systems that are present in Stephenville-Port au Port might bolster the environment in favour of positive health effects more so than might occur in some jurisdictions in the United States. The physical and chemical

characteristics of the Green Point Shale are different from shales in other places, so effects related to the shales that are seen elsewhere might not be pertinent to the Port au Port area. During the Panel's visit to northeastern Pennsylvania it was observed that wells had been drilled and were still operating in close proximity to family homes, a situation which is unlikely to be permitted in the Port au Port area. Considerations such as local geology and air movements might influence exposures to toxicants in water or air. For example, it is difficult to imagine that the rates of dispersal and dilution of an air-borne contaminant would be the same in a geographic "bowl" in a western state or a valley in Pennsylvania in comparison to the open atmosphere and exposed coast of the Port au Port Peninsula.

Effects Related to Transportation

Transportation of water, chemicals, sand, waste fluids and the hydrocarbons produced present risks to health through potential accidents, leaks of toxicants, noise, and release of exhaust materials. These issues should be dealt with through means of transportation that avoid built-up areas such as by the use of barges, or by upgrading or rerouting roads , using pipelines, or some combination of these approaches. Organization and timing of transport to reduce stress on citizens should be paramount in the development stage of drilling and fracturing wells.

Other Determinants of Health

The discussion above deals mainly with the risk to health caused by factors in the physical environment. This approach was taken because so much of the discussion about the influence of hydraulic fracturing has been cast in the light of these factors.

Other factors that could negatively impose on the overall health of populations need to be considered. These are factors that tend to have accompanied other large scale industrial resource developments such as increases in venereal diseases and increases in violence and are referred to as a "boomtown effect". Others have noted the potential for "boomtown" effects to have a negative impact on health and place increased demands on health and social services systems (e.g., Council of Canadian Academies, 2014; Newfoundland and Labrador Chief Medical Officer of Health, 2105; Chief Medical Officer of Health, New Brunswick, 2012; Nova Scotia Independent Panel on Hydraulic Fracturing, 2015; Storey, 2015; Roman Catholic Religious Leaders, 2015). In the case of local area 37 there could be increased demands on the health care system and stress on residents caused by major traffic increases and other intrusive activities during the development phase of an industrial development. The perception of risk can also cause increased stress and have a deleterious effect on health, especially mental health. The impact of this stress can be mitigated against by ensuring that industry and government are open and transparent about all aspects that impact on people. There are also likely to be increases in local costs for goods and services which could reduce the impact of income gains for some people. These are areas that have been commented upon in other places, but the number of published refereed papers with quantitative analyses in these areas is very small.

It is beyond the scope of this commentary to determine how large a risk to overall health will be presented by these factors in Stephenville-Port au Port, and if the positive effects would outweigh these possible adverse ones. It should be possible to learn from other jurisdictions about ways to reduce the impact that might accompany a boomtown effect. Good public health education and adequate policing would be helpful in this regard. The positive aspect of having the knowledge accrued elsewhere is that if hydraulic fracturing were to proceed, the local area can make use of others' experience to design a system that can avoid or mitigate potential negative health effects while optimizing conditions that promote positive health effects.

A PRECAUTIOUS APPROACH TO MINIMIZE POTENTIAL ADVERSE EFFECTS ON HUMAN HEALTH

Both positive and negative effects on human health could be associated with the development of an unconventional oil and gas industry around Port au Port Bay. The magnitude of positive and negative health outcomes cannot be determined with certainty at this time, but it is important to note that government policy and regulation can have a substantial influence on both. On balance, the record suggests that it should be possible to proceed with a hydraulic fracturing industry in a precautious fashion using adaptive management to respond to changing conditions. The following commentary and associated recommendations have been developed considering the experience of other jurisdictions, input from citizens (Storey, 2015) and officials such as the Chief Medical Officer of Health of Newfoundland and Labrador (2015), and comments and advice from public health and toxicology experts. They provide guidance on a precautious approach with regard to minimizing risk to human health that would be consistent with development of a large-scale hydraulic fracturing industry.

Health Impact Assessment

It is recommended that a full health impact assessment of a large scale hydraulic fracturing be carried out. Any industrial scale development of the Green Point Shale around the Port au Port Bay will potentially have health impacts on the local population. The need for a Health Impact Assessment to be performed in advance of a policy decision to permit activities such as hydraulic fracturing has been put forward from many sources (e.g., Keon and Pépin, 2009; Newfoundland and Labrador Chief Medical Officer of Health, 2015; Nova Scotia Independent Panel on Hydraulic Fracturing, 2015; Allderdice, 2015; Simpson, 2015). Based on the concept that those most likely to bear adverse effects, even if they share in positive benefits, should have influence on the decision to proceed with an industry, a potential development should elicit a formal health impact assessment. In terms of seeking and maintaining a social licence to proceed, conducting a health impact assessment would be a necessary process. Such an assessment requires full consideration of potential benefits and risks with an attendant estimation of the magnitude and probability of both. A health impact assessment, as currently understood, includes the participation of the potentially effected community, industry, government and appropriate content experts. The National Collaborating Centre for Health Public Policy (www.ncchpp.ca/54/Health_Impact_Assessment.ccnpps) provides information and guidance on health impact assessments. A few jurisdictions such as the State of Maryland (Maryland Institute for Applied Environmental Health, 2014) and the Province of British Columbia (Intinsik Environmental Sciences, 2015) have carried out health risk assessments as part of consideration of permitting hydraulic fracturing. These assessments have not considered potential positive impacts on health as would be done in a full health impact assessment.

In a health impact assessment citizens, industry, government and experts need to work together to identify and assess potential benefits and risks, and determine potential means of optimizing benefits and minimizing risks. This cannot be accomplished unless all parties, including citizens, have a good understanding of the processes being undertaken. Public health authorities need to have a voice in these consultations. So a health impact assessment needs to begin with processes of information gathering and learning. Experts will be best equipped to carry out formal estimations of benefits and risks whereas citizens will be able to provide advice on acceptability of possible outcomes as they understand community issues such as overall economic activity and risk tolerance in the community.

It must be emphasized that all those involved in a health impact assessment, including citizen representatives, need to have a good understanding of the industrial processes involved and their attendant benefits and risks, especially as they might apply to the local area. This means that those facilitating the assessment will need to provide a level of education about processes and rationale so that participants can make informed input. There will need to be a high level of trust among all parties to the assessment – citizens, industry, government and experts.

The health impact assessment should be carried out to inform government as well as the local citizenry, but needs to be independent of government. Government, however, will need to initiate and bear the costs of the assessment. The assessment will need to be guided by an individual or group who has an appreciation of the industrial development,

and who has the confidence and trust of government, industry and the community. Subject matter experts can be brought to the process as necessary, and it will be important to find the right mix of representatives of the citizenry. The choices of the consultative group membership and the specific processes need to be in the hands of the agreed leader(s) of the process. Openness to the process and its outcomes by all participants will be essential.

Measuring and Monitoring

It is recommended that a monitoring program for potential environmental toxicants be established in advance of the start of any development and that it operate throughout the operating lifetime of the industry. One of the greatest concerns expressed by citizens and experts is for potential for harm to human, animal and ecosystem health through the release of toxicants during the development and operation of wells. In order to recognize any threat to health that might accompany development and operations it is essential that baseline measures be completed before the onset of development. The Council of Canadian Academies (2014) has commented extensively on monitoring.

Monitoring for toxicants in air and drinking water needs to include compounds that have been identified from studies in other jurisdictions as carrying the greatest risks to health. Measurement of trace amounts of highly toxic metals and radioactive substances should be included. Given susceptibility during fetal and child development with their long term potential consequences, including transgenerational effects, monitoring for a range of endocrine disrupters (e.g., Kassotis et al., 2013) must be included. Environmental public health experts must be consulted on the development of the monitoring plan, particularly in identifying the most egregious compounds that might be expected to adversely affect health.

Monitoring of health status should also occur on a regular basis for early signs of adverse impact that might be evidenced by increased use of health care services and diagnoses by health professionals of conditions or syndromes that arise from environmental causes. Data from the Western Health Region would be central to such surveillance, but it is worthwhile considering more specific monitoring for potentially affected populations. There should be special focus on conditions where associations between increased morbidities and hydraulic fracturing have been found in other jurisdictions. Monitoring for stress which might arise for a number of reasons should be included; this could be done by determination of serum or hair cortisol levels. Particular attention should be paid to the perinatal age group. A more thorough approach would be to establish a representative group or cohort of residents that will be monitored for selective health conditions on a regular basis over the lifetime of the project.

Public health authorities must be involved and the process must be adequately resourced to ensure that it is viable throughout the life of the industry and capable of adjusting to changing situations and new information.

Composition of Fluids

It is recommended that full disclosure of all components in and the volumes of fracturing fluids and waste fluids as well as those in the hydrocarbons produced be made to the Regulator. The Regulator should require that compounds with low potential toxicity be employed. Health professionals must have access to composition data if they have reason to believe that patients might be adversely affected. Proper treatment of patients requires timely access to knowledge of potential exposure. This is an important principle, and needs to be given effect without also adversely effecting companies involved. However, human health should take precedence over company proprietary information, and this should be a condition of licensing.

The Regulator should require ongoing testing and full disclosure of composition of flowback and produced water, being guided by records from other jurisdictions to identify the components to be measured, but recognizing that the full spectrum of tested components will need to be specific to the local shale.

Best Practice to Protect Human Health

It is recommended that during development and ongoing operations of wells all operators and contractors be required to follow the highest level of industry best practice that is pertinent to the local situation. Some of the early work done on the development of fracked wells was carried out by small and inexperienced operators. Even the larger operators were learning in the early stages of the industry. Therefore, many of the reported potential or observed adverse effects on health are based on data that includes a period when procedures and protections were not as good as they are now. While processes have improved in ways that should provide better protection for human health than in earlier work, the Regulator should insist upon and monitor for the use of current approved best practice by operators and all subcontractors.

The Center for Sustainable Shale Development (CSSD) in Pittsburgh was developed out of an extensive two-year multi-stakeholder consultation in Pennsylvania. It is a non-governmental organization supported by and participated in by major international and local environmental groups, major international energy companies, and large regional and international service companies. CSSD is identifying best practices and is working on the development of standards for various practices with a view to developing a possible certification standardization process. Developers and operators of an unconventional oil and gas industry in Newfoundland and Labrador should develop practices and standards by working with other stakeholders in a similar fashion. Public health authorities should be involved in that process. The Regulator should consider requiring operators and service companies to adhere to common standards developed in a similar fashion.

It is recommended strongly that experts knowledgeable in all aspects of public and population health be involved in policy and regulation development from the start of the process. Many of the current challenges to the current industry might have been avoided if experts with appropriate environmental and public health knowledge had been involved in decision making when policies and regulations were developed. This was a remarkable omission in this day and age, and it must not happen in Newfoundland and Labrador. Ultimately much better policy and regulation and much less controversy will occur if environmental and public health experts participate in policy making and regulation development.

It will be essential to train emergency responders to recognize and deal with situations that might occur during fracking and subsequent well operations. It will also be important to improve the ability of regional family physicians and community nurses to be alert to conditions that might develop from exposures to possible toxicants. It is important that any source of negative exposure be pinpointed and rectified quickly.

There are likely to be some other negative effects of large scale industry developing in a small region such as what is sometimes called a 'boomtown effect'. Government and the operators should be proactive before and during development in promoting health education and good health practices to minimize these effects. Active engagement of community support systems including social services and law enforcement should help with reduction of adverse health effects. Again, it is not possible to give an estimate of the magnitude of such an effect in the local area, so good preparation, active monitoring and adaptive management will be necessary.

While processes in the industry have been improving and should lead to better safety and fewer human health hazards in the future, vigilance by the regulator will be necessary to ensure ongoing safety for public health. To ensure that best practices are part of the culture of the various components of the industry, the regulator should consider the environmental and human health safety records of operating companies, as well as their workplace health and safety records, as permits are being issued.

Adaptive Management

It will be important for both the regulator and the operators to practice adaptive management. It will not be possible to foresee all the positive or negative occurrences, so vigilance and responsiveness must be the order of the day. This is most likely to lead to more harmonious relations between operators and the community, and will certainly be required for a continuing social licence to operate.

Realizing Health Benefits

There is potential for population health benefits to accrue to the region over the life of the project if local people and local communities make gains in income and are able to apply them to promote healthy outcomes. It is incumbent on government to ensure that substantial opportunities are afforded for the local population to be trained and employed, and for local communities to develop infrastructure that facilitates better health. While it can be seen that the risks associated with a future unconventional oil and gas development can be mitigated to a level acceptable to many in the population, there would be no incentive to go ahead with industrial development without the counterbalancing and enriching effects of generation of income and potential for improvement in local health conditions.

General Conclusion

By taking a precautionary approach to development in ways such as those outlined above it should be possible to develop a safe, well-managed and productive industry that could serve the region and its people well over the next generation. To maintain community confidence, transparency and timely provision of information must be part of the standard operating procedure for industry and government.

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Distinguished University Professor Emeritus
Departments of Pediatrics, Pathology, Physiology and Pharmacology
University of Western Ontario

Dr. David Butler-Jones
Professor
Department of Medical Microbiology
University of Manitoba
Previous Chief Public Health Officer of Canada

Dr. Bernard D. Goldstein
Emeritus Professor
Environmental and Occupational Health
University of Pittsburgh
Member, United States Academy of Medicine