RAS B-81

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD PANEL
Before Administrative Judges:
Ann Marshall Young, Chair
Dr. Richard F. Cole
Dr. Fred W. Oliver

In the Matter of CROW BUTTE RESOURCES, INC. (In Situ Leach Facility, Crawford, NE)	Docket No. 40-8943 ASLBP No. 07-859-03-MLA-BD01 September 22, 2008

PETITION FOR LEAVE TO FILE NEW CONTENTION RE: ARSENIC

Judge Young, Chair
Atomic Safety Licensing Board Panel
US Nuclear Regulatory Commission

Dear Judge Young:

Pursuant to 10 CFR Section 2.309(f)(2), Petitioners WNRC respectfully requests that the presiding officer in this Proceeding grant leave to Petitioner to file a new contention based on the connection between low-level arsenic in the water resulting from Applicant's ISL uranium mine and failures of the pancreas including diabetes and pancreatic cancer in the people living near the mine.

This information was assembled beginning on or about August 20, 2008 when a new study by the Johns Hopkins Bloomberg School of Public Health was published in the Journal of the American Medical Association, an abstract of which is attached as Exhibit A hereto (the "Johns Hopkins Study")[1]. The Johns Hopkins Study shows that low level

[1] Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults, Ana Navas-Acien, MD, PhD; Ellen K. Silbergeld, PhD; Roberto Pastor-Barriuso, PhD; Eliseo Guallar, MD, DrPH;

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exposures of inorganic arsenic in the water such as that resulting from ISL uranium mining increases the risk of Type 2 Diabetes in adults. Diabetes is already an epidemic at Pine Ridge Indian Reservation reported to be 800% higher than the national average.[2] A related article in the same issue of the Journal of the American Medical Association states that diabetes is the seventh leading cause of death in the United States and complications from diabetes profoundly affect the quality of life and contribute to high morbidity and mortality.[3]

Section 2.309(f)(2) specifically provides that new contentions may be filed after the initial filing only with leave of the presiding officer upon a showing that—

> (i) The information upon which the new contention is based was not previously available;
>
> (ii) The information upon which the new contention is based is materially different than information previously available; and
>
> (iii) The new contention has been submitted in a timely fashion based on the availability of the subsequent information. 10 C.F.R. §2.309(f)(2).

APPLICATION OF SECTION 2.309(f)(2) TO OUR FACTS

First, it should be noted that arsenic is referenced in the Petition in this case as one of the groundwater contaminants of concern. See Petition at p3, paragraph (5) and paragraph (7); and p7, paragraph (c). Arsenic is also mentioned as the reason for the closures of 98 wells at Pine Ridge Indian Reservation. Id. at p3, paragraph (7). Diabetes was not referenced in the Petition but was mentioned during the January 16, 2008 Oral

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Journal of the American Medical Association (August 20, 2008) (Vol. 300(7):814-822). http://www.jhsph.edu/publichealthnews/press_releases/2008/navas_acien_arsenic.html.

[2] See, e.g., http://www.backpacksforpineridge.com/Stats_About_Pine_Ridge.html.

[3] Environmental Arsenic Exposure and Diabetes, Molly L. Kile, MS, ScD; David C. Christiani, MD, MPH, MS; Journal of the American Medical Association (August 20, 2008) (Vol. 300(7):845-46).

Arguments in the remarks of Chief Joe American Horse. Transcript at 129 ("I am a diabetic...we have diabetics. I don't know where it came from.")

The Application admits that arsenic is rising in the Brule Aquifer. Petition at p13 (re: ER Table 3.4-15) and these are part of Petitioners' environmental and safety contentions in this case. See Petition at p15 ("the returned water is geochemically different and contains high levels of arsenic and continues to have higher than natural concentrations of radioactivity.")

As this case has progressed, more has been learned about the connections between Applicant's ISL uranium mine in the Chadron Aquifer and the release of arsenic and related health impacts to the people living nearby in the form of diabetes and pancreatic cancer.

(i) New Information Not Previously Available

On or about August 20, 2008, Petitioners became aware of the Johns Hopkins Study and the connection between arsenic in the drinking water and adult onset of Type 2 diabetes. On or about August 28, 2008, WNRC Attorney David Frankel became aware of a high incidence of pancreatic cancer in Chadron. See Affidavit of David Frankel, filed herewith, at paragraph 3. WNRC Attorney Frankel left a message with one of the cancer suffers, Mr. Watson, but failed to reach him. Based on information and belief, there are at least seven (7) cases of pancreatic cancer in Chadron[4] which has a population of 5,208[5] which is about 20 times the national average of 11.5 cases per 100,000

[4] Including Messrs. Daniels, Hageman, Trafinigan, & Watson; Frankel Affidavit at paragraph 3.

[5] See http://www.bestplaces.net/city/Chadron-Nebraska.aspx ("as of 2007, Chadron's population is 5,208 people.")

Americans.[6] See US National Institute of Health National Cancer Center at http://seer.cancer.gov/statfacts/html/pancreas.html; During discovery, the parties can ascertain the exact status of these cases several of which resulted in the death of the cancer patient. Upon information and belief, the families of each of the victims are available for testimony in Chadron.

(ii) Materially Different Information

Although Petitioners became aware of the connection between the oxidizing impacts of Applicant's ISL mining and the release of arsenic, it wasn't until July 25, 2008 that Petitioners became aware of the 1982 Baseline Study. See, Baseline Hydrogeochemical Investigation in a Part of Northwest Nebraska, A Report Prepared for the Nebraska Department of Environmental Control; starting at page 126 of the July 28, 2008 Petition (Renewal) at ML082170525 ("the 1982 Baseline"). The 1982 Baseline shows that Arsenic levels increase in an oxidizing environment such as that intentionally created by Applicant's mining activities. The 1982 Baseline concludes in part that:

> "Arsenic levels exceeded the MCL of 50 ppb in only one well water...." Id. at ii.
>
> ***
>
> "Arsenic levels were quite variable but showed a generalized increase in older **oxidizing** formation waters. This is demonstrated in a trend towards higher average As concentrations in lower Brule and upper Chadron formation waters than in either the Brule or Arikaree waters....**Therefore, in slightly oxidizing environments such as those reported in the upper Chadron and lower Brule where there are occurrences of relatively high arsenic levels in the sediments, the groundwater could become enriched in As.**

[6] Statistically, Chadron should have no more than 0.60 cases of pancreatic cancer in its population.

> Arsenic levels exceeded the maximum contaminant level (MCL) of 50 ppb in only one well. **Thus in terms of the water quality, arsenic is not of particular concern in the groundwater of the investigated area.**
>
> Id. at 52 (emphasis added.)

***

> "Slightly elevated As and Mo appeared in #649 which is believed to be a spring originating in the Chadron formation. Highest concentrations of pathfinder elements result from a relatively high component of White River Group seepage in the base flow of the creeks.
>
> Id. at 55.

***

The connection between Applicant's ISL mine and the high levels of Arsenic (As) in the water are revealed by the fact that Arsenic was said in 1982 not to be a problem and is now a problem. *Res Ipsa Loquitor*; See Petition at p3, paragraph (7). Further, the high incidence of pancreatic cancer in Chadron indicates that the mine's operations during the past 20 years have severely and negatively impacted the water quality through the release of measurable levels of Arsenic. The Arsenic is released due to the oxidizing of the Uranium by Applicant's mining operations. Such levels of Arsenic have adversely impacted public health particularly causing ailments associated with the pancreas such as diabetes and pancreatic cancer. These connections were not fully known until on or about August 28, 2008 and this information taken together constitutes materially different information than what was previously known to Petitioners when the initial Petition was filed in November 2007.

(iii) Timeliness of Filing

Petitioners understand that general NRC practice is that new contentions are to be filed within thirty days after the new information is received. See Judge Young's

remarks during July 23, 2008 Oral Argument, Transcript at 425-426. Further, Petitioners understand that NRC practice is to file the petition for leave and the new contention at the same time. The thirty day period should not start until August 28, 2008 when the information was received concerning the high incidence of pancreatic cancer in Chadron. Accordingly, this Petition for New Contention is timely filed on September 22, 2008.

ADMISSIBILITY OF CONTENTION

If the Presiding Officer grants Petitioners leave to file a new contention related to Arsenic as described above, such contention should be admitted under Section 2.309(f)(1) which requires that Petitioners:

> (i) Provide a specific statement of the issue of law or fact to be raised or controverted;
> (ii) Provide a brief explanation of the basis for the contention;
> (iii) Demonstrate that the issue raised in the contention is within the scope of the proceeding;
> (iv) Demonstrate that the issue raised in the contention is material to the findings the NRC must make to support the action that is involved in the proceeding;
> (v) Provide a concise statement of the alleged facts or expert opinions which support the requestor's/petitioner's position on the issue and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the requestor/petitioner intends to rely to support its position on the issue;
> (vi) Provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact.

For these purposes, the facts and contentions raised in the Petition are incorporated herein by this reference, including the specific references to the Application. Accordingly, the findings of the Board in LBP-08-06 support the findings that this new contention is within the scope of the proceeding, is material to the findings that NRC must make to support the action involved, may be based on a plausible fact-based

argument, and constitutes a genuine dispute with Applicant.

For this new contention, it is only necessary to provide a specific statement of the issue to be raised under (i), a brief explanation for the contention under (ii), and a concise statement of the alleged facts supporting Petitioners' position on the issue and on which Petitioners intend to rely at the hearing under (v).

Under (i), the issue raised by this new contention is that Arsenic being released by the oxidizing of Uranium due to Applicant's injection of lixiviant and that such levels of Arsenic (even if within US drinking water standards) constitutes ongoing low-level exposure to Arsenic which causes failures in the pancreas to people drinking water affected into which the Arsenic flows. Such pancreatic failures result in diabetes and pancreatic cancer.

Under (ii), the basis for this contention is that the AEA and NRC Regulations cited in the Petition require Applicant's operations to be conducted without harm to public health and safety. Further, NEPA requires that the water not be contaminated with Arsenic to the detriment of the health of the people drinking water affected by the mine.

Under (v), the alleged facts and references are those discussed above including that the Johns Hopkins Study shows a link between low-levels of Arsenic in the drinking water and Type 2, Adult-Onset Diabetes. Diabetes reflects a failure in the pancreas. Chadron appears to have a very high incidence of pancreatic cancer that is 20 times the national average. The testimony of the Chadron victims of pancreatic cancer and further investigation into the incidence of pancreatic cancer at Pine Ridge Indian Reservation is required and contemplated to support this new contention. In addition, further testing needs to be done to show the exact levels of Arsenic in the drinking water of the people

of Crawford, Chadron and Pine Ridge Indian Reservation.

Diabetes can be caused by pancreatic failure. See Pancreatic Cancer Symptoms and Signs, Pancreatic Cancer UK, at http://www.pancreaticcancer.org.uk/PCSymptoms.htm. There is a link between diabetes and pancreatic cancer. See Probability of Pancreatic Cancer Following Diabetes: A Population-Based Study, Journal of the Institute of the American Gastroenterological Association, Vol. 129, No. 2 at 504-511 (August 2005) ("Approximately 1% of diabetes subjects aged ≥50 years will be diagnosed with pancreatic cancer within 3 years of first meeting criteria for diabetes.")

The Application shows that Applicant is aware that its ISL Uranium mining causes oxidation of the Uranium and the release of Arsenic into the water including the Brule Aquifer. Prior findings by the Board in LBP-08-06 show that the Petitioners have met their initial burden that there exist fractures and faults and pathways along The White River which lead to the human and environmental exposure to increased Arsenic levels from Applicant's mine. These exposures to Arsenic from Applicant's mine are related to the high incidence of diabetes and pancreatic cancer and appear to be a causal and contributing factor to such diseases being suffered by the people nearby the mine. The foregoing shows a plausible link between low levels of Arsenic in the water and failures of the pancreas in the form of diabetes and pancreatic cancer for the people downstream and downgrade of the Mine.

CONCLUSION

For the reasons stated above, the Presiding Officer should grant Petitioner leave to file this new contention in this proceeding and should find this new contention to be an admissible contention as to the three Petitioners already granted standing in this proceeding.

Dated this 22nd day of September, 2008.

Respectfully submitted,

David Frankel
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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD PANEL
Before Administrative Judges:
Ann Marshall Young, Chair
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In the Matter of CROW BUTTE RESOURCES, INC. (In Situ Leach Facility, Crawford, NE)	Docket No. 40-8943 ASLBP No. 07-859-03-MLA-BD01 September 22, 2008

CERTIFICATE OF SERVICE

I hereby certify that copies "PETITIONER WNRC'S REQUEST FOR LEAVE TO FILE A NEW CONTENTION RE ARSENIC" in the above captioned proceeding has been served on the following persons by electronic mail as indicated by a double asterisk (**), and by deposit in the United States Mail as indicated by an asterisk (*); on this 22nd day of September, 2008:

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD PANEL

In the Matter of CROW BUTTE RESOURCES, INC. (In Situ Leach Facility, Crawford, NE)	Docket No. 40-8943 License SUA-1543 September 22, 2008

AFFIDAVIT

I, David C. Frankel, hereby state as follows:

1. I make this affidavit in connection with a new contention to be added in the Proceedings related to the application of Crow Butte Resources, Inc. d/b/a Cameco Resources, a/k/a The Crow Butte Project concerning *in situ leach* uranium mine near Crawford, Nebraska (the "Mine"). I am fully familiar with the facts stated in this affidavit.

2. I am attorney for Western Nebraska Resources Council which is a petitioner to intervene in the Mine's North Trend Expansion Proceeding and the Mine's Renewal Proceeding.

3. During the course of my representation, I interviewed certain persons in the town of Chadron, Nebraska, concerning the incidence of pancreatic cancer. Such interviews included an interview on or about August 28, 2008, with an individual named Mike Waugh at Hills Tire, Chadron, NE, who informed me that at least seven (7) people that he personally knew or knew of had pancreatic cancer, which people included Mr. Watson, Mr. Daniels, Mr. Hageman and Mr. Trafinigan. I left a phone message for Mr. Watson and have not yet attempted to contact the others.

4. A cursory review of available data shows that the national average for pancreatic cancer is 11.5 out of 100,000 people. See US National Institute of Health National Cancer Center at http://seer.cancer.gov/statfacts/html/pancreas.html. Chadron has a population of about 5,200 people. Accordingly, the seven (7) cases of pancreatic cancer represent a cancer cluster that is 20 times greater than the national average.

5. The Journal of the American Medical Association recently published a study showing a linkage between low levels of arsenic in the water and adult onset of diabetes. See Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults, Ana Navas-Acien, MD, PhD; Ellen K. Silbergeld, PhD; Roberto Pastor-Barriuso, PhD; Eliseo Guallar, MD, DrPH; Journal of the American Medical Association (August 20, 2008) (Vol. 300(7): 814-822). See also, http://www.jhsph.edu/publichealthnews/press_releases/2008/navas_acien_arsenic.html.

6. Diabetes can be caused by pancreatic failure. See Pancreatic Cancer Symptoms and Signs, Pancreatic Cancer UK, at http://www.pancreaticcancer.org.uk/PCSymptoms.htm. There is a link between diabetes and pancreatic cancer. See Probability of Pancreatic Cancer Following Diabetes: A Population-Based Study, Journal of the Institute of the American Gastroenterological Association, Vol. 129, No. 2 at 504-511 (August 2005) ("Approximately 1% of diabetes subjects aged ≥50 years will be diagnosed with pancreatic cancer within 3 years of first meeting criteria for diabetes.")

7. The foregoing shows a plausible link between low levels of Arsenic in the water and failures of the pancreas in the form of diabetes and pancreatic cancer for the people downstream and downgrade of the Mine.

8. The Mine's oxidation of Uranium deposits results in the release of arsenic into the water. See Baseline Hydrogeochemical Investigation n a Part of Northwest Nebraska prepared by Nebraska Department of Environmental Control, starting at page 126 of the July 28, 2008 Petition (Renewal) at ML082170525 (the "1982 Baseline").

9. The Mine's operation releases Arsenic which contributes to or causes diabetes and/or pancreatic cancer in nearby populations in Crawford, Chadron and Pine Ridge Indian Reservation.

This Affidavit is submitted in accordance with 10 C.F.R. Section 2.304(d) and 28 U.S.C. Section 1746. I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 22, 2008 at Seattle, Washington.

DAVID C. FRANKEL

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Preliminary Communication

Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults

Ana Navas-Acien, MD, PhD; Ellen K. Silbergeld, PhD; Roberto Pastor-Barriuso, PhD; Eliseo Guallar, MD, DrPH

JAMA. 2008;300(7):814-822.

Context High chronic exposure to inorganic arsenic in drinking water has been related to diabetes development, but the effect of exposure to low to moderate levels of inorganic arsenic on diabetes risk is unknown. In contrast, arsenobetaine, an organic arsenic compound derived from seafood intake, is considered nontoxic.

Objective To investigate the association of arsenic exposure, as measured in urine, with the prevalence of type 2 diabetes in a representative sample of US adults.

Design, Setting, and Participants Cross-sectional study in 788 adults aged 20 years or older who participated in the 2003-2004 National Health and Nutrition Examination Survey (NHANES) and had urine arsenic determinations.

Main Outcome Measure Prevalence of type 2 diabetes across intake of arsenic.

Results The median urine levels of total arsenic, dimethylarsinate, and arsenobetaine were 7.1, 3.0, and 0.9 μg/L, respectively. The prevalence of type 2 diabetes was 7.7%. After adjustment for diabetes risk factors and markers of seafood intake, participants with type 2 diabetes had a 26% higher level of total arsenic (95% confidence interval [CI], 2.0%-56.0%) and a nonsignificant 10% higher level of dimethylarsinate (95% CI, −8.0% to 33.0%) than participants without type 2 diabetes, and levels of arsenobetaine were similar to those of participants without type 2 diabetes. After similar adjustment, the odds ratios for type 2 diabetes comparing participants at the 80th vs the 20th percentiles were 3.58 for the level of total arsenic (95% CI, 1.18-10.83), 1.57 for dimethylarsinate (95% CI, 0.89-2.76), and 0.69 for arsenobetaine (95% CI, 0.33-1.48).

Conclusions After adjustment for biomarkers of seafood intake, total urine arsenic was associated with increased prevalence of type 2 diabetes. This finding supports the hypothesis that low levels of exposure to inorganic arsenic in drinking water, a widespread exposure worldwide, may play a role in diabetes prevalence. Prospective studies in populations exposed to a range of inorganic arsenic levels are needed to establish whether this association is causal.

Author Affiliations: Department of Environmental Health Sciences (Drs Navas-Acien and Silbergeld), and Department of Epidemiology, and Welch Center for Prevention, Epidemiology, and Clinical Research (Drs

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Navas-Acien and Guallar), Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland; National Center for Epidemiology, Instituto de Salud Carlos III, Madrid, Spain, and CIBER en Epidemiología y Salud Pública, Madrid, Spain (Dr Pastor-Barriuso); Department of Cardiovascular Epidemiology and Population Genetics, Centro Nacional de Investigaciones Cardiovasculares, Madrid, Spain, and Department of Medicine, Johns Hopkins Medical Institutions, Baltimore (Dr Guallar).

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Editorial

Environmental Arsenic Exposure and Diabetes

Molly L. Kile, MS, ScD; David C. Christiani, MD, MPH, MS

JAMA. 2008;300(7):845-846.

Since this article does not have an abstract, we have provided the first 150 words of the full text and any section headings.

Type 2 diabetes mellitus emerged as a pandemic in the later half of the 20th century. In the United States alone, diabetes affects an estimated 7.8% of the US population (24 million individuals) and its prevalence is projected to almost double in the next 25 years.[1-2] The complications associated with diabetes including cardiovascular disease, retinopathy, nephropathy, neuropathy, and lower limb amputation profoundly affect the quality of life and contribute to the high morbidity and mortality associated with this disease. Diabetes is ranked as the seventh leading cause of death in the United States in 2006[2]; the economic costs of diabetes are also high. Approximately $1 of every $10 in US health care expenditures can be attributed to the direct costs associated with diabetes.[3] When indirect costs to caregivers are included, it is estimated that the annual cost of . . . *[Full Text of this Article]*

Author Affiliations: Department of Environmental Health, Environmental and Occupational Medicine and Epidemiology Program, Harvard University School of Public Health, Boston, Massachusetts.

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Ana Navas-Acien, Ellen K. Silbergeld, Roberto Pastor-Barriuso, and Eliseo Guallar
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Arsenic Exposure and Risk for Type 2 Diabetes
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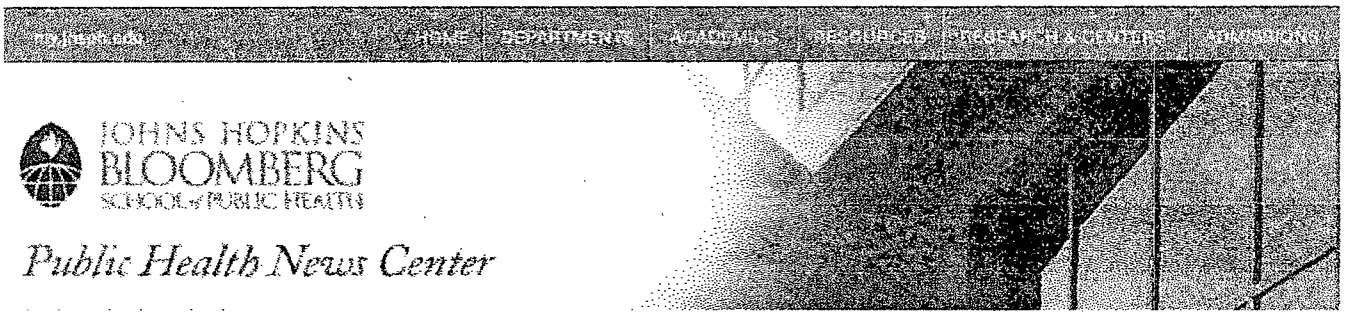

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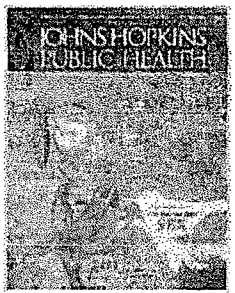

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August 19, 2008

Arsenic Exposure Could Increase Diabetes Risk

Inorganic arsenic, commonly found in ground water in certain areas, may increase the risk of developing type 2 diabetes, according to a study by researchers at the **Johns Hopkins Bloomberg School of Public Health**. The study found that individuals with diabetes had higher levels of arsenic in the urine compared to individuals without diabetes. The results are published in the August 20, 2008, issue of ***JAMA***.

"Our findings suggest that low levels of exposure to inorganic arsenic may play a role in diabetes," said Ana Navas-Acien, MD, PhD, lead author of the study and assistant professor with the Bloomberg School's Department of Environmental Health Sciences. "While prospective studies are needed to establish whether this association is causal, these findings add to the existing concerns about the long-term health consequences of low and moderate exposure to inorganic arsenic."

Inorganic arsenic is found naturally in rocks and soils. In the U.S., most exposure to inorganic arsenic comes from contaminated drinking water. Foods such as flour and rice can also provide small quantities of inorganic arsenic, particularly if grown or cooked in areas with arsenic contamination in soil or water. Seafood is a source of organic arsenic compounds that have little or no toxicity.

Researchers examined randomly selected urine samples taken from 788 U.S. adults 20 years or older that participated in a 2003—2004 National Health and Nutrition Examination Survey. The results were adjusted for diabetes risk factors, including body mass index and for organic arsenic compounds found in seafood.

In the U.S., approximately 13 million people live in areas where the concentration of inorganic arsenic in the public water supply exceeds standards established by the U.S. Environmental Protection Agency, primarily in the West, Midwest and Northeast regions. Dietary intake of inorganic arsenic in the U.S. ranges from 8.4 to 14 micrograms per day for various age groups.

The authors concluded that given widespread exposure to inorganic arsenic from drinking water worldwide, clarifying the contribution of arsenic to the diabetes epidemic is a public health research priority with potential implications for the prevention and control of diabetes.

"Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults" was written by Ana Navas-Acien, MD, PhD; Ellen K. Silbergeld, PhD; Roberto Pastor-Barriuso, PhD; and Eliseo Guallar, MD, DrPH.

The researchers were funded in part by a grant from the National Institute of Environmental Health Sciences Center in Urban Environmental Health.

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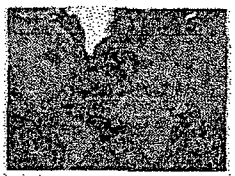

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Probability of Pancreatic Cancer Following Diabetes: A Population-Based Study

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Background & Aims: Although diabetes occurs frequently in pancreatic cancer, the value of new-onset diabetes as a marker of underlying pancreatic cancer is unknown. *Methods:* We assembled a population-based cohort of 2122 Rochester, Minnesota, residents age ≥50 years who first met standardized criteria for diabetes between January 1, 1950, and December 31, 1994, and identified those who developed pancreatic cancer within 3 years of meeting criteria for diabetes. We compared observed rates of pancreatic cancer with expected rates based on the Iowa Surveillance Epidemiology and End Results registry. In a nested case control study, we compared body mass index (BMI) and smoking status in diabetes subjects with and without pancreatic cancer. *Results:* Of 2122 diabetic subjects, 18 (0.85%) were diagnosed with pancreatic cancer within 3 years of meeting criteria for diabetes; 10 of 18 (56%) were diagnosed <6 months after first meeting criteria for diabetes, and 3 were resected. The observed-to-expected ratio of pancreatic cancer in the cohort was 7.94 (95% CI, 4.70–12.55). Compared with subjects without pancreatic cancer, diabetic subjects with pancreatic cancer were more likely to have met diabetes criteria after age 69 (OR = 4.52, 95% CI, 1.61–12.74) years but did not differ significantly with respect to BMI values (29.2 ± 6.8 vs 26.5 ± 5.0, respectively). A larger proportion of those who developed pancreatic cancer were ever smokers (92% vs 69%, respectively), but this did not reach statistical significance. *Conclusions:* Approximately 1% of diabetes subjects aged ≥50 years will be diagnosed with pancreatic cancer within 3 years of first meeting criteria for diabetes. The usefulness of new-onset diabetes as marker of early pancreatic cancer needs further evaluation.

Abbreviation used in this paper: REP, Rochester Epidemiology Project

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Pancreatic Cancer Symptoms and Signs

General Information

It is very difficult to diagnose pancreatic cancer as the pancreas is so deep within the body and symptoms vary depending on the exact location of the tumour in the pancreas and which cells or function of the pancreas is affected by the tumour or cancer.

It is principally a disease affecting middle-aged and older patients but this is not always the case and the diagnosis can be missed in younger patients.

Although the commonest form of pancreatic cancer - pancreatic ductal adenocarcinoma - is so deadly, there are other much rarer forms - eg. endocrine tumours - which can affect younger patients and have a much better outlook with surgery and chemotherapy or immunotherapy.

Unfortunately there are frequently no symptoms at all at the very early stages. The tumour may have grown significantly before it causes any obvious recognised symptoms.

Unfortunately the symptoms of pancreatic cancer can also be quite vague and non specific ie may be caused by many other more common and less serious conditions. Diagnosis can be delayed as the GP or specialist tries to rule out other causes such as hepatitis, gall stones, irritable bowel syndrome and stress.

Not everyone has every symptom, it depends very much on the location of the tumour in the pancreas. For example jaundice can be an early sign of a tumour in the head of the pancreas affecting the bile duct and back pain can be a late sign of a tumour in the body or tail of the pancreas possibly affecting the nerves and spine.

Jaundice may also be a late sign of a tumour that has developed initially further away from the bile duct and then grown or spread until it causes obstruction of the bile duct.

Early Symptoms can include:

- General discomfort or pain around the stomach area
- Sickness
- Bowel disturbances
- Diabetes
- Jaundice
- Skin itching

Later signs:

- *Loss of appetite*
- Unexplained weight loss
- Back pain
- Low mood and depression

Understanding Symptoms

The pancreas helps to digest your food and also produces insulin which balances the sugar level in the blood. It is behind the stomach and shaped like a tadpole.

As mentioned above the symptoms of pancreatic cancer can be quite vague and common to many other less serious conditions. However if cancer is affecting the function of the pancreas it can potentially cause 2 problems:

- Poor absorption of food, especially fat leading to weight loss and rather fatty, pale, smelly stools and diarrhoea
- Diabetes if too little insulin is produced

About 70% of patients have obstructive jaundice at the time of diagnosis, due to a tumour in

the head of the pancreas obstructing the bile duct, and hence the associated symptoms (yellowing eyes and skin, dark urine, pale stools, itchy skin). The jaundice is often painless and accompanied by no other symptoms so that the patient first notices something is wrong when their skin starts itching, their urine becomes very dark and they start to turn yellow (it is noticeable first in the whites of the eyes).

Most tumours occur in the head of the pancreas and typical early symptoms can include

- Jaundice and associated symptoms
- Feeling of sickness (nausea)
- Slight weight loss
- Unexpected development of diabetes

Tumours in the body and tail of the pancreas are more difficult to pick up early as they do not cause obstructive jaundice at an early stage. Typical symptoms can include:

- Vague abdominal pain
- Dyspepsia (indigestion)
- Stomach ulcer-like pain
- Intermittent diarrhoea
- Feeling of sickness (nausea)
- Unexplained weight loss
- Unexpected development of diabetes
- Back pain that does not go away
- Unexplained blood clots (venous thrombosis)

Although there is a link between diabetes and pancreatic cancer, diabetes is more commonly not associated with pancreatic cancer. However the liklihood of it being associated with pancreatic cancer increases if the onset is sudden and unexpected (eg no family history) and occurs in someone over 50 years old who is not obese. There is still scientific debate about whether diabetes causes pancreatic cancer or whether it is just a symptom of something going wrong with the pancreas ie cancer affecting the production of insulin.

A variety of bowel disturbances can be experienced with pancreatic cancer including both diarrhoea and constipation. One aspect that doesn't seem to get emphasised is the effect due to poor fat absorption. The lack of digestion of fat causes steatorrhoea which is pale, greasy stools that can be foul smelling and float and be difficult to flush away.

Explanation of Symptoms

Pancreatic cancer may have few obvious or specific symptoms at the early stages.

The most obvious symptom is **jaundice** (a yellow discolouration of the eyes and skin) which is often associated with dark urine and pale motions (stools) and itching of the skin. If the head of the pancreas is enlarged or abnormal then the bile duct may become blocked as it enters the pancreas, this blockage causes a build up of bile which causes the jaundice, dark urine, pale motions and itching. The symptoms should rapidly disappear once the blockage is cleared or bypassed by surgery or insertion of a stent.

If the cancer blocks the pancreatic duct this will lead to poor digestion, loose motions and weight loss. This can be relieved by clearing the blockage or by giving pancreatic enzyme tablets. **Steatorrhoea** is the medical term for the loose, pale, fatty, floating, offensive bowel motions which occur when the pancreas is not releasing digestive juices into the intestines and there is failure to absorb fats from the gut.

Weight loss is common because of the interference with digestion (due to blocked bile and/or pancreatic ducts or interference with production of pancreatic enzymes) and sugar metabolism, loss of appetite and the action of cancer itself.

Diabetes can be caused by pancreatic failure, it is usually characterised by weight loss, lethargy, thirst, blurred vision, increased volumes of urine and drowsiness. Diabetes may

already be present in a number of patients prior to developing the cancer or become apparent soon after it is diagnosed or following surgery.

Pain is also a common symptom of pancreatic cancer once the tumours are large enough to press on other organs or the spine and nerves. However only about half of all pancreatic cancer patients have any pain at the time of their diagnosis and pain is more common in cancers of the body and tail of the pancreas. Patients describe it as a dull pain that feels like a screwdriver boring into you. The pain is very typically worse when you lie down and is better if you sit or lean forward. It can start in the stomach area and spread around to the back. It can be worse after meals. Patients may also have a generally tender or painful abdomen if the liver, pancreas or gall bladder are inflamed or enlarged. In the case of enlarged liver or gall bladder this pain will be on the right hand side of the body.

When the pancreas is inflamed (e.g. acute **pancreatitis**) it often causes pain, this is usually felt in the central or upper part of the abdomen and is often associated with back pain. The pain may be sharp, aching or burning in nature. Some patients with pancreatic cancer may also have pancreatitis either due to disease in the pancreas or as a result of investigative procedures such as ERCP. The presence of pancreatitis can complicate diagnosis as it may mask pancreatic cancer in diagnostic imagery.

A feeling of **nausea** and actual sickness/vomitting may be the result of a number of things. It may be associated with a blocked bile-duct and hence jaundice or due to an inflamed pancreas. The change in chemical balance of the body caused by these conditions can make you feel sick. If the duodenum becomes blocked or restricted by cancer or inflamation this can stop food passing through and cause vomitting.

Some patients may develop **high temperature (fever)** and start **shivering** and feel cold despite the high temperature. This can be a side-effect of a blocked bile-duct (jaundice) or an inflamed pancreas.

Endocrine type cancers can also have symptoms associated with **excessive production of different types of hormones** and these are described on our page on pancreatic cancer types.

Link between diabetes and pancreatic cancer

The link with sudden onset diabetes has been backed up by a recent study (August 2005 issue of American Gastroenterological Association (AGA) journal Gastroenterology) that has shown that middle-aged patients with sudden onset diabetes have greater risk of developing pancreatic cancer within 3 years of diagnosis with diabetes than the general population. According to the study 1 in 120 people newly diagnosed with diabetes age 50 and older have a higher risk of developing pancreatic cancer--a risk that is eight times more than expected for the general population.

While study findings show that older patients have less than a 1 percent chance of having pancreatic cancer as the cause of their diabetes, they are still considered a high-risk group for developing the cancer. According to reports on the study between 55 and 65 percent of people with pancreatic cancer have hyperglycemia and diabetes. For these factors to be useful in establishing the need for screening in relatively asymptomatic patients, researchers say it is necessary to find the difference between pancreatic cancer-induced diabetes and type 2 diabetes.

However reports of incidence of hyperglycemia and diabetes in patients with pancreatic cancer vary from 5% to 80%. This appears to be due to the fact that the hyperglycemia and diabetes has also been undiagnosed although patients may have the associated (but possibly unreported) symptoms of weight loss, lethargy, thirst, blurred vision, increased volumes of urine and drowsiness. According to Diabetes UK one in four cases of diabetes are undiagnosed or unrecorded in England.

Further Reading

Do Early Symptoms of Pancreatic Cancer Exist that Can Allow an Earlier Diagnosis? 2001, Gullo et al, Pancreas, Vol22, No 2, pp210-213.

Pancreatic cancer: clinical presentation, pitfalls and early clues.DiMagno EP, 1999 Ann Oncol;10 Suppl 4:140-2.

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Surveillance Epidemiology and End Results

providing information on cancer statistics to help reduce the burden of this disease on the U.S. population

SEER Stat Fact Sheets

Cancer: --Choose a Cancer Site-- Go

It is estimated that 37,680 men and women (18,770 men and 18,910 women) will be diagnosed with and 34,290 men and women will die of cancer of the pancreas in 2008 [1] .

The following information is based on NCI's SEER Cancer Statistics Review [2] .

Incidence & Mortality

SEER Incidence

From 2001-2005, the median age at diagnosis for cancer of the pancreas was 72 years of age [3] . Approximately 0.0% were diagnosed under age 20; 0.4% between 20 and 34; 2.4% between 35 and 44; 9.6% between 45 and 54; 18.9% between 55 and 64; 26.6% between 65 and 74; 29.5% between 75 and 84; and 12.5% 85+ years of age.

The age-adjusted incidence rate was 11.5 per 100,000 men and women per year. These rates are based on cases diagnosed in 2001-2005 from 17 SEER geographic areas.

Incidence Rates by Race

Race/Ethnicity	Male	Female
All Races	13.0 per 100,000 men	10.3 per 100,000 women
White	13.0 per 100,000 men	10.0 per 100,000 women
Black	16.2 per 100,000 men	14.3 per 100,000 women
Asian/Pacific Islander	10.1 per 100,000 men	8.2 per 100,000 women
American Indian/Alaska Native [a]	10.9 per 100,000 men	8.2 per 100,000 women
Hispanic [b]	10.9 per 100,000 men	10.3 per 100,000 women

US Mortality

From 2001-2005, the median age at death for cancer of the pancreas was 73 years of age [4] . Approximately 0.0% died under age 20; 0.2% between 20 and 34; 1.8% between 35 and 44; 8.2% between 45 and 54; 17.4% between 55 and 64; 26.3% between 65 and 74; 31.3% between 75 and 84; and 14.8% 85+ years of age.

The age-adjusted death rate was 10.6 per 100,000 men and women per year. These rates are based on patients who died in 2001-2005 in the US.

Death Rates by Race

Race/Ethnicity	Male	Female
All Races	12.2 per 100,000 men	9.3 per 100,000 women
White	12.1 per 100,000 men	9.0 per 100,000 women
Black	15.4 per 100,000 men	12.4 per 100,000 women
Asian/Pacific Islander	8.0 per 100,000 men	6.9 per 100,000 women
American Indian/Alaska Native [a]	8.6 per 100,000 men	7.2 per 100,000 women
Hispanic [b]	9.1 per 100,000 men	7.6 per 100,000 women

Trends in Rates

Trends in rates can be described in many ways. Information for trends over a fixed period of time, for example 1995-2005, can be evaluated by the **annual percentage change (APC)** . If there is a negative sign before the number, the trend is a decrease; otherwise it is an increase. If there is an asterisk after the APC then the trend was significant, that is, one believes that it is beyond chance, i.e. 95% sure, that the increase or decrease is real over the period 1995-2005. If the trend is not significant, the trend is usually reported as stable or level. **Joinpoint analyses** can be used over a long period of time to evaluate when changes in the trend have occurred along with the APC which shows how much the trend has changed between each of the joinpoints.

The joinpoint trend in SEER cancer incidence with associated APC(%) for cancer of the pancreas between 1975-2005

All Races					
Male and Female		Male		Female	
Trend	Period	Trend	Period	Trend	Period
-2.1	1975-1978	-0.9*	1975-1993	1.3*	1975-1983
1.1	1978-1984	0.3	1993-2005	-0.1	1983-2005
-0.9*	1984-1993				
0.4*	1993-2005				

The joinpoint trend in US cancer mortality with associated APC(%) for cancer of the pancreas between 1975-2005

All Races					
Male and Female		Male		Female	
Trend	Period	Trend	Period	Trend	Period
-0.1*	1975-2003	-0.8*	1975-1986	0.8*	1975-1984
1.2	2003-2005	-0.3*	1986-2003	0.1*	1984-2005
		1.3	2003-2005		

Survival & Stage

Survival rates can be calculated by different methods for different purposes. The survival rates presented here are based on the **relative survival rate**, which measures the survival of the cancer patients in comparison to the general population to estimate the effect of cancer. The overall 5-year relative survival rate for 1996-2004 from 17 SEER geographic areas was 5.1%. Five-year relative survival rates by race and sex were: 5.1% for white men; 4.9% for white women; 3.6% for black men; 5.4% for black women.

The **stage distribution** based on historic stage shows that 7% of pancreas cancer cases are diagnosed while the cancer is still confined to the primary site (localized stage); 26% are diagnosed after the cancer has spread to regional lymphnodes or directly beyond the primary site; 52% are diagnosed after the cancer has already metastasized (distant stage) and for the remaining 15% the staging information was unknown. The corresponding 5-year relative survival rates were: 20.0% for localized; 8.2% for regional; 1.8% for distant; and 4.3% for unstaged.

Lifetime Risk

Based on rates from 2003-2005, 1.33% of men and women born today will be diagnosed with cancer of the pancreas at some time during their lifetime. This number can also be expressed as 1 in 75 men and women will be diagnosed with cancer of the pancreas during their lifetime. These statistics are called the **lifetime risk** of developing cancer. Sometimes it is more useful to look at the **probability of developing** cancer of the pancreas between two age groups. For example, 0.51% of men will develop cancer of the pancreas between their 50th and 70th birthdays compared to 0.40% for women.

Prevalence

On January 1, 2005, in the United States there were approximately 29,445 men and women alive who had a history of cancer of the pancreas – 14,355 men and 15,090 women. This includes any person alive on January 1, 2005 who had been diagnosed with cancer of the pancreas at any point prior to January 1, 2005 and includes persons with active disease and those who are cured of their disease. **Prevalence** can also be expressed as a percentage and it can also be calculated for a specific amount of time prior to January 1, 2005 such as diagnosed within 5 years of January 1, 2005.

References

All statistics in this report are based on SEER incidence and NCHS mortality statistics. Most can be found within:

Ries LAG, Melbert D, Krapcho M, Stinchcomb DG, Howlader N, Horner MJ, Mariotto A, Miller BA, Feuer EJ, Altekruse SF, Lewis DR, Clegg L, Eisner MP, Reichman M, Edwards BK (eds). *SEER Cancer Statistics Review, 1975-2005*, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov /csr/1975_2005/, based on November 2007 SEER data submission, posted to the SEER web site, 2008.

Footnotes

1 Table I-1 (http://seer.cancer.gov/csr/1975_2005/results_single/sect_01_table.01.pdf)
2 Pancreas Section (http://seer.cancer.gov/csr/1975_2005/results_merged/sect_22_pancreas.pdf)
3 Table I-11 (http://seer.cancer.gov/csr/1975_2005/results_single/sect_01_table.11_2pgs.pdf)
4 Table I-13 (http://seer.cancer.gov/csr/1975_2005/results_single/sect_01_table.13_2pgs.pdf)
* The APC is significantly different from zero (p<.05).
a Incidence data for Hispanics is based on NHIA and excludes cases from Alaska Native Registry and Kentucky. Hispanic death rates exclude deaths from Minnesota, New Hampshire and North Dakota.
b Incidence and mortality data for American Indians/Alaska Natives is based on the CHSDA (Contract Health Service Delivery Area) counties.

Definitions

Annual percent change (APC)

The average annual percent change over several years. The APC is used to measure trends or the change in rates over time. For information on how this is calculated, go to Trend Algortihms in the SEER*Stat Help system. The calculation involves fitting a straight line to the natural logarithm of the data when it is displayed by calendar year.

Joinpoint analyses

A statistical model for characterizing cancer trends which uses statistical criteria to determine how many times and when the trends in incidence or mortality rates have changed. The results of joinpoint are given as calendar year ranges, and the annual percent change (APC) in the rates over each period.

Survival rates

Survival examines how long after diagnosis people live. Cancer survival is measured in a number of different ways depending on the intended purpose.

Relative survival rate

A measure of net survival that is calculated by comparing observed (overall) survival with expected survival from a comparable set of people that do not have cancer to measure the excess mortality that is associated with a cancer diagnosis.

Stage distribution

Stage provides a measure of disease progression, detailing the degree to which the cancer has advanced. Two methods commonly used to determine stage are AJCC and SEER historic. The AJCC method (see Collaborative Staging Method) is more commonly used in the clinical settings, while SEER has standardized and simplified staging to ensure consistent definitions over time.

Lifetime risk

The probability of developing cancer in the course of one's lifespan. Lifetime risk may also be discussed in terms of the probability of developing or of dying from cancer. Based on cancer rates from 2003 to 2005, it was estimated that men had about a 44 percent chance of developing cancer in their lifetimes, while women had about a 37 percent chance.

Probability of developing cancer

The chance that a person will develop cancer in his/her lifetime.

Prevalence

The number of people who have received a diagnosis of cancer during a defined time period, and who are alive on the last day of that period. Most prevalence data in SEER is for limited duration because information on cases diagnosed before 1973 is not generally available.