

Potential Cancer Cluster Investigation for Sterilization Services of Tennessee located in Memphis, TN.

Conducted and prepared by the Tennessee Department of Health in collaboration with the Shelby County Health Department.

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Executive Summary

Based on recent studies, the US Environmental Protection Agency identified a potentially higher than usual risk of cancer due to ethylene oxide exposure.

A cancer cluster investigation study was conducted by the Tennessee Department of Health in collaboration with the Shelby County Health Department to see if there are more cancer cases than expected in the area surrounding the facility.

This cancer cluster investigation provided no evidence for the clustering of high numbers of leukemia, Non-Hodgkin Lymphoma, breast, or stomach cancer near the facility when compared to a group away from the facility in 2000-2009 or 2010-2019. Hot and cold spots of breast cancer were found. Due to the location of the breast cancer clustering, we cannot say the clusters are due to the facility.

Detailed findings of this study are presented below. Some potential clustering of cancer cases in areas not near the facility were identified.

About Ethylene Oxide (EtO) and the Sterilization Services of Tennessee

Ethylene oxide (EtO) is a colorless, flammable gas that is a known carcinogen, meaning that it can cause cancer.^{15,18} EtO has been linked to leukemia, Non-Hodgkin Lymphoma, stomach, and breast cancers.¹⁸ Usually, humans get exposed to this cancer-causing gas by breathing it in.¹⁸

The Sterilization Services of Tennessee is a facility located in Memphis, TN that uses EtO to sterilize equipment and supplies. The facility is currently meeting the Environmental Protection Agency's (EPA) safety regulations, but the EPA has two new findings that are causing changes to the regulations.

1. Recent studies show that EtO is more harmful to human health than we previously knew.⁹
2. Sterilization Services of Tennessee, along with 28 other facilities in the United States, are suspected by the EPA to have higher than usual risks of causing cancer.^{8,10}

These new findings have caused two recent EPA actions:

1. The EPA is now making new regulations about EtO to help better protect individuals living and working near facilities that use EtO across the nation.⁶
2. The Shelby County Health Department started an investigation in collaboration with the Tennessee Department of Health to see if there is a cancer cluster near the facility.

About Cancer Cluster Investigations

Purpose: To see if there are more cancer cases than expected and to address the community's concerns about EtO.

Criteria of a true cancer cluster:⁴

1. Detection of a higher number of a rare cancer or more cancers than normally expected
2. Identifying the same type of cancer or cancers that develop in the same way
3. Cancer in a specific location, that is, cancers that appear to group close together, cluster together
4. Cancer found during a specific time period

Even when an increase in cancers is identified, establishing a link between a potential environmental contaminant and an increase in cancer rates is unlikely⁴ because:

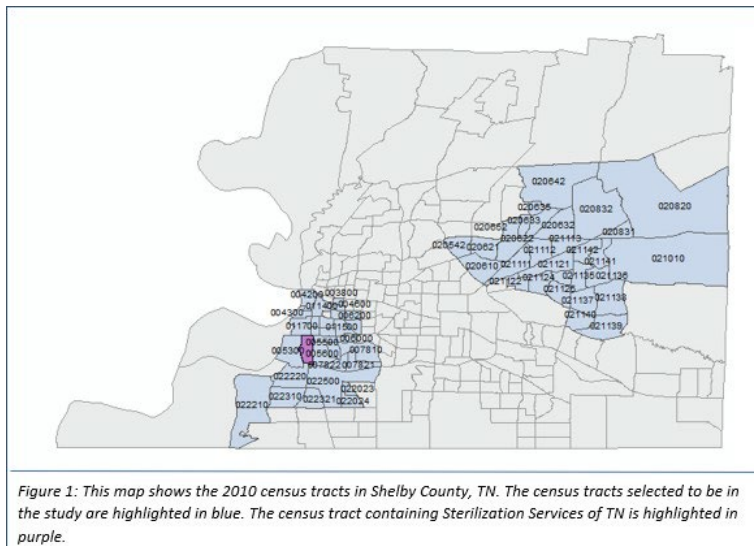
1. Cancer is not one disease, but a group of more than 100 diseases that may have different causes, different times between exposure to a cancer-causing agent and development of symptoms, may affect the body in different ways, and more.
2. Cancer is common
3. Cancer is usually not caused by one thing, but is caused by a combination of things including:
 - Increasing Age and Gender
 - Behavioral: smoking, drinking, diet, and exercise habits
 - A person's genes
 - Things in the environment
4. There is a natural variation in rates of cancer.
5. Other factors influence rates of cancer such as:
 - Access to healthcare
 - Rates of screening for cancer
 - Socioeconomic-related factors like education, income, and more

Limitations:

- Statistical considerations: small sample sizes of cancer case counts, resulting in unstable age-adjusted incidence rate calculations.¹³
- Geographical challenges: cluster investigations rely on geospatial analyses which are dependent on existing administrative borders, like zip codes, county lines, or census tracts.¹³ The geographic borders, selected with high uncertainty, define the population in the study and make the study susceptible to "sharpshooter fallacy" or "clustering illusion" which refers to the idea of drawing a target after the bullets are shot.³ Anytime data is collected, clusters may be seen. In some cases, patterns could be identified where there really are none and we might focus on the similarities while ignoring differences which can lead to false conclusions.¹¹
- Ecological Study limitations: This is an ecological study, meaning that it analyzes groups of individuals. Because ecological studies do not analyze people individually, they cannot claim to determine a specific cause of disease.

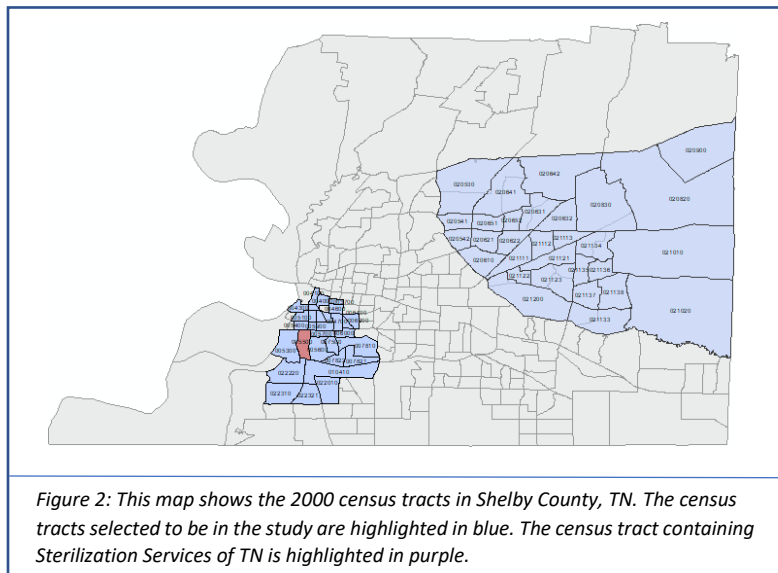
The Shelby County Cancer Cluster Investigation

In the cancer cluster investigation, we looked for possible relationships between the facility and the numbers of cancer cases around the facility. To do this, we compared the number of cancer cases in an area near the facility to an area away from the facility, on the other side of the county (*See Figure 1*). The census tract containing the facility is highlighted in purple and the two groups in the study are highlighted in blue.



To compare the number of cancer cases in these areas, we calculated age-adjusted incidence rates for new cases of cancer that were diagnosed from 2010 to 2019 with one of the four types of cancer that are linked to EtO. We used these age-adjusted rates to look for areas with elevated rates of cancer where the cancers appear to group together (cluster), so-called “hot spots.”

The community requested that we also look at cancer cases a little further back in time, so we repeated the same process for cases diagnosed between the years of 2000 and 2009. Since census tracts changed between these decades, we selected different census tracts that existed in 2000 to 2009, shown in Figure 2.



Results

Figures 3a – 3d show the results of the hot spot analyses. Grey represents no clustering of cancer, blue represents tracts that had lower numbers of cancer cases clustered together, and red represents tracts that had higher numbers of cancer cases clustered together. The left side in each figure is the map of the area near the facility, and the right side of each figure is the map of the area away from the facility.

Leukemia

In 2000-2009, the rate of Leukemia in the group near the facility was comparable to the TN rate and was significantly lower than the rate in the group away from the facility. In 2010-2019, the rate of leukemia near the facility was comparable to the rate in TN and to the rate in the group away from the facility.

The 2000-2009 spatial analyses displayed cold spots bordering the facility's census tract and identified a hot spot far away from the facility's census tract. The 2010-2019 spatial analyses revealed no clustering (See Figure 3a).

These results do not provide evidence that there is clustering of leukemia cases near the facility.

Non-Hodgkin Lymphoma (NHL)

In 2000-2009, the rate of NHL in the group near the facility was comparable to the TN rate and was significantly lower than the rate in the group away from the facility. In 2010-2019, the rate of NHL in the group near the facility was significantly lower than the rate in TN and was comparable to the rate in the group away from the facility.

In the groups near the facility, the 2000-2009 and the 2010-2019 hot spot analyses revealed no hot spots or clustering (See Figure 3b).

These results show that there is no clustering of Non-Hodgkin Lymphoma near the facility.

Breast Cancer

In 2000-2009 and in 2010-2019, rates of Breast Cancer in the groups near the facility were comparable to rates in TN and were significantly lower than the rates in the group away from the facility.

In the groups near the facility, the 2000-2009 and 2010-2019 hot spot analyses found hot spots and cold spots bordering the facility's census tract (See Figure 3c). The facility's census tract had no clustering, so therefore, we cannot say that the high/low numbers of breast cancer in adjacent census tracts are due to the facility.

The location of the hot and cold spots found do not support an association between the facility and higher numbers of breast cancer cases and clustering in census tracts adjacent to the facility census tract.

Stomach Cancer

In the group near the facility, rates of stomach cancer were significantly higher than the rates in TN and the rates in the group away from the facility in 2000-2009 and 2010-2019.

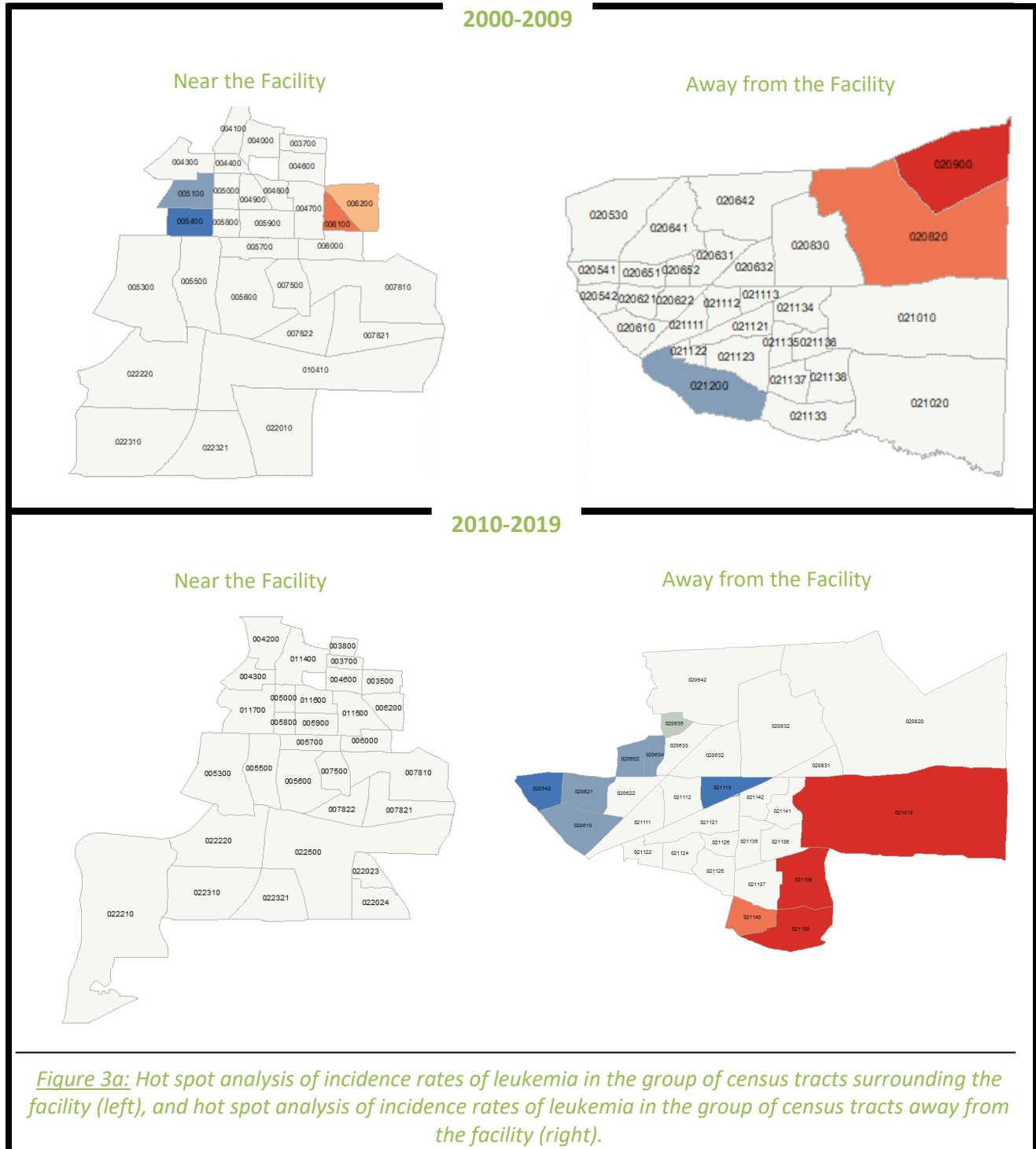
In the group near the facility, the 2000-2009 spatial analyses displayed one warm spot positioned geographically away from the facility in the 2000-2009 analyses, as shown in Figure 3d. In the groups located near the facility, the spatial analyses revealed no clustering in the 2010 to 2019 analyses.

Although stomach cancer rates were significantly higher in the groups near the facility, the geospatial analyses revealed no clustering of stomach cancer near the facility's census tract. These results do not provide evidence of clustering of stomach cancer near the facility.

Summary of Results

In conclusion, the geospatial analyses did not provide evidence that there is clustering of leukemia, Non-Hodgkin Lymphoma, or stomach cancer near the facility when compared to a group away from the facility in 2000-2009 or 2010-2019. Hot and cold spots of breast cancer were found, but due to the location of the clustering, we cannot say the clusters are due to the facility. Although there was no clustering of stomach cancer, the rates of stomach cancer in the group of census tracts including the sterilization facility were significantly higher than the rates in the group away from the facility.

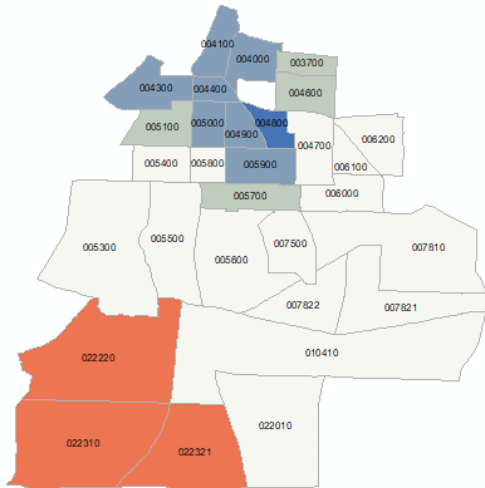
Leukemia



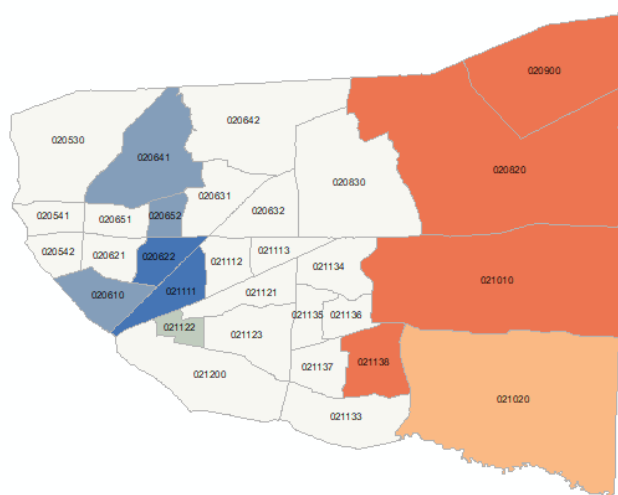
Breast

2000-2009

Near the Facility

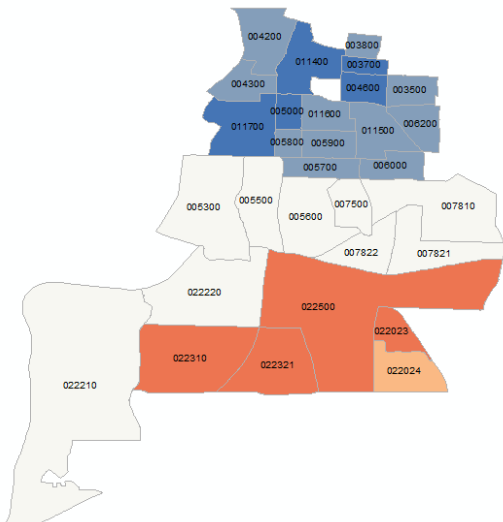


Away from the Facility



2010-2019

Near the Facility



Away from the Facility

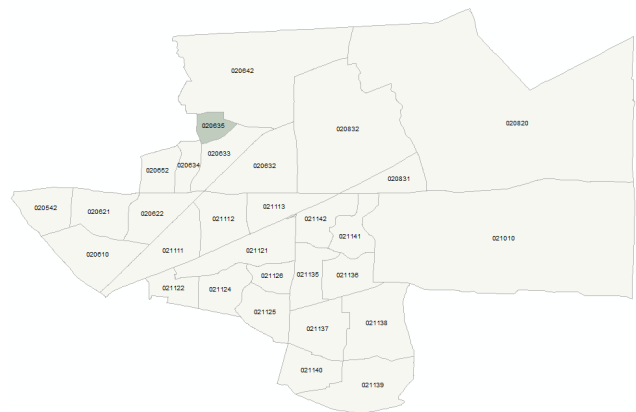
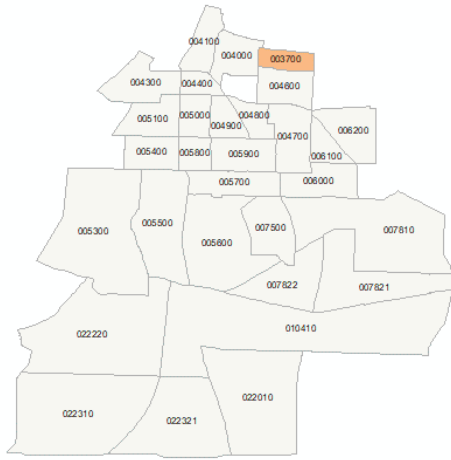


Figure 3c: Hot spot analysis of incidence rates of breast cancer in the group of census tracts surrounding the facility (left), and hot spot analysis of incidence rates of breast cancer in the group of census tracts away from the facility (right).

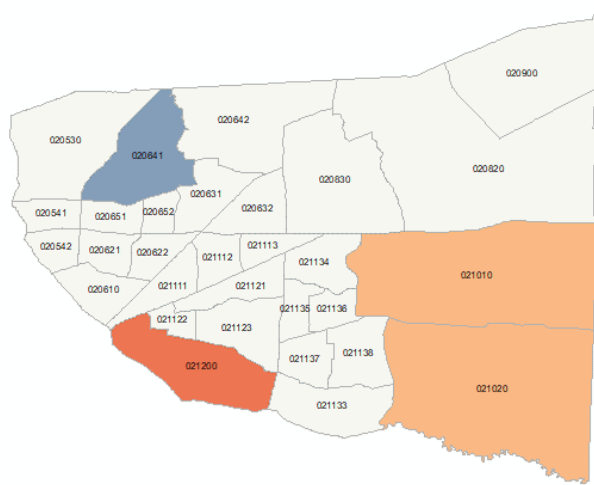
Stomach

2000-2009

Near the Facility

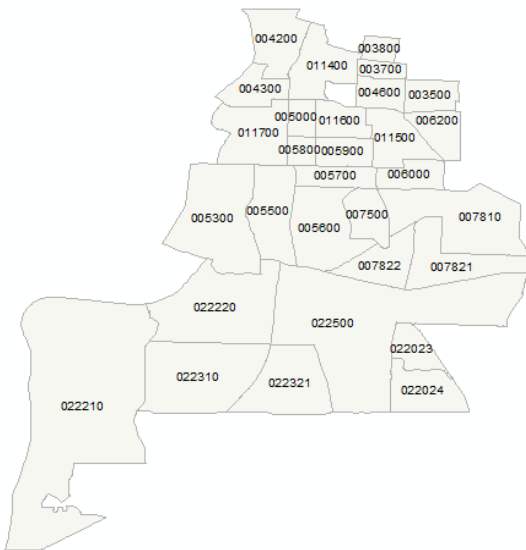


Away from the Facility



2010-2019

Near the Facility



Away from the Facility

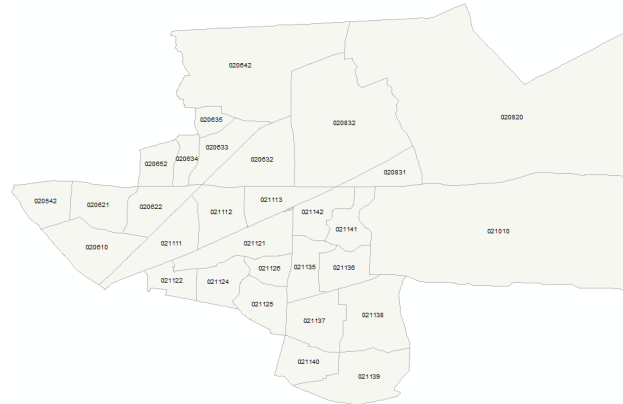


Figure 3d: Hot spot analysis of incidence rates of stomach cancer in the group of census tracts surrounding the facility (left), and hot spot analysis of incidence rates of stomach cancer in the group of census tracts away from the facility (right).

Cancer Resources in Shelby County, TN:

- ❖ Shelby County's Tennessee Breast and Cervical Screening Program
 - Phone number: 901-545-8720
- ❖ Christ Community Health Services located in Third Street Health Center
 - Phone number: 901-842-3166.
- ❖ Baptist Women's Health Center Mobile mammography unit
 - Phone number: 901-227-PINK (7465)
- ❖ Methodist/LeBonheur Healthcare Mobile Mammography
 - secureapps.methodisthealth.org/Mammo/

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