

Harborview Medical Center Elective PCI Rulemaking Request and Current Status of PCI Program

 JULY 9, 2024

Harborview Medical Center

- Largest public safety net hospital in Washington state
- 70% of patient revenue is Medicaid, Medicare and over governmental payers
- \$44 million in charity care FY234
- \$394 million in total uncompensated care FY23
- Under hospital services agreement with King County, express mission is to treat every patient who comes to us, regardless of economic, social or legal status
- Primary teaching hospital for UW School of Medicine
- Designated Level I adult and pediatric trauma center and the disaster preparedness and disaster control hospital for King County
- The tertiary referral site for local FQHC's (NeighborCare, SeaMar, ICHS, HealthPoint)

Harborview PCI

- Majority of elective PCI are referred from clinic visits not the ED
- Standard of care is to perform PCI at the time of diagnostic catheterization; Harborview is not able to do this
- Patients who seek care at Harborview are generally unwilling/unable to seek care at other providers on First Hill
- Harborview's PCI patients are vulnerable
 - Disproportionately minority, including 20% American Indian and 13% Pacific Islander
 - > 40% Medicaid/under- or non-insured

Harborview Medical Center PCI

Patients needing intervention and then referred for follow up CY2022 and CY2023

Emergent PCI volumes

- 105 Q4 2021-Q3 2022
- 131 Q4 2022-Q3 2023

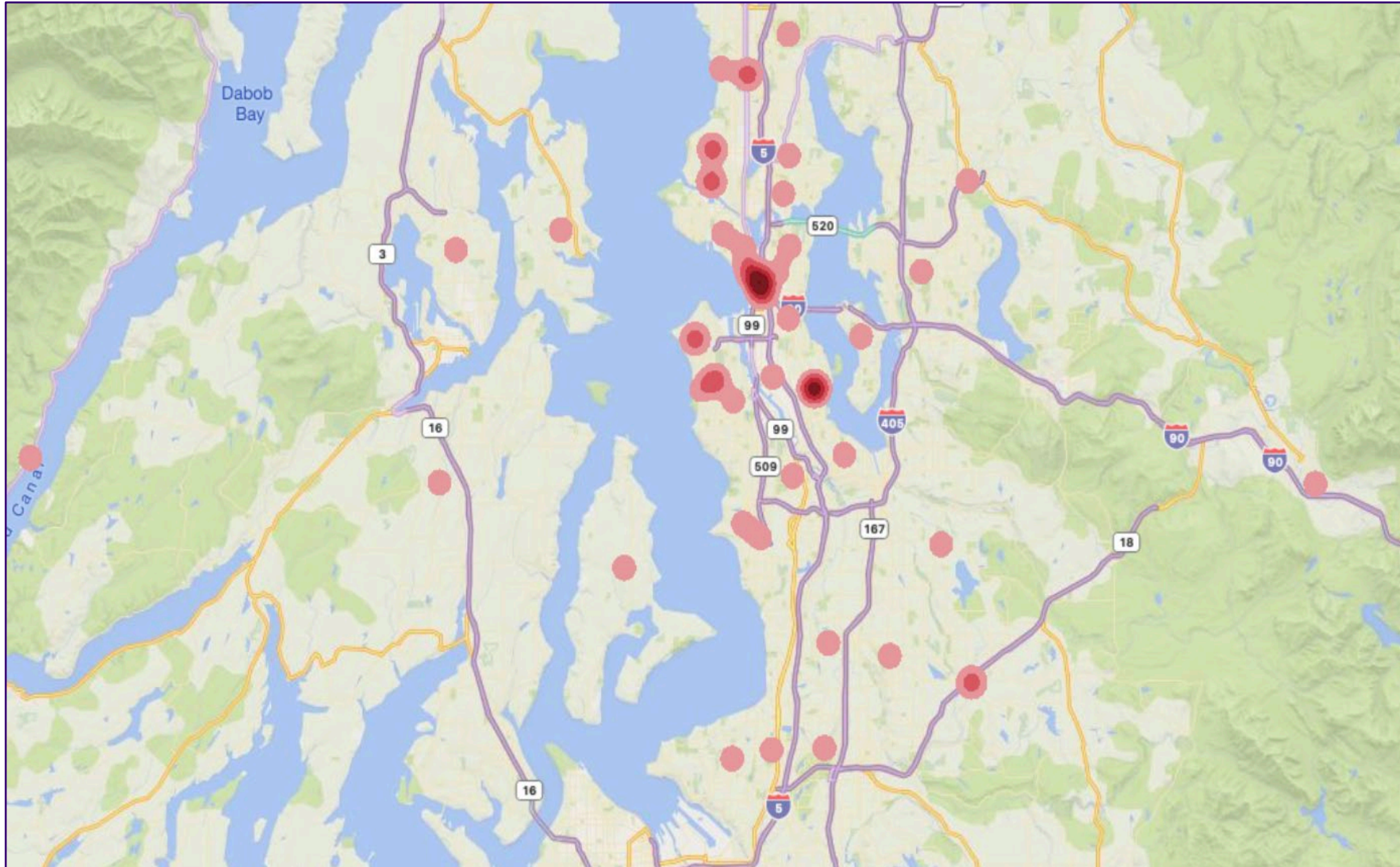
Staged Interventions- Diagnostic at HMC, Intervention at UWMC.

- 130 Patients
- 107 completed interventions
- 23 cancelled
 - 2 died
 - 21 Lost to follow up, disposition unknown.

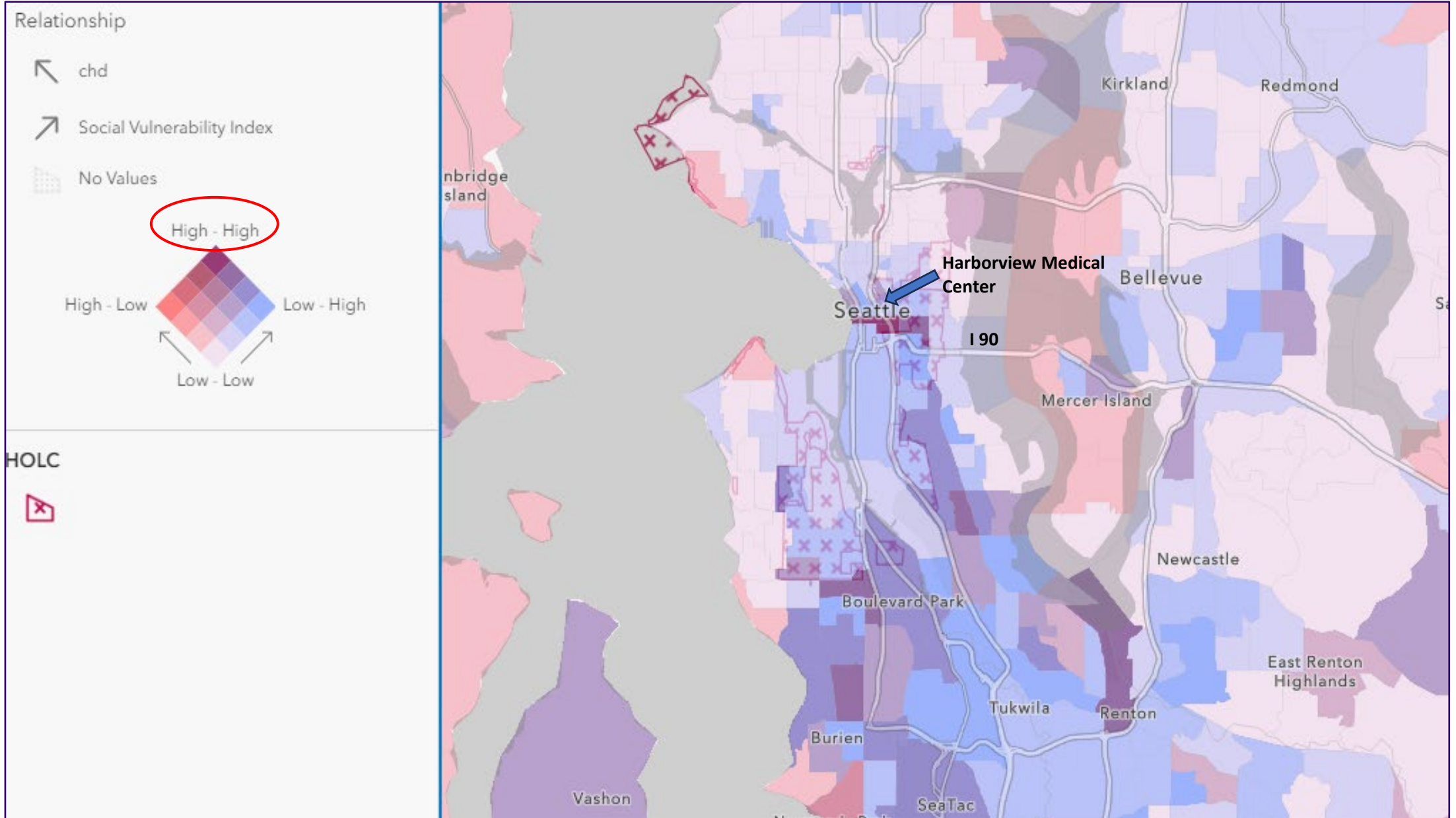
HMC referrals to UWMC for Elective Intervention

- 91 for CY22&23

HMC's PCI Patients are from Downtown and Rainier Valley/South King County

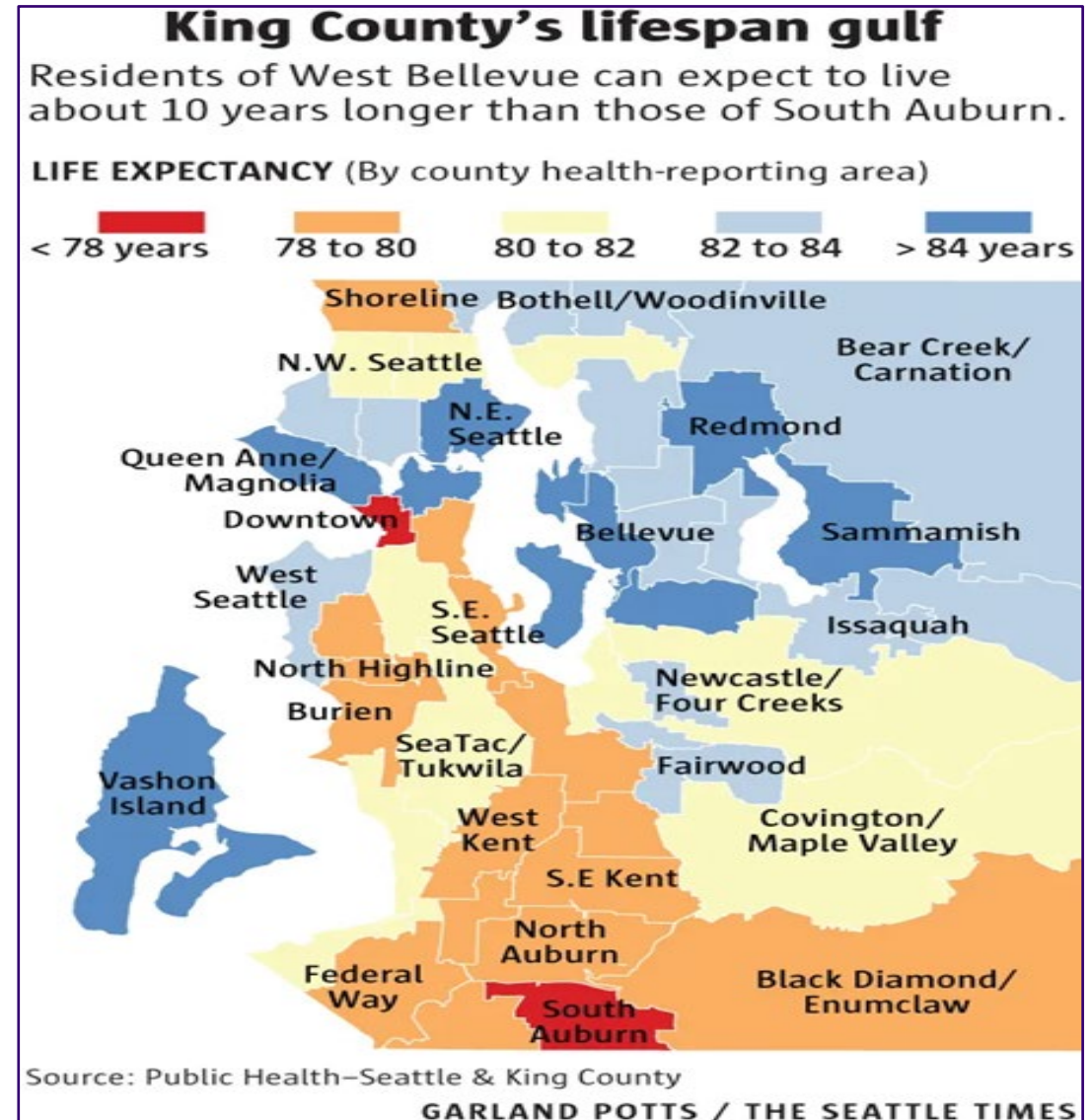


Coronary Heart Disease Burden and Social Vulnerability Index



Our vulnerable patients experience disparities in life expectancy and cardiac mortality and morbidity

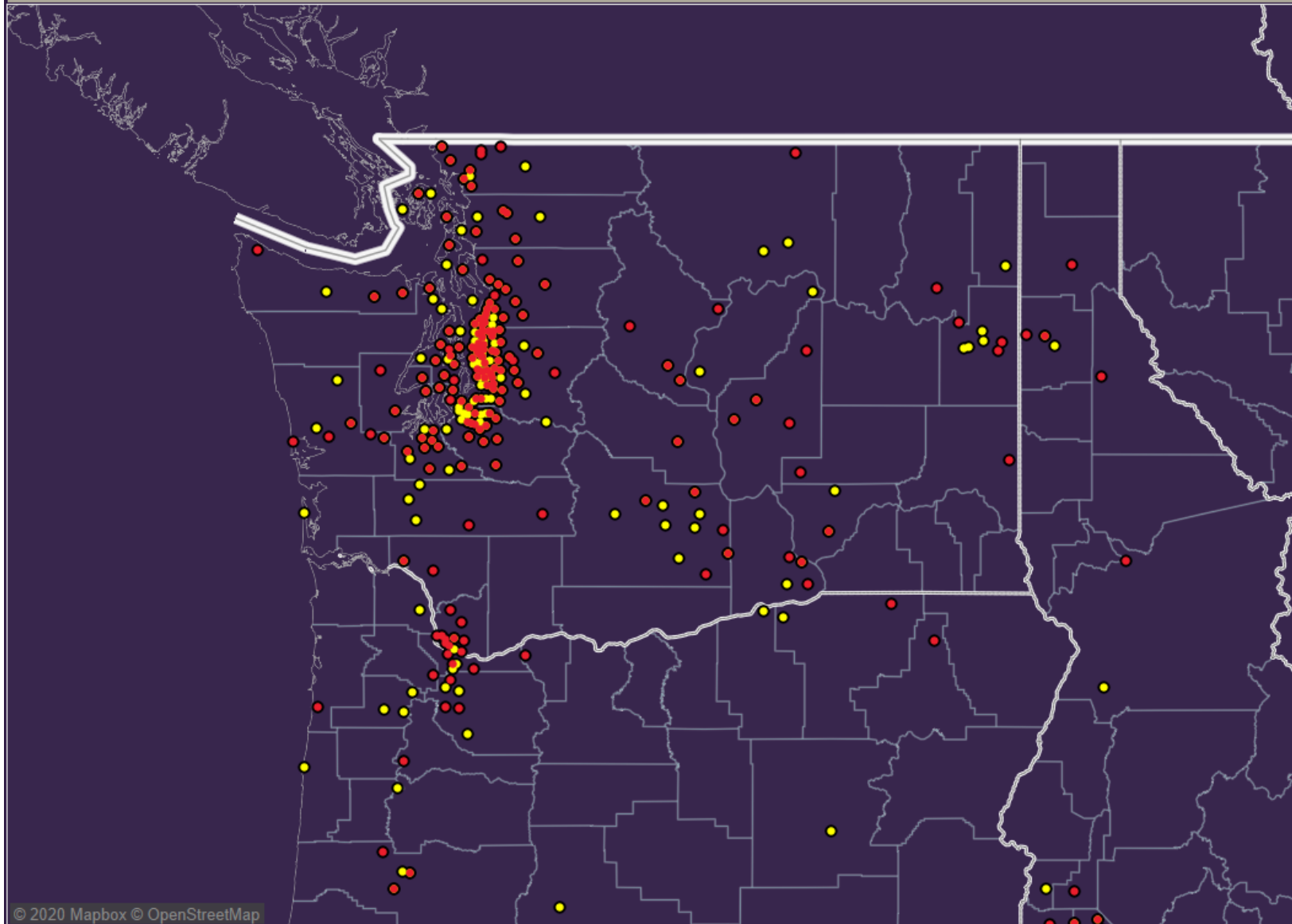
- Significant gap in life expectancy between downtown Seattle and communities along the Rainier Valley (where Harborview's mission population reside) compared to the more traditional "Eastside"; yet all these areas are part of the King West PCI Planning Area.



Background: Harborview's Elective PCI and Rulemaking Request

- Harborview has been providing emergent PCI since 2005
- Our experience:
 - Despite comprehensive referral management, high rate of no-shows (~20%)
 - No numeric need in the King West Planning Area and futile for Harborview to attempt CN under rules adopted in 2008.
 - Therefore, changes are needed.

Example: Issue with Numeric Need West King: 2019 UWMMC PCI Referrals



Yellow = PCI
Red = CTO PCI
Total PCI = Both

Harborview has been Pursuing Rule Change Since 2019

- **July 8, 2019** - Petition for Rulemaking submitted to DOH
- **September 2019** - DOH notifies Harborview that it will open chapter 246-310 WAC, Certificate of Need, to clarify, streamline and modernize the rules including consideration of request to update elective PCI rules.
- **May-October 2022** - DOH holds series of Strategic Listening Sessions to identify changes and to gain input on two “tactical” projects including PCI. Intent was to have rules finalized by 12/31/2022.
- **January 2023** - Harborview sends another request to DOH to commence rulemaking, with no response
- **January 2024** - Harborview sends another request to DOH. Response received indicating that CR101 was filed on January 16, 2024
- First rulemaking meeting held in **June 2024**– organizational meeting, not substantive.

Requested WAC Changes and Rationale:

The two requested rulemaking changes were/are narrow and intended to eliminate a flaw inherent in the current rules that increases clinical risk, results in duplication, has the potential to impact outcomes, results in higher costs and disproportionately affects Harborview's mission population.

- Without a CN approval, Harborview must transfer all patients that are not having an immediate event. The risk of transfer has the potential to impact outcomes; it also creates duplication and increases costs.
- Harborview's mission population is disproportionately Medicaid or under/non-insured, which can and does make the timely referral to other providers challenging. Transportation barriers for the mission population and navigation through unfamiliar neighborhoods and hospitals leads to high rates of no-show for those referred to other hospitals.
- The "Planning Area" to which WAC assigns Harborview is projected to have a surplus of capacity for the foreseeable future. Any Harborview CN application, under the current rules, would be futile as DOH does not have the latitude to approve a CN application absent numeric need.
- The current rules also fail to recognize that Harborview has already achieved the minimum volume threshold of 200 cases annually, and that allowing its program to begin treating elective cases would have no demonstrable impact on any other existing hospital in West King.

#1: WAC 246-310-720 (3) Change/Addition Allows an Applicant to be Approved Absent Numeric Need, if the Applicant:

- a) Can demonstrate using CHARS, COAP and internal data for the most recent 12- month period for which data is available that it already manages 200 PCI cases, inclusive of cases actually performed at the applicant hospital and cases they refer to other providers;
- b) Has operated and staffed a cardiac catheterization laboratory 24/7 and performed emergency PCI for at least 10 years; and
- c) Serves a vulnerable population with a rate of at least 40% Medicaid/under or non- insured.

Proposed WAC modification:

WAC 246-310-720 Hospital Volume Standards

(1) Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) The department shall only grant a certificate of need to new programs within the identified planning area if:

(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and

(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

(3) The department may grant a certificate of need to new programs within the planning area if:

(a) The state need forecasting methodology does not project unmet volumes sufficient to establish one or more programs; and

(b) The applicant demonstrates that it:

i. Already manages 200 PCI cases, inclusive of cases actually performed at the applicant hospital and cases they refer to other providers;

ii. Has operated and staffed a cardiac catheterization laboratory 24/7 and performed emergency PCI for at least 10 years; and

iii. Serves a vulnerable population with a rate of at least 40% Medicaid/under or non- insured

#2: Change Step 4 of the Methodology in WAC 246-310-745:

- **Proposed WAC Modification:**

Step 4. Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than two hundred, the department will not approve a new program, except for programs which may be approved under WAC 246-310-720 (3).

Reiterating our Workshop 1 Request for Acceleration, Adoption and Effective Date Prior to YE 2024 for the Changes Requested.

- Continuation of the current rules means that patients will continue to be harmed; especially Harborview's mission patients.
- Our petition is now more than 5 years old.
- There is precedence for DOH to adopt a section of rules, while still in rulemaking.

Thank You for Your Attention