

# Sample Size Necessary to Validate CLABSI Surveillance

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# Goals

1. Calculate the number of medical record reviews necessary to accurately estimate the proportion of false positive and false negative CLABSIs annually in the State of Texas.
2. Calculate the number of auditors necessary to conduct the necessary number of medical record reviews.

# False Positives and Negatives

**Table 2.** Comparison of central line associated bloodstream infections reported by Connecticut hospitals and the Connecticut Health Department reviewers

| CT DPH reviewers | CT hospital reports to the National Healthcare Safety Network |           |       |
|------------------|---|-----------|-------|
|                  | CLABSI  | No-CLASBI | Total |
| CLABSI           | 23  | 25        | 48    |
| No-CLABSI        | 4   | 424       | 428   |
| Total            | 27  | 449       | 476   |

CLABSI, central line-associated bloodstream infections; CT, Connecticut; CT DPH, Connecticut Health Department.

$$\text{False Positives} = 4/27 = \mathbf{0.1481}$$

$$\text{False Negatives} = 25/449 = \mathbf{0.0557}$$

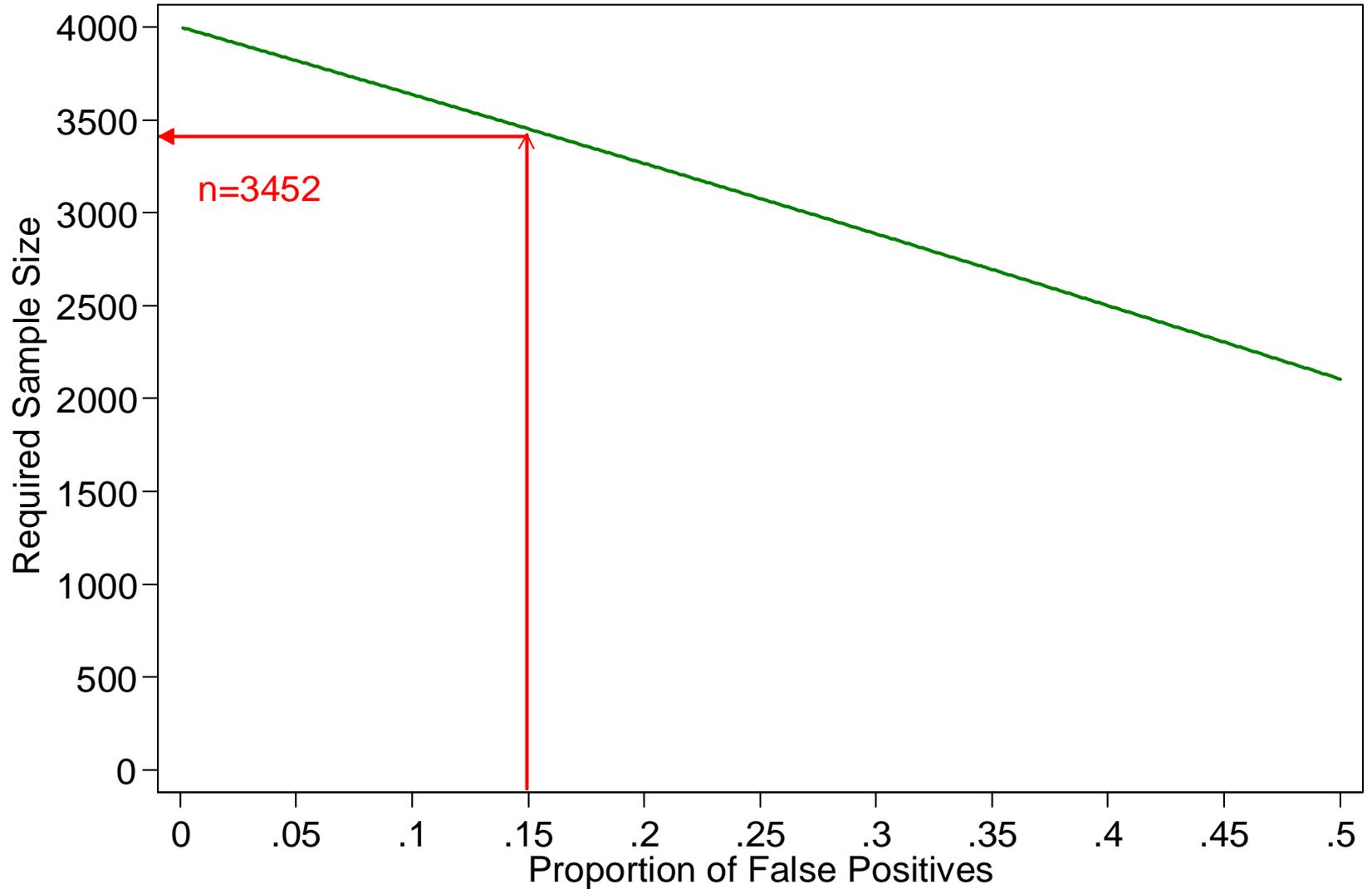
# CLABSI Definition

- CLABSIs were defined as records in the Texas Hospital Discharge data with a primary diagnosis of “Infection due to central venous catheter”
- field = “PRINC\_DIAG\_CODE”
- 2011 ICD-9-CM Diagnosis Code 999.31

# Non-CLABSI Definition

- Records without CLABSIs were defined as records in the Texas Hospital Discharge data that involved time in an ICU without a primary diagnosis of “Infection due to central venous catheter”

# Required Sample Size by Proportion of False Positives



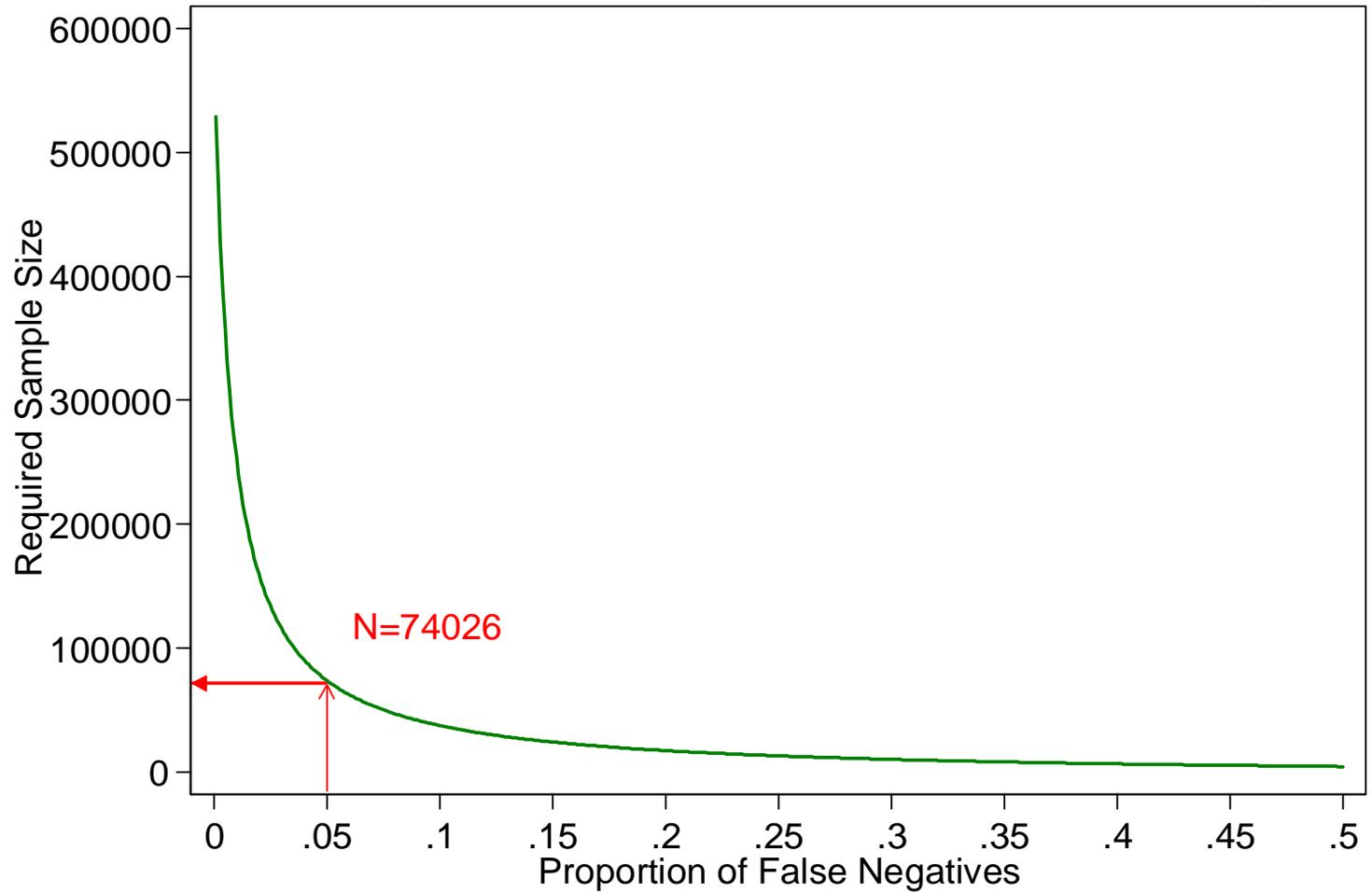
# Sample Size Calculations

How large a sample would we need to have the 95% confidence interval equal to a  $\pm 3\%$  margin of error around a proportion of  $P = 0.15$  if we were sampling from a population of  $N = 4,000$

$$n \geq \frac{z^2 NP (1 - P)}{z^2 P (1 - P) + (N - 1) \varepsilon^2 P^2}$$

$$n \geq \frac{(1.96)^2 (4000)(0.15)(1 - 0.15)}{(1.96)^2 (0.15)(1 - 0.15) + (4000 - 1)(0.03)^2 (0.15)^2} = 3452$$

# Required Sample Size by Proportion of False Negatives



# Sample Size Calculations

How large a sample would we need to have the 95% confidence interval equal to a  $\pm 3\%$  margin of error around a proportion of  $P = 0.05$  if we were sampling from a population of  $N = 600,000$

$$n \geq \frac{z^2 NP (1 - P)}{z^2 P (1 - P) + (N - 1) \varepsilon^2 P^2}$$

$$n \geq \frac{(1.96)^2 (600,000)(0.05)(1 - 0.05)}{(1.96)^2 (0.05)(1 - 0.05) + (600,000 - 1)(0.03)^2 (0.05)^2} = 74026$$

# Sample Size Calculations

- The total sample size necessary to “accurately” estimate the proportion of false positive and false negative CLABSIs annually in the State of Texas would be:

$$3452 + 74026 = \mathbf{77478}$$

# Sample Size Calculations

- If we assume that one auditor can review 20 charts per day working 250 days per year, DSHS would have to employ approximately 16 full-time auditors.