

The Hidden Limit Problem: Non-Detection, Censoring and the Values That Were Never Measured

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Abstract

A reported non-detect is not a measured zero. It states that, under a defined analytical method and decision rule, the experiment did not produce sufficient evidence to quantify or detect the target above a stated capability threshold. Confusing non-detection with absence, replacing censored values by zero, or treating every value below a quantification limit as identical can distort averages, trends, comparisons and downstream models. This methodological article develops the hidden limit problem: the scientific information lost when the measurement floor, reporting threshold or censoring rule is treated as though it were the physical state of the sample. Examples from extractables analysis and bounded physical measurements show why detection capability, coverage, blank behaviour, recovery and the chosen statistical treatment must travel with the result. The central proposition is that the experiment can only support claims inside the region it was capable of observing.

Keywords: detection limit; quantification limit; censoring; non-detect; analytical sensitivity; missingness; threshold; uncertainty; reporting

1. Purpose and evidence boundary

HEB-001 established that numerical output is informative only within the capability of the complete measurement system [1]. HEB-007 isolates one consequence: an instrument or analytical workflow has a finite region in which it can distinguish signal from background and, often, a narrower region in which it can quantify with acceptable performance. The article is methodological rather than a validation protocol. ER-086 and ER-253 retain the application-specific architecture for extractables and analytical evaluation thresholds [4,5]. The central proposition is: A non-detect describes the measurement process before it describes the sample.

2. Zero, non-detect and below-quantification are different statements

A true zero is a physical claim about the measurand. A non-detect is a decision outcome produced by a method, threshold and data-reduction rule. A detected but not reliably quantified signal is a third state. These statements become interchangeable only if the method demonstrates that equivalence, which is unusual. Reporting $<LOD$ or $<LOQ$ therefore preserves information that a substituted zero destroys [2].

3. Detection capability belongs to the method and matrix as much as to the molecule

Detection and quantification limits depend on the analytical platform, analyte response, sample preparation, matrix, blank distribution, calibration, recovery, integration and decision rule. ER-086 explicitly requires a method to state not only what it detected but what it was capable of detecting [4]. A target-list non-detect also says nothing about compounds that were never targeted. The observable chemical space is therefore defined jointly by the sample and the method.

4. Censoring changes the statistical problem

When values are known only to lie below a threshold, the dataset is censored. Replacing censored observations by zero biases location downward and can inflate dispersion when true low values are positive; replacing them by the threshold biases location upward and typically compresses the unresolved lower tail; replacing them by one-half of the threshold imposes a value that was not measured. Each shortcut can alter means, variances, correlations and fitted models. Currie formalised the distinction among analytical decision and detection limits, while later censored-data methods treat the unresolved region explicitly rather than converting it into invented observations [6,7]. The first requirement is to preserve the censoring state rather than erase it.

5. A threshold can create an apparent discontinuity

Physical concentration, intensity or defect size may vary continuously while the reporting system produces a binary detected/not-detected output. A sample just below a threshold and one just above it can be physically similar yet reported as qualitatively different. This is a measurement discontinuity, not necessarily a natural discontinuity. Decisions may legitimately use thresholds, but the threshold must not be mistaken for a boundary in nature.

6. Blanks and recovery determine the meaning of low-level results

At low signal, blank variability and recovery can dominate interpretation. Blank evidence must be retained as part of the measurement context rather than being used mechanically to erase every coincident feature. Poor recovery can likewise create an apparently reassuring below-threshold result even when the analyte is present. A low result is therefore interpretable only together with evidence that the method would have responded had the measurand been present at a decision-relevant level [6]. ER-253 retains the application-specific architecture for analytical evaluation thresholds and chemical-space coverage [5].

7. The measurement floor can hide a trend

Suppose a response falls with time until several later observations become censored. Plotting those values as zero can create an artificial cliff; omitting them can make the surviving data look flatter; substituting the threshold can create a plateau. The experiment may still support a qualitative statement that the response declined, but the late-time kinetics are unresolved. A measurement floor can therefore hide mechanism even while preserving direction.

8. Bounded quantities create a second limit problem

HEB-001 used quantum yield to show that a numerical estimate can become uninformative when uncertainty spans most of the physically admissible range [1]. This is not censoring in the analytical sense, but the logic is related: the experiment has failed to resolve the measurand within the region needed for the claim. Physical bounds should be respected, but clipping an uncertain estimate to a permissible interval does not create information. The uncertainty attached to the estimate remains part of the reported measurement result [3].

9. Negative results require a capability statement

A scientifically useful negative result states what was challenged, how the method responded to controls, what sensitivity was demonstrated and what range remained unobserved. 'No difference' can mean evidence of equivalence only under an appropriate design and margin; otherwise it may simply mean that the experiment could not resolve a difference. Absence of detected evidence and evidence of absence are different inferential products.

10. Practical discipline

Before interpreting a low or missing value, ask: What was the detection rule? What was the quantification rule? What blank and recovery behaviour support them? Was the analyte within the calibrated range? Was the non-detect preserved as censored information? Would the method have detected the smallest effect that matters to the scientific claim? The hidden limit problem is controlled when the observable region is defined before the conclusion.

11. Case example: analytical extractables and the target-list trap

ER-086 provides a concrete analytical context for the hidden limit problem. A chromatographic method can report no target compound above its validated limit while remaining silent about non-target species, poorly responding chemical classes or unresolved coelution [4]. That result is scientifically useful if worded narrowly: the specified analyte was not detected above the demonstrated capability of the specified method. It becomes misleading when rewritten as 'no extractables' or 'nothing harmful was present'. The stronger statement requires broader chemical coverage and, where relevant, a separate toxicological chain. This distinction is not pedantic. A method can be exquisitely sensitive inside a narrow target list while having almost no information about the rest of chemical space. Analytical sensitivity and analytical coverage are orthogonal questions. The methodological question is whether each non-detect can be traced to the analyte identity, matrix, preparation, detection/quantification model and coverage boundary that made the statement possible.

12. Censoring can distort comparisons between groups

Consider two treatment groups in which many low values fall below the same reporting threshold. If one group contains a larger proportion of censored observations, replacing all of them by a common number can determine the apparent difference as much as the experiment does. Even when the same substitution rule is used for both groups, the bias need not cancel because the hidden distributions can differ. A second complication appears when the threshold itself differs between runs, matrices or instruments. Then ' $<x$ ' values are not exchangeable across the dataset. The correct response is not one universal statistical method; it is to retain the censoring information, examine how much of the conclusion depends on the unresolved tail and use a method appropriate to the design and scientific question. When the conclusion changes materially under plausible treatments of the censored region, the experiment has not strongly resolved that conclusion [7].

13. Detection thresholds and decision thresholds must be separated

A detection limit answers whether a signal can be distinguished from background under stated rules. A decision threshold may instead be set by regulation, engineering function or risk management. The two can coincide numerically, but they answer different questions. A method may be capable of detecting far below the application threshold, providing comfortable margin; alternatively, its quantification limit may sit close to the decision boundary, making classification sensitive to uncertainty. The most dangerous case is when the application threshold lies below the method's demonstrated capability. Then the experiment cannot support the required decision even if every reported value appears as a non-detect. Measurement capability must therefore be compared with the smallest effect or concentration that matters, not merely with the instrument's nominal sensitivity.

14. Sensitivity analysis is part of honest low-level inference

Where censored values materially affect a conclusion, a useful discipline is to test alternative plausible representations of the unresolved region and ask whether the substantive conclusion survives. This does not mean assigning arbitrary replacement values and choosing the preferred result. It means treating the unobserved region as uncertainty. If every plausible treatment preserves the ordering or decision, the conclusion can be robust despite censoring. If small changes in assumptions reverse the result, the evidence is fragile. This approach turns the hidden limit into an explicit inferential boundary. It also prevents later readers from interpreting a clean table of numbers as though every entry had been directly measured with equal information content.

15. Conclusions

The principal conclusions are: non-detect is not zero; detection capability is method- and matrix-dependent; censoring must remain visible in the data structure; thresholds can create artificial categories; low-level claims require blank, recovery and calibration evidence; and a negative

conclusion is only as strong as the demonstrated capability to observe the effect of interest. The values that were never resolved cannot be recovered by later arithmetic.

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Knowledge boundary

HEB-007 owns the general inferential problem created by detection limits, reporting thresholds and censoring. It does not prescribe analytical validation for a specific application. ER-086 and ER-253 retain extractables-specific analytical coverage, thresholds and qualification.

Limitations

This methodological article is a bounded synthesis of the controlled HEB and Engineering Review corpus. It does not report a new experimental dataset, does not establish universal numerical thresholds, and does not convert examples from one domain into application-wide specifications. Claims that require application-specific qualification remain with the corresponding technical review or primary study.