



FORENINGEN FOR BIVIRKNINGSRAMTE - COVID19 VACCINATION

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Public Comment to CDC – Implementation of ICD-10 Code T50.B25x and Global Impact

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A Global Standard in the Making

I am writing to strongly support the proposed ICD-10-CM code:

T50.B25x – Adverse effect of COVID-19 vaccines

The decision made by the Centers for Disease Control and Prevention (CDC) will have consequences far beyond the United States.

The CDC functions as a global reference authority. Its definitions and classifications shape:

- international clinical practice
- epidemiological research
- health data infrastructure worldwide

What the CDC recognizes, other systems tend to follow. This is therefore not only a coding decision—it is a global standard-setting moment.

The Core Issue: Patients Without Codes Become Invisible

Across healthcare systems, including Denmark, a critical structural failure exists:

Patients without a diagnostic code cannot be identified

This leads to:

- absence from registries
- exclusion from datasets
- inability to track outcomes
- lack of recognition in clinical practice

This absence is then misinterpreted as evidence: *no data* → *no problem*

Findings from the Danish national Covid evaluation, (VIVE)

The independent national evaluation of Denmark's COVID-19 response conducted by VIVE <https://www.vive.dk/media/pure/yze6my0x/28451467> commissioned by the Danish Parliament, also highlights systemic shortcomings.

The report concluded that authorities should have given **greater priority to investigating and addressing vaccine side effects**, including earlier clarification of responsibility and better follow-up of adverse events. These systemic failures contribute to erosion of public trust in health authorities.

Real-World Evidence: When Data Overrides Clinical Reality

Documented experience from Denmark shows that:

- patients with hospital admissions and serious diagnoses following vaccination
- are still not recognized as vaccine-injured
- because no specific diagnostic code is applied

As a result:

- they are not included in relevant datasets
- their conditions are reinterpreted or dismissed
- research conclusions contradict clinical reality

This demonstrates a critical failure:

data systems are overriding real-world medical evidence

Impact on Safety Studies: Distorted and Misleading Data

The lack of coding fundamentally compromises safety research.

When affected patients are:

- misclassified
- included in control groups
- or not captured at all

then:

- risk estimates are diluted
- safety signals are masked
- studies produce false reassurance

This creates structurally flawed datasets and leads to:

systematic underestimation of adverse effects due to misclassification bias

A Self-Reinforcing System Failure

The absence of coding creates a closed loop:

1. No diagnostic code
2. No registry data
3. No research signal
4. Studies conclude no problem
5. Authorities deny recognition

Meanwhile, patients:

- are hospitalized
- have documented diagnoses
- and remain severely ill

Yet are treated as statistically non-existent.

Clinical Consequences: Delayed and Inappropriate Care

Without a specific diagnostic code:

- clinicians lack a framework for classification
- appropriate diagnostic pathways are not established
- treatment becomes inconsistent or delayed

Many of these conditions are complex and require:

- targeted diagnostics
- specialized treatment approaches

Without recognition, patients are left without adequate care.

Implementation Gap: Lessons from the WHO

The experience from systems linked to the World Health Organization (WHO) demonstrates a critical lesson:

Creating a code is not enough.

In practice:

- existing codes are largely unknown to clinicians
- they are not consistently used
- they have not been integrated into clinical workflows

This is due to lack of:

- communication to national authorities
- training of healthcare professionals
- implementation strategies

As a result, the codes exist **in theory—but not in practice.**

The Critical Next Step: Education and Implementation

For the proposed code to have impact:

- clear clinical guidance on when and how to use the code
- education of physicians and specialists
- integration into electronic health record systems
- alignment with pharmacovigilance and research frameworks

Ethical and Public Health Implications

When real patients are not reflected in data systems:

- research validity is compromised
- safety monitoring becomes unreliable
- trust in health authorities is weakened

Prioritizing incomplete datasets over documented patient reality: *harms both science and public health*

Retrospective Coding: A Necessary Step for Data Integrity and Patient Recognition

It is essential that the proposed ICD-10 code **T50.B25x** is not only implemented prospectively, but also applied retrospectively to cases dating back to the beginning of the COVID-19 vaccination programs.

A large proportion of affected patients have already been:

- hospitalized
- diagnosed with serious conditions
- and documented within healthcare systems

However, because no specific diagnostic code existed at the time:

- their conditions were recorded under non-specific or unrelated diagnoses
- the causal relationship to vaccination was not captured
- they remain invisible in registry-based data

This creates a permanent distortion in health data:

- historical cases are missing from datasets
- incidence rates are underestimated
- long-term outcomes cannot be properly studied

Without retrospective coding, even a new code will only capture future cases, while the largest and most critical patient population remains excluded.

This has significant consequences:

- safety studies will continue to rely on incomplete data
- affected patients will remain unrecognized
- healthcare systems will be unable to assess the true scale and nature of long-term adverse effects

Retrospective application would allow:

- reclassification of existing patient records
- accurate identification of affected individuals
- correction of biased datasets
- and meaningful long-term follow-up

Without this step, the data gap created during the vaccination rollout will persist indefinitely.

For both scientific integrity and patient justice, retrospective implementation is not optional—it is necessary.

Why CDC Leadership Matters

Because of the CDC's global influence, this decision will:

- shape international standards
- influence how future vaccine safety is monitored
- determine whether systems prioritize **data integrity or data convenience**

This is a defining moment.

The introduction of **T50.B25x** is essential.

The CDC now has the opportunity to set a global standard—not only in classification, but in implementation, scientific integrity, and patient recognition.

Sincerely

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Chair