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Light Chain Disorders Indicative of Immune Disorders and/or Cancers Associated with the COVID-19 Infections and Injections[1]

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Abstract

Serum free light chain (sFLC) elevation following COVID-19 infection/illness and COVID-19 mRNA vaccination may indicate adverse immunological responses, such as clonal proliferation or inflammation. To evaluate the use of sFLC measurements, the Vaccine Adverse Event Reporting System (VAERS), maintained by the Centers for Disease Control and Prevention and the Food and Drug Administration, was diligently searched for sFLC abnormalities following COVID-19 vaccination. Seventy-five cases were identified as having free light chain disorders following at least one injection of COVID-19 vaccine. Twenty-five cases (33%) were singled out that had complete quantitative data for serum kappa (sFLCκ), serum lambda (sFLCλ), and the kappa/lambda ratio (sFLCR). Those 25 cases are in focus in this paper. Six patterns of sFLC elevations were identified. Case reports are given as examples. COVID-19 vaccines target lymphocytes to produce antibodies to neutralize the SARS-CoV-2 virus. Serum free light chain analysis provides insight into lymphocyte responses to mRNA including both polyclonal and monoclonal proliferation. Based on this study, careful evaluation of out-of-range values for sFLCκ and/or sFLCλ is advisable even when sFLCR is within the normal range. FLC measurements should be further evaluated as a tool to guide clinical diagnosis and to monitor inflammatory and neoplastic (cancer) disease activity in persons affected by the COVID-19 injectables.

Keywords: *cancers, COVID-19 vaccines, immune diseases, inflammation, kappa chains, lambda chains, multiple myeloma, serum free light chains, VAERS*

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[1] A draft of this paper appeared earlier with a different title at https://www.preprints.org/manuscript/202506.0904/v3.

[2] **Editor's Note:** Diligence on the part of the author, together with carefully monitored AI assistance from Grok3 (xAI) and ChatGPT5, was required because the federal agencies responsible for managing VAERS — namely, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) — seem to have gone out of their way to mangle the VAERS data with reference to COVID-19. Some of the existing reports from doctors, pharmacists, and clinicians, though well-written in the cases where they have not been scrambled, or dated incorrectly in a way that hides relevant cases in years preceding the COVID-19 biowarfare gene therapies by up to two decades or more, had to be identified and unscrambled to make use of them. Our hats are off to Robert Chandler, MD and MBA extraordinaire, for his tenacity, perseverance, and brilliance in finding the 25 central cases that form the core of this critical examination as well as the other data samples with which the key cases are compared and contrasted.

Introduction

In this paper, readers of the ***IJVTPR*** are first introduced to a brief summary of the biology pertaining to the diagnostic use of serum free light chains in the first section titled **sFLC Biology**. Readers already familiar with that subject-matter may want to skim through that first section, but it is included so the relevant **Laboratory Testing During the Pre-Clinical and Clinical Trials** of BNT162b2 and mRNA-1273 vaccines can be understood to be followed by a brief explanation of the particular **Study Aims** of this paper.

sFLC Biology

In 1848 Henry Bence Jones reported finding a novel protein in the urine of a patient with *mollities ossium* (an historical term for multiple myeloma), a fatal condition characterized by softening and deformities of bone (Jones, 1848). Early in the 20th century the proteins identified by Bence Jones were determined to be produced by neoplastic plasma cells (Kyle et al., 2008). Bence Jones proteins are small, monoclonal immunoglobulin light chains that are produced by plasma cells. Serum free light chain (sFLC) measurements later replaced urinary Bence Jones protein analysis for screening and monitoring multiple myeloma (Jenner, 2014).

Produced by B lymphocytes, immunoglobulins consist of two heavy and two light polypeptide chains. The heavy chains come in IgG, IgM, IgA, IgD, and IgE varieties. The light chains have two forms, kappa (κ) and lambda (λ). Light chains are produced in greater quantities than heavy chains with kappa produced in quantities double that of lambda chains. The range of normal values for sFLCκ chains is 3.3-19.4 mg/L and 5.7-26.6 mg/L for sFLCλ, with a normal sFLCR of 0.26-1.65 (Katzmann et al., 2002).

Serum free light chain determinations have had an expanding role in medical diagnostics and disease management for both neoplastic and, more recently, inflammatory disorders. Key facts about sFLC patterns are explained by reference to Figure 1 from Jenner (2014). He compiled data from multiple sources to identify a "broad spectrum" of neoplastic monoclonal plasma cell variants. As shown there, two critical facts must be borne in mind: (1) The area bounded by the two diagonal lines defines the reference values for sFLC kappa/lambda ratio (0.26 to 1.65). Note that the normal ratio zone is populated by cases of AL Amyloidosis (ALM) *yellow circles*, Non Secretory Multiple Myeloma (NSMM) *green circles,* Intact Immunoglobulin Multiple Myeloma (IIMM) *blue diamonds* that are outliers with respect to monoclonal gammopathies having normal values for sFLCR. Emphasis is placed on outliers with normal ratios herein as these cases require careful evaluation over time when the diagnosis of monoclonal gammopathy is not clear. The existence of cases with a normal sFLC kappa/lambda ratio but elevated sFLCκ, or sFLCλ, is a stimulus for this report. (2) Clustering is present for four out of the five monoclonal gammopathies as shown in Figure 1 suggesting discrete patterns of plasma cell dysfunction. There is a large degree of scatter in the Non Secretory Multiple Myeloma cases displayed in the figure as *green circles*.

Cases with the sFLCR kapa/lambda ratio in the range < 0.26 or > 1.65 are associated with hematopoietic neoplasms, paraneoplastic (associated with cancer), or preneoplastic (precedingcancer) conditions.[3] The sFLC abnormalities have been studied in the following plasma

[3] Neoplastic, preneoplastic, and paraneoplastic conditions are combined for the analysis in this report.

cell neoplastic or paraneoplastic conditions (Table 1), which is a small sample of the 39 B-cell and 23 T-cell neoplasms recognized by the World Health Organization (Salama & Hoffman, 2023).

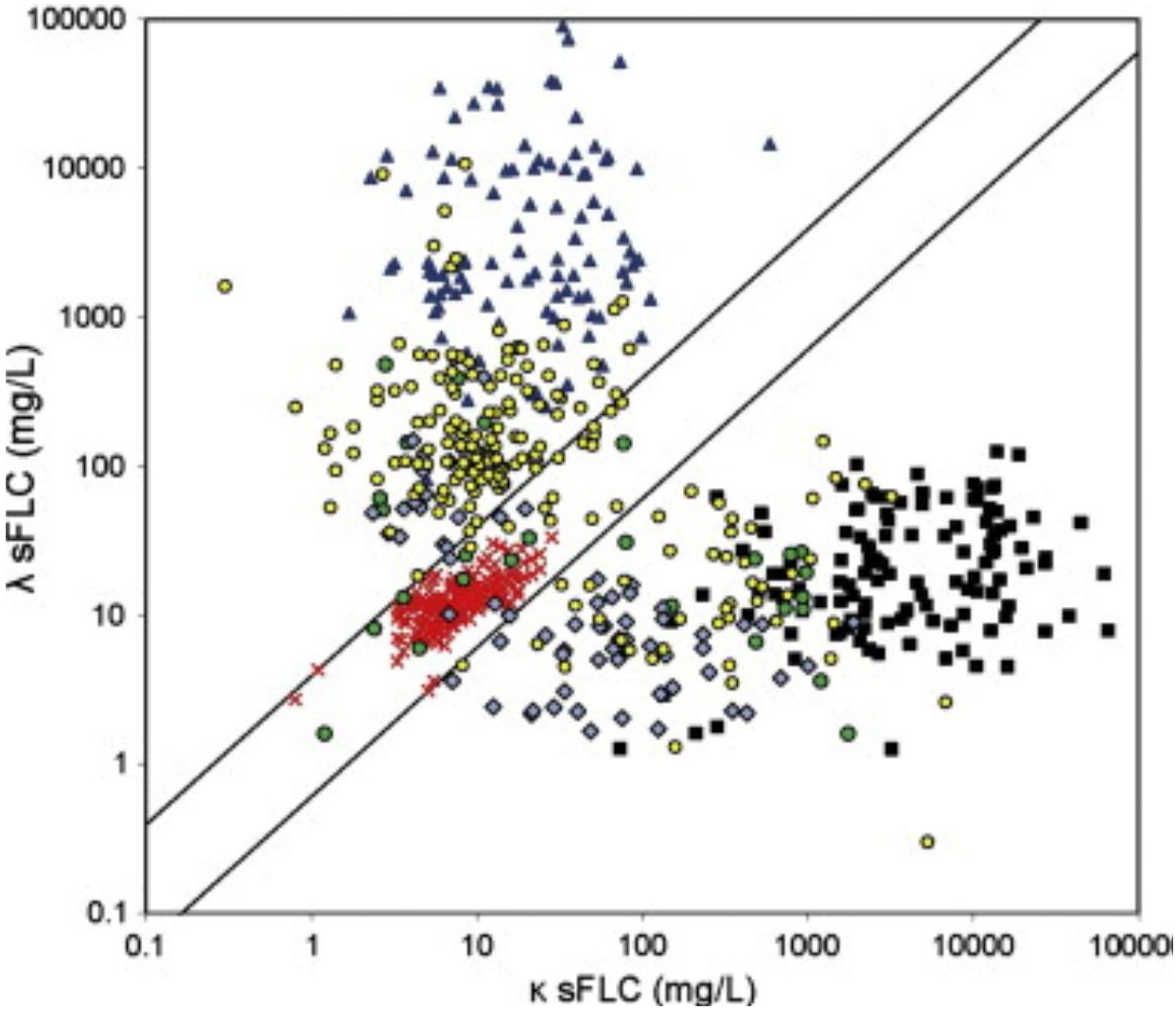

Figure 1. Numerical data for monoclonal gammopathies identifiable in κ, λ, and serum Free Light Chain (sFLC) patterns: κ Light Chain Multiple Myeloma (κLCMM) cases are shown as *black squares*; λ Light Chain Multiple Myeloma (λ LCMM) cases appear as *blue triangles*; Non Secretory Multiple Myeloma (NSMM), *green circles*; Intact Immunoglobulin Multiple Myeloma (IIMM), light gray *diamonds*; and AL Amyloidosis (ALM), *yellow circles*. Normal sera are given in the *red rosses* that appear on or between the diagonal lines. Adapted from Jenner (copyright Elsevier, 2014, p. 16). Open Access under CC BY-NC-ND License.

Gudowska-Sawczuk and Mroczko (2023) performed a comprehensive search of the literature up to 2023 in which they identified FLCs as biomarkers of inflammatory diseases including SARS-CoV-2 infection as well as monoclonal gammopathies. Their results are summed up in Table 2.

Table 1
Classification of Plasma Cell Neoplasms and Paraneoplastic Conditions Neoplastic and Paraneoplastic Conditions Associated with Out-of-Reference Values for sFLCR†

1. Non-IgM MGUS (monoclonal gammopathy of undetermined significance)
2. Smoldering myeloma
3. Multiple myeloma
4. Solitary bone plasmacytoma
5. Solitary extraosseous plasmacytoma
6. Immunoglobulin light chain amyloidosis
7. Localized AL amyloidosis
8. Waldenström macroglobulinemia
9. Light chain deposition disease (LCDD)
10. POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes)

†Adapted from Aklaghi et al. (2025); Davids et al. (2010); Dispenzieri (2019); Gertz (2024); Kaplan et al. (2011); Katzmann et al. (2009); Kyle et al. (2018); Zhu et al. (2024).

Table 2
Conditions Associated with Abnormal sFLC

Monoclonal Gammopathies	Diabetes
Multiple Sclerosis	Cardiovascular disease
SARS-CoV-2 infection	Rheumatoid arthritis
Hepatitis C	Sjögren's syndrome
Hepatitis B	Systemic Lupus Erythematosus
Human Immunodeficiency Virus	Lung cancer
Lyme disease	Breast cancer
Tick-born encephalitis	Bowel disease

Use of sFLCκ, sFLCλ and sFLCR measurements continues to expand as a diagnostic and management tool that gives insight into the function of terminally differentiated B-cells known as plasma cells. These cells are active in responding to inflammatory conditions and a growing array of neoplastic, monoclonal gammopathies and related conditions.

Recent studies highlight the diagnostic utility of sFLC levels in various conditions, including Central Nervous System (CNS) disorders, type 2 diabetes (T2D), cardiac disorders, renal disorders, protein deposition in multiple organs (amyloid), as disease conditions following COVID-19 vaccination:

- Hegen et al. (2022) reported on cerebrospinal fluid sFLCκ free light chains as useful biomarkers in multiple sclerosis from diagnosis to prediction of disease activity.

- Demortiere et al. (2025) found FLC levels in patients with inaugural optic neuritis were useful to sort out multiple sclerosis (MS), myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD), and neuromyelitis spectrum disorder (NMOSD).
- Bracco et al. (1987) found that FLC in cerebrospinal fluid of multiple sclerosis patients implicated recent immunological stimulation leading to increased synthesis of FLCs within the central nervous system.
- Matsumori et al. (2020) found sFLCR to be more specific and sensitive for the diagnosis of T2D than hemoglobin A1c.
- Basile et al. (2019) found sFLCR > 0.63 to be associated with left ventricular ejection fraction improvement in a small number of patients with NSTEMI (Non-ST-Elevation Myocardial Infarction), STEMI (ST-Elevation Myocardial Infarction), and stable angina at one year follow-up.
- Nakao et al. (2023) reported an increase in IgA nephropathy following COVID-19 mRNA vaccination.
- Park and Kwon (2024) pointed out the role of monoclonal FLCs in producing kidney damage in Monoclonal Gammopathy of Renal Significance (MGRS) without multiple myeloma or other forms of neoplasia.
- Martins et al. (2024) reported on 23 cases of non-myeloma light chain cast nephropathy (non MM-LCCN) pointing out that LCCN develops 4.4-14.3 years after the hematologic malignancy in 10/23 (43%) of the cases they examined.
- Lan et al. (2024) presented a case of light chain proximal tubulopathy (LCPT) and light chain cast nephropathy (LCCN) in a 49 year-old patient with acute kidney injury associated with sFLCλ light chain multiple myeloma (λ-LCMM).
- Cassano et al. (2025) reported on light chain deposition disease (LCDD), a condition in which non-amyloid monoclonal light chains accumulate in various organs — most notably the kidneys. In affected patients, typically those with plasma cell dyscrasias, or even monoclonal gammopathy of undetermined significance (MGUS), these abnormal immunoglobulins deposit along the vascular, glomerular, and tubular basement membranes.

Laboratory Testing during the Pre-Clinical and Clinical Trials

BNT162b2 and mRNA-1273 vaccines produced reactive lymphoid/hematopoietic changes in Pre-Clinical repeat-dose rat studies. After BNT162b2, germinal center hypercellularity with plasmacytosis was noted in iliac and inguinal lymph nodes. The spleen showed splenomegaly and extramedullary hematopoiesis**,** and the bone marrow showed myeloid-predominant hypercellularity**.** Lymph-node plasmacytosis, germinal center hypercellularity persisted in some animals**.** Enlarged inguinal, iliac, and popliteal lymph nodes with increased cellularity with mixed inflammatory infiltrates were observed after mRNA-1273**.** Lymph-node changes were not resolved at the end of the recovery period (European Medicines Agency, 2020; BioNTech Manufacturing GmbH, 2021; Therapeutic Goods Administration, 2021; European Medicines Agency, 2021).

The pre-clinical studies found cytokines were released with the BNT162 platform versions but the 30 μg dose of BNT162b2 Version 9 Process 2, the product released under the Emergency Use Authorization, was not specifically tested. Other formulations were tested and it was claimed that cytokine release did occur but resolved. Cytokines were studied with the final version of mRNA-

1273 claiming that cytokines MCP-1 (CCL2), IP-10 (CXCL10), MIP-1α (CCL3) were elevated but levels were improving at end of the study (EMA, 2021).

The Pfizer phase 1 trial enrolled 195 subjects in total (Walsh et al., 2020). Twelve participants aged 18 to 55 and 12 aged 65 to 85 received 30 μg of BNT162b2 (n = 24). Blood studies obtained in the phase 1 trial consisted of **Hematology**: Complete Blood Count with differential (CBC with Diff.), **Chemistry:** sodium, potassium, chloride, bicarbonate, glucose, BUN, creatinine, calcium, total protein, albumin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin, **Serology**: HBsAg, anti-HBc, HCV Ab, HIV Ag/Ab, and **Urine**: human chorionic gonadotropin (β-hCG) before each dose in Women of Childbearing Potential (WOCBP). Blood draws were collected at baseline, Dose 1/Day 1–3, Dose 1 Day 6–8, Pre-dose 2 and Dose 2 Day 6 to 8. There were no test results reported for the critical 72 hours following the second dose (Pfizer, 2020).

Safety data (hematology, chemistry and urine) were summarized in Walsh et al. (2020) as brief decreases in post-vaccination lymphocyte counts with no associated clinical findings; raw values were not provided. The online supplement Figure S3 c. and d. for BNT162b2 presented here as Figure 2 shows a drop in the lymphocyte counts 1-3 days after dose 1.

Data for Days 1-3 after dose 2 are not presented. The final determination 7 days after dose 2 showed elevation of the median above baseline in the 15-55 year-old subgroup. Note the Y-axis has been enlarged for the 55-85 year-old subgroup while in the 15-55 year-old subgroup the whiskers, showing the minimum value at the bottom and the maximum at the top, were removed from the box plot for the final set of data possibly indicating sufficient variability to require an increase in the range of the Y-axis.

A single baseline blood draw for hematology and chemistry was in the protocol for the Pfizer Phase 2/3 clinical trial. Follow-up hematology, chemistry and specialized studies were not done or systematically sampled for the approximately 40,000 subjects enrolled in the trial though these were called for in the protocol. Additional laboratory studies were supposed to be done for two specific reasons: one, if clinically indicated; and two, for special studies. There is no information about the number of such cases nor are there any clinical findings or results of laboratory testing for any of these cases. No additional laboratory data are presented for safety testing in phase 1/2/3 of the clinical trials (Walsh et al., 2020; Polack et al., 2020; Thomas et al., 2021). The Moderna trials for mRNA-1273 only noted a drop in lymphocytes, but no specific data was published. No hematology studies were routinely performed during the phase 3 trial.

Lymphocytes were targeted with BNT162b2 and mRNA-1273 yet there was almost no investigation as to what exactly happens to lymphocytes after exposure to COVID-19 modRNA/LNP beginning with marrow-based pluripotential stem cells through the differentiation process in germinal centers and terminal differentiation in tissues and organs. The duration of BNT162b2 and mRNA-1273 induced antigen production, amount produced, metabolic degradation, tissue toxicity, and location of production were not studied (BioNTech, 2021). The exact nature of the proteins produced was not characterized nor was the fate of the mRNA determined.

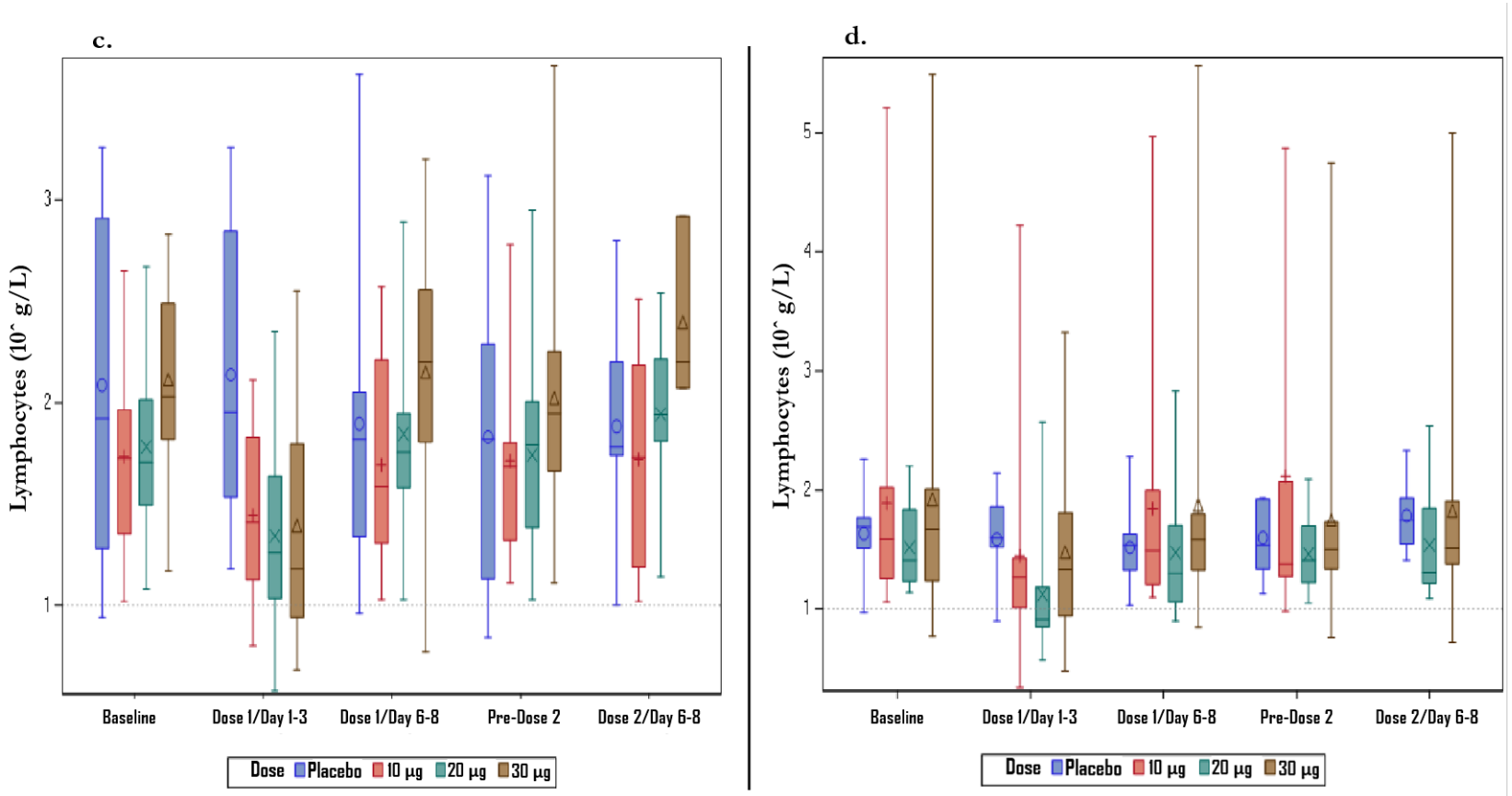

Figure 2. An abbreviated version of Figure 3S on page 5 in the Supplementary Appendix (hyperlinked here) of Walsh et al. (2020). Fonts have been clarified to make the figure more readable and parts a. and b. have been omitted. Lymphocyte counts following the first and second doses of 10 µg, 20 µg, or 30 µg of Pfizer BNT162b2 are reported. Doses at 100 µg were also tested, but no results concerning those large doses are reported..The original caption reads: "Figure S3 | Postvaccination changes in lymphocyte count over time. Figure represents box-and-whisker plots for observed values at the following time points: Dose 1/Day 1-3: ~1 day after Dose 1; Dose 2/Day 6-8: ~7 days after Dose 1; Pre-Dose 2: before Dose 2; Dose 2/Day 6-8: ~ 7 days after Dose 2. Symbols denote group means – O: placebo; +: 10 µg; X: 20 µg; Δ: 30 µg; : □ : 100 µg. [In fact, the □ symbol for the 100 µg dose never appears in any of the boxes.] Center line of box denotes median; lower and upper edges denote first and third quartiles; lower and upper whiskers denote minimum and maximum. a. BNT162b1 18–55 years of age; b. BNT162b1 65–85 years of age; c. BNT162b2 18–55 years of age; d. BNT162b2 65–85 years of age." Copyright © 2020 Massachusetts Medical Society. Adapted from Walsh EE, Frenck RW Jr, Falsey AR, et al. Safety and immunogenicity of two RNA-based COVID-19 vaccine candidates. *New England Journal of Medicine* 2020;383:2439-50. Supplementary Appendix, Figure S3. Adapted with permission from the Massachusetts Medical Society, https://doi.org/10.1056/NEJMoa2027906.

Study Aims

The desired outcome from studying sFLCs is identification of a biomarker for immune system and neoplastic diseases with greater specificity and sensitivity than common inflammatory indicators, such as the erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). This article examines sFLC patterns (sFLCk, sFLCλ and sFLCR) following vaccination with Pfizer/BioNTech's BNT162b2 and Moderna's mRNA-1273 using cases drawn from the VAERS database.

Materials and Methods

VAERS reports are voluntarily submitted by individuals, including healthcare professionals, who suspect a potential causal link between the reported adverse events and the administration of one or more vaccines. VAERS is a US government surveillance system that collects data on adverse events following all types of vaccinations, not just those related to COVID-19. However, as of July 25, 2025, more than 64% of the 2,678,868 total adverse event cases reported in VAERS throughout the history of its existence were reported pertaining to COVID-19 vaccines.

Search terms included all FLC-related identifiers and free-text field searches for FLC reporting in Adverse Event Descriptions and Lab Data sections of VAERS reports. Specific conditions searched included multiple organ system related diagnoses such as renal disorders, Central Nervous System (CNS) disorders, hematological disorders, and cardiac disorders. Microsoft Excel, Grok3 (xAI) and ChatGPT5 were used for research, data analysis, preparation of tables, and proofing. AI output was carefully screened for errors.

In total, 75 cases of sFLC abnormalities were identified. This study examines 25 unique VAERS cases reporting free light chain (FLC) abnormalities potentially associated with adverse events following COVID-19 mRNA vaccination, with data updated as of June 21, 2025. Attempts to use adverse event and lab data from VAERS for clinical analysis in this report were abandoned due to incomplete data in complex cases. Hematopoietic neoplasia, the development of such cancers over time, often requires extensive effort to reach a definitive diagnosis. VAERS has not included follow-up reports although with change in administration efforts of the relevant federal agencies, especially those under the Department of Health and Human Services, to add follow up data to VAERS reports have been initiated.

The framework summed up in Table 3 was used to analyze the quantitative VAERS data. Normal versus abnormal sFLCR was used as an ordering principle to analyze data with subset analysis according to sFLCκ and/or sFLCλ levels.

Table 3
Inflammation versus Neoplasm Judged by the Serum Free Light Chain Ratio (sFLCR)

	sFLCR	sFLC
Inflammation	0.26 to 1.65	κ, λ, κ and λ
Neoplasm	either < 0.26 or > 1.65	κ, λ, κ and λ

Results

The average time to onset of inflammation and/or neoplasm was 50 days, with 45% (10/22) of cases with onset occurring within 7 days.

Outlier Analysis

The series of 25 cases considered here includes some instances of hematologic cancer with very high levels of free light chains. Free light chains are known to rise to levels in such patients exceeding 10,000 mg/L for both sFLCκ and sFLCλ (Snozek, et al. 2018, Xu, et al. 2022; Pratt et al. 2023; Huang, et al. 2024). Table 4 shows the distortion of the mean caused by high values in this data set with the outliers included in the values reported in the left half of the table but excluded in the right half. The medians are less impacted than the means and standard deviations. The reason for the dramatic impact of outliers on the means and standard deviations is simple algebra, but supposing the entries pertaining to the outliers are grounded in facts and not errors, they demand closer examination. All three outlier cases were diagnosed with hematological malignancies confirmed with biopsies. Judging from relevant medical literature extreme cases with rapid onset and extreme levels of sFLCs such as LC #16 and LC #63 may indicate unusually aggressive forms of cancer — precisely, the type of development that some have called "turbo cancer" (Krüger, 2024; Debord, 2025; Marik & Hope, 2025; Hulscher, 2025).

Table 4
Serum Free Light Chain (sFLC) Quantitative Data

Quantitative Cohort with Outliers (LC #16, LC #29, and LC #63) Included				Quantitative Cohort with Outliers (LC #16, LC #29, and LC #63) Excluded			
***n* = 25**	**sFLCκ µg/L**	**sFLCλ µg/L**	**sFLCκ/ sFLCλ**	***n* = 22**	**sFLCκ µg/L**	**sFLCλ µg/L**	**sFLCκ/ sFLCλ**
Mean	201.50	467.07	9.47	**Mean**	86.58	84.61	3.20
SD	588.55	1380.49	33.20	**SD**	83.79	167.33	7.08
Median	58.80	35.79	1.47	**Median**	50.05	30.35	1.61
Minimum	4.27	0.44	0.01	**Minimum**	4.27	1.96	0.08
Maximum	3000.00†	5975.00†	165.61†	**Maximum**	338.00	799.00	34.50

†The three outlier cases contributed the key maximum values marked here in the left half of the table. Each of them though presenting a unique profile with respect to the key measures at issue, was impacted by biopsy proven hematological cancer, these cases multiple myeloma.

Lymphoproliferative neoplasm does not necessarily elevate sFLCR.

Aklaghi et al. (2025) reported that a kappa/lambda ratio over 100 indicates myeloma. The cohort featured in this paper had one case with sFLCR > 100 — that was a myeloma case supporting this conclusion. However, cases LC #60 lymphoma and LC #63 myeloma had normal ratios, evidence that a normal ratio does not rule out the presence of hematological neoplasia.

Cases in which the ratio ≤1.65 but in which sFLCκ and/or sFLCλ exceed the normal range should be considered for serial monitoring. Malignant transformation is reported to occur in up to 30% over 20 years for non-IgM Monoclonal Gammopathy of Undetermined Significance (MGUS) in

patients with two risk factors — namely, an elevated sFLC kappa/lambda ratio and high serum monoclonal protein greater than or equal to 1.5 g per deciliter (Kyle et al. 2018). Bird et al. (2009, p. 33) concluded,

> Clinicians responsible for monitoring patients should be aware that the risk of progression to myeloma or other LPD (Lympho-Proliferative Disorders) remains lifelong and that risk never disappears even if the M-protein (monoclonal protein) remains stable.

ILLUSTRATIVE CASES

- Case LC #11 (VAERS ID# 2619645) received five doses of COVID-19 vaccines (three Moderna and two Pfizer) and was subsequently identified as having Monoclonal Gammopathy of Undetermined Significance on the basis of elevation of sFLCκ (27.5 mg/L) with normal sFLCR (1.31). Serial sFLC follow up measurements should be considered in such a case.

- Case LC #63 (VAERS ID# 2509414) was a 60-year-old male who obtained medical care 1 week after a second dose of BNT162b2 because of weight gain, proteinuria, and hypoalbuminemia. Urinary Bence Jones proteins were positive, both sFLCκ (3000 mg/L) and sFLCλ (3846 mg/L) were elevated but the ratio was normal at 0.78. A kidney biopsy was positive with Congo Red stain indicating the presence of amyloid deposits. A bone marrow biopsy revealed amyloid deposits along with 10% plasma cell aggregates consistent with multiple myeloma.

- Case LC #24 (VAERS ID# 2516749) was a 41-year-old woman with HLA-B27-positive arthritis in remission who had onset of nephrotic syndrome 7-10 days after dose four of BNT162b2 with lower extremity edema, hematuria, proteinuria, hypoalbuminemia, and elevated sFLCκ (37.74 mg/L) and sFLCλ (37.95 mg/L) with sFLCR normal (0.99). A renal biopsy revealed focal segmental glomerulosclerosis (FSGS). A bone marrow biopsy would be of interest in this case.

- LC #42 (VAERS ID# 2267797) was a 47-year-old woman who received three doses of mRNA-1273 June 4, 2021, July 2, 2021 and the third dose was received on January 13, 2022. In November of 2021 she had the onset of anemia. In January of 2022 an IgG monoclonal band and an elevated sFLCλ (173 mg/L) with an sFLC kappa/lambda ratio of 0.09 were identified. A bone marrow biopsy showed 7-9% monoclonal plasma cell infiltration.

- Case LC #16 (VAERS ID# 2130959) was a 46-year-old woman with past history of hypothyroidism and labile hypertension who had onset of severe bilateral knee pain and flu-like symptoms 31 days after her second dose of mRNA-1273. A rheumatologist obtained sFLCs showing sFLCκ was 72.87 mg/L with a ratio of 165.61. After consultation with a hematologist, a bone marrow biopsy confirmed Kappa Light Chain Multiple Myeloma. She was rated as permanently disabled due to the chronic and progressive nature of multiple myeloma.

- Case LC #29 (VAERS ID# 1948754) was a 62-year-old man with IgG-lambda multiple myeloma on chemotherapy when he received BNT162b2 dose #2 on April 7, 2021. Eleven days later he developed a progressive, non-pruritic generalized erythematous rash beginning on the hands, accompanied by lower-extremity weakness. On May 4, 2021 he was found to have inguinal lymphadenopathy and bilateral pulmonary infiltrates and was hospitalized (May 5, 2021) for 10 days. A skin biopsy showed subacute eczematous dermatitis. CT confirmed bilateral pneumonia that improved on piperacillin/tazobactam and clarithromycin. By May 19, 2021 the rash and weakness had resolved. He recovered from pneumonia. Underlying myeloma activity included marked lambda FLC elevation (5975 mg/L, $\kappa/\lambda < 0.01$), proteinuria (2.25 g/day), and bone marrow showed 50–60% plasma cells. A causal relationship with the COVID-19 vaccine could not be excluded.

Discussion

In this section, first a discussion of sFLC patterns observed in COVID-19 infections and injections, and the case is then made that sFLC provides a better diagnostic tool than other acute phase reactants.

COVID-19, COVID-19 Vaccines and sFLC Patterns

Malecka-Gieldowska et al. (2021) observed a 3-fold increase in sFLCκ light chain synthesis in SARS-CoV-2-infected Intensive Care Unit (ICU) patients compared to non-infected ICU cases, distinguishing COVID-19 ICU from non-ICU patients. Cell population data (CPD) revealed variations in leukocyte size, granularity, and amount of genetic material in the three groups.

> COVID-19 ICU patients had the greatest size, granularity, and nucleic acid content in neutrophils and lymphocytes (WDF-Y, NE-SFL, LY-X, LY-Y, NE-SSC, WDF-X, WDF-WX, and WDF-WY) when compared with other groups. In contrast, patients without SARS-CoV-2 infection hospitalized in the ICU had the lowest values of the mentioned parameters (Malecka-Gieldowska et al., 2021 p. 7).[4]

These findings indicate that SARS-CoV-2 infection stimulates sFLC production, particularly in severe cases. Gudowska-Sawczuk et al. (2022) extended this analysis, reporting significantly higher sFLC concentrations in COVID-19 patients and vaccinated controls compared to unvaccinated controls ($p < 0.001$).

The current study of 25 VAERS cases identifies even higher sFLC levels post-COVID-19 vaccination in cases of adverse reactions in Table 5 for the ***n* = 22 cases with the three outliers** removed as discussed above, with a mean sFLCκ at 86.58 mg/L, sFLCλ at 84.61 mg/L, and sFLCR at 3.20. These values can be compared with those for COVID-19 ICU patients in Table 5 with an sFLCκ mean at 47.03 mg/L, sFLCλ mean at 34.71 mg/L, and non-ICU patients with an sFLCκ mean at 24.62 mg/L, and an sFLCλ mean at 25.83 mg/L. If we rank the data in Table 5 from least

[4] Abbreviations used in this quotation are these: WDF = white blood cell differential channel (Sysmex XN series); X = side scatter (SSC; cell complexity/granularity); Y = side fluorescence (SFL; nucleic-acid content); WX/WY = distribution width (spread) along the X or Y axis; NE = neutrophil cluster; LY = lymphocyte cluster. Thus, WDF-X = mean SSC of total WBCs; WDF-Y = mean SFL of total WBCs; NE-SSC = neutrophil SSC; NE-SFL = neutrophil SFL; LY-X = lymphocyte SSC; LY-Y = lymphocyte SFL.

to most impacted we find a gradient of immune challenge, from natural infection to reported adverse events following COVID-19 vaccination.

The gradient of sFLC elevation — highest in VAERS reported vaccine adverse event cases, followed by COVID-19 ICU, non-ICU, vaccinated controls, and non-COVID controls suggests increasing immune challenge from SARS-CoV-2 infection to adverse events following COVID-19 vaccination. This work identifies sFLC abnormalities as a potentially useful biomarker for diagnosis and management of COVID-19 vaccine related adverse events.

Table 5
Comparison of sFLC for Cases from VAERS Adverse Event Reports after COVID-19 Vaccination: COVID-19 ICU patients, COVID-19 non-ICU patients, Vaccinated Controls, and Unvaccinated Controls[1]

Groups Defined and Ranked by Ascending sFLCκ and sFLCλ After COVID-19 Vaccination	**sFLCκ (mg/L)** **Average (Min-Max)**	**sFLCλ (mg/L)** **Average (Min-Max)**	**κ/λ Ratio** **Average (Min-Max)**
Unvaccinated Controls [2]	10.25 ± 2.13	10.26 ± 2.76	1.03 ± 0.22
n = 20	(6.28–15.04)	(6.84–18.89)	(0.51–1.41)
Mild COVID-19[2]	16.76 ± 5.51	16.38 ± 6.17	1.10 ± 0.28
n = 80, (67 vaccinated)	(5.25-42.50)	(6.32-36.50)	(0.44-1.94)
Vaccinated Controls[2]	17.83 ± 3.03	13.22 ± 3.87	1.40 ± 0.24
n = 20	(12.10–23.70)	(9.24–22.00)	(0.88–1.77)
COVID-19 non-ICU[3]	24.62	25.83	1.27
n = 43	(21.22–36.45)	(19.26–28.38)	(1.06–1.35)
COVID-19 ICU[3]	47.03	34.71	1.34
n = 45	(43.52–64.76)	(30.66–47.23)	(1.20–1.52)
VAERS Adverse Events [4]	86.58	84.61	3.20
***n* = 22**	(4.27–338)	(1.96-799)	(0.08–34.50)

[1] Elevated sFLC values and abnormal ratios are in red.

[2] Gudowska-Sawczuk, et al. (2022). Numbers in parentheses are for the range.

[3] Malecka-Gieldowska, et al. (2021). Numbers in parentheses represent 95% CI for the mean.

[4] For reasons discussed earlier, the three outliers were excluded from the calculation of the values on this row. Numbers in parentheses are for the range.

The current study identified 25 cases with complete sFLC data out of 75 total cases with reported free light chain disorders using the search criteria based upon out-of-range values. This small sample was remarkably diverse with the following six patterns identified in Table 6. There are two categories of normal sFLCR with either elevation of sFLCκ, or an elevation of both sFLCκ and sFLCλ.

Three of the four categories of abnormal sFLCR consist of elevation of sFLCκ, sFLCλ, and both sFLCκ and sFLCλ. The fourth category had two cases of low sFLCλ with normal sFLCκ which disqualifies this pattern as a gammopathy since there is no excess sFLC and suppression of λ producing plasma cells is likely.

sFLC As A Better Diagnostic Tool Than Other Acute Phase Reactants

Compared to traditional inflammatory markers like ESR and CRP, sFLC offers greater sensitivity for detecting immune dysregulation, supporting its potential for monitoring neoplasia or inflammation. As demonstrated in this review cases with abnormal ratios (red) are used clinically in the context of hematological neoplasms both for diagnosis and monitoring. Less clear is the clinical use in cases

Table 6
Six Patterns of Free Light Chain Elevations in VAERS Cases

Pattern	*N* = 25	sFLCκ (mg/L)	sFLCλ (mg/L)	κ/λ Ratio
1. Normal Ratio, sFLCκ Elevated	4	29.9	22.5	1.3
2. Normal Ratio, sFLCκ and sFLCλ Elevated	6	564.59	696.68	1.04
3. Elevated Ratio, sFLCκ Elevated	5	103.48	17.06	9.45
4. Ratio, sFLCκ & sFLCλ All Elevated	5	158.64	74.69	34.74
5. Low Ratio, sFLCλ Elevated	3	68.48	2315.67	0.09
6. Elevated Ratio, sFLCλ Low[1]	2	7.05	3.49	2.07
Average		201.50	467.07	9.47

[1]Probable suppression of sFLCl producing plasma cells with normal sFLC kappa/lambda ratios but with out-of-range values for sFLCκ, or sFLCλ must be considered carefully. Out of the expected range values are not perfect indicators of neoplasia but such cases require further evaluation.

Furthermore, as shown by Gudowska-Sawczuk (2022) and others sFLCs may be useful for diagnosis and management of inflammatory conditions extending the value of this biomarker to a wider assortment of medical conditions. COVID-19 illness and COVID-19 vaccination research reported by Malecka-Gieldowska et al. (2021) and Gudowska-Sawczuk et al. (2022) was applied to groups and not individuals. Longitudinal data is needed to define individual patient patterns.

Sample Size and Lab Data

VAERS contains no incidence or prevalence data for the adverse event reports. The Health and Human Services sponsored Harvard-Pilgrim Health Care review of VAERS from December 1, 2007 to September 30, 2010 estimated that fewer than 1/100 of the vaccine adverse events that occurred were actually reported (Lazarus, 2010). The current level of reporting is unknown.

The prevalence of light chain disorders in persons reporting adverse events following COVID-19 vaccination is not known. Lymphocyte counts *(search terms lymphocyte count, lymphocyte count abnormal,*

lymphocyte count decreased, lymphocyte count increased, and lymphocyte count normal) are far more common than light chain analysis as they are part of the very common complete blood count with differential *(CBC with Diff)* but have been reported in only 5,656 out of 2,678,868 (0.21%) of the case reports in VAERS.

POLYCLONAL AND MONOCLONAL INDUCTION BY COVID-19 VACCINATION

Röltgen et al. (2022) found detectable spike protein in plasma in 96% of healthy subjects for one to two days and in 63% at a week post-vaccination. In some subjects Spike antigen and mRNA presence in lymph node germinal centers persisted for the entire 60 day duration of their study. When axillary lymph nodes from vaccinated healthy subjects were compared to peribronchiolar lymph nodes in patients with severe COVID-19, the germinal centers in infection cases were disorderly and depleted, while those in vaccinated subjects were hyperplastic and orderly. Recently, the Yale LISTEN PVS study (Krumholz, et al. 2023) identified circulating whole spike and S_1 subunit antigen presence for as long as 709 days after vaccination from which they claimed prolonged immune stimulation owed to the COVID-19 vaccinations.

Prolonged vaccine induced spike proteins in tissues and in circulation are either not being degraded and or are continually being produced. Long term production of these foreign proteins might originate in host cytoplasm through long-term translation of modified mRNA coding for spike protein with 728 substitutions of N-1 methylpseudouridine for uridine (Santiago & Oller, 2023), a synthetic mRNA that is deliberately "cloaked" (Nance & Meier, 2021) and artificially stabilized to slow or possibly halt its degradation. A second possibility is that the spike coding sequences are incorporated in part or whole by reverse transcriptase from the synthetic mRNA into the host chromosomal DNA (Aldén, et al., 2022) then are transcribed in the nucleus and translated in the cytoplasm. Nuclear penetration by the N-1 methylpseudouridine modified RNA and incorporation into host chromosomes raises not only the possibility of heritability but also mutagenesis that could lead to the monoclonal expansion and neoplasia as seen in a subset of the VAERS cohort reported here. It may, also, as implied by Nyström and Hammarström (2022) and argued extensively by Santiago and Oller (2023) be the primary source of the strange clotting phenomena associated with the COVID-19 injections.

POST COVID-19 VACCINATION LYMPHOCYTE INFILTRATION

Burkhardt et al. (2024) and Krüger et al. (2025) demonstrated spike proteins with associated tissue destruction in histological and immunohistochemical analyses of autopsy and biopsy specimens following vaccination. Using immunohistochemical techniques COVID-19 vaccine-induced changes were differentiated from those of COVID-19 thus identifying vaccine-induced spike protein in inflamed and degraded tissues. Spike protein persisted for at least a year. Multiorgan involvement with unique histopathological findings is characteristic of the findings in this unique collection of histopathological and immunohistochemical analyses of autopsy and biopsy specimens performed following COVID-19 vaccination. Krüger et al. (2025) concluded that in 74% of the 89 autopsy cases studied that a causal relationship with COVID-19 vaccination was probable to near certainty based on unique patterns of tissue changes.

Lymphocyte Infiltration with Local Tissue Destruction

A common finding across many organ systems in the Burkhardt/Lang data was infiltration and aggregation of lymphocytes in areas undergoing destruction of tissues leading to irreversible fibrosis.

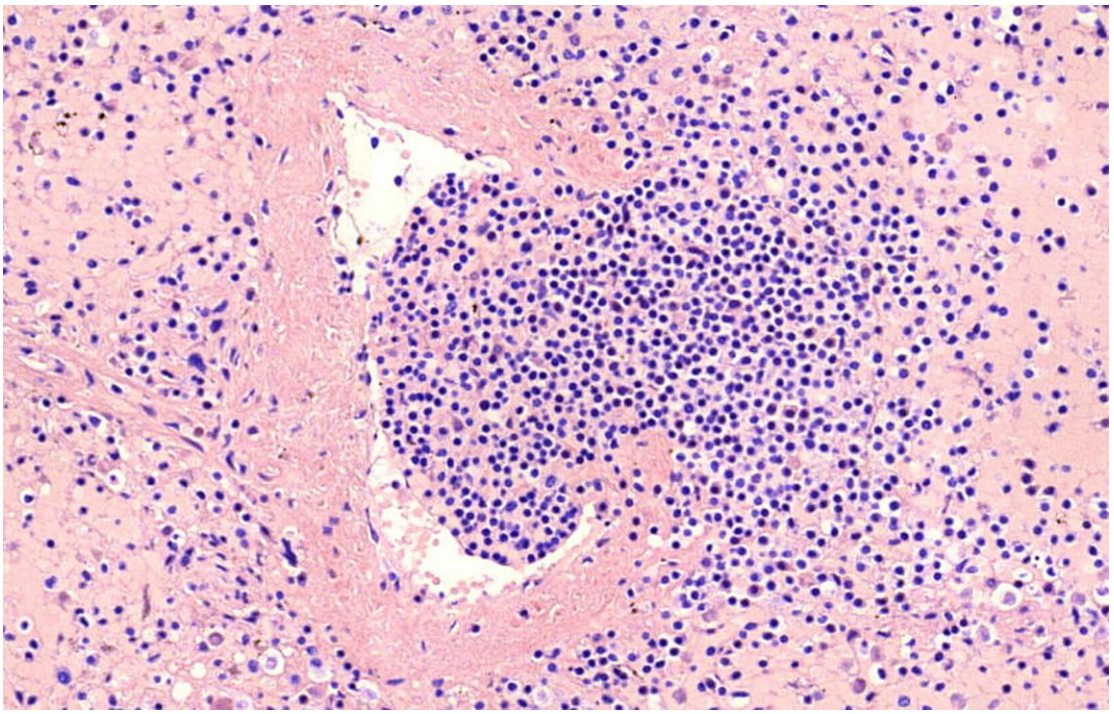

Figure 3. Penetration of a splenic arterial wall by infiltrating lymphocytes in case 24. From the Pfizer Papers (p. 56) by A Burkhardt, 2024. Reprinted with permission from Drs. Lang and Schwartz.

In some cases, large, dense basophilic (hematoxylin and eosin stain) clusters of lymphocytes resembling ectopic germinal centers were identified (Figure 2). Vasculopathy, amyloid deposition, and associated clotting and bleeding were common findings along with unidentified brownish to black inclusions noted in multiple organs. Similar findings have been described in the medical literature (Baumeier, et al. 2022; Nushida, et al. 2023; Rosati, et al. 2023).

Case 24 (again refer to Figure 3) was an 81-year-old woman who collapsed 17 days after her third COVID-19 vaccination. The figure illustrates dense lymphocytic perivascular inflammation with vascular wall injury consistent with microangiopathy/endarteritis lymphocytic infiltration. Microangiopathy and T-cell–predominant lymphocytic inflammation waswere identified in the deceased's heart, lung, kidney, spleen and liver, including low-grade lymphocytic myocarditis. Dr. Burkhardt's (2024, page 56) comment about this lymphocytic accumulation, "…this is a phenomenon that none of the pathologists that I work together with have ever seen."

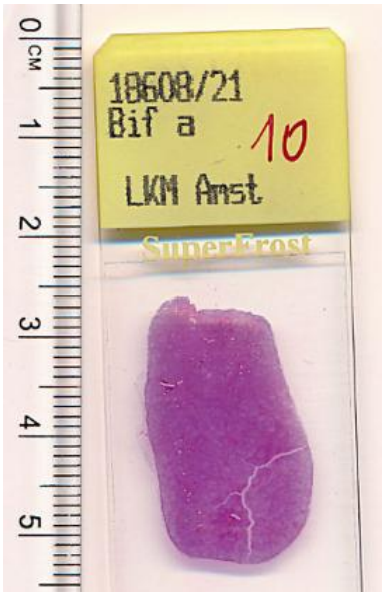

Figure 4. Case 7 "Pseudolymphoma". From the *Pfizer Papers* (p. 56) by A. Burkhardt (2024).

https://doi.org/10.56098/mmk5wh51

Burkhardt was a senior pathologist who conducted and supervised over 40,000 autopsies.

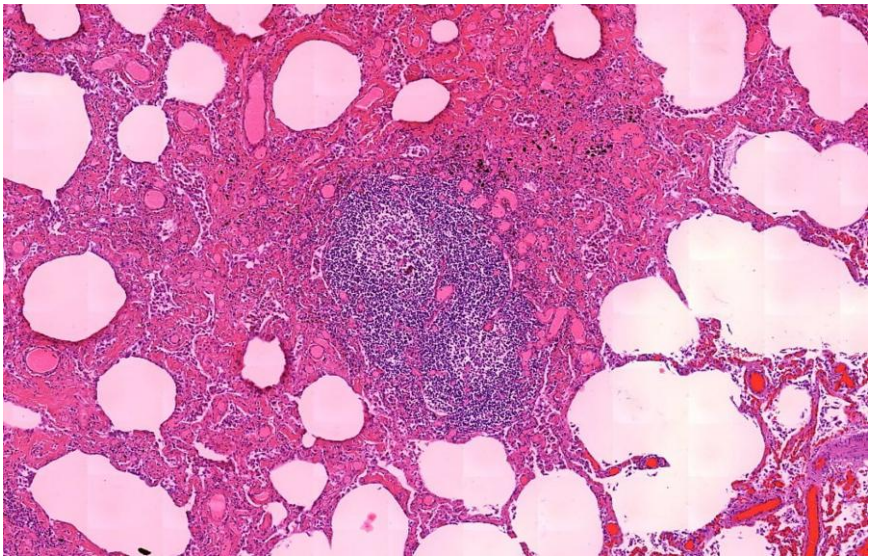

Figure 5. Case 7 — Lung, H&E. Yellow circle/arrow highlights a compact peribronchiolar/perivascular lymphoid aggregate with a pale germinal-center–like core and darker mantle, morphologically consistent with a tertiary follicle–like TLS candidate. Adjacent alveoli show interstitial pneumonitis and congestion. From the *Pfizer Papers* (p. 63) by A. Burkhardt (2024).

Lymphocyte Accumulation and Tertiary Lymphoid Structure-like Formation

Tertiary lymphoid structures (TLS) are organized lymphocyte clusters in non-lymphoid organs like lung and kidney in distinction from secondary lymphoid structures such as mucosa-associated lymphoid tissue (MALT), spleen and lymph nodes and primary lymphoid structures like bone marrow (B cells) and thymus (T cells). TLSs have positive influence in cancer cases, but the opposite is true in non-cancer diseases like chronic infections, autoimmune disorders, and transplants. In the latter instances TLSs carry a negative prognosis (Zhao, et al. 2024). TLS formations have not been definitively confirmed after COVID-19 vaccination in the Burkhardt and Lang collection but lymphoproliferative disorders have been reported following COVID-19 vaccination (Zamfir, et al. 2022; Gordon, et al. 2024).

Case 7 (see Figures 4 and 5) was a 55-year-old man who died of a myocardial infarction 7 days after his second dose of BNT162b2. Burkhardt determined at a level of near certainty that the man's death was caused by the vaccine. In addition to the cardiovascular pathology, he had generalized lymphocyte activation. A solid mass almost 3 cm in length was found in a lymph node that Burkhardt referred to as a pseudolymphoma. Similar cases have been reported previously (Mintoff, et al. 2021; Verdaguer-Faja, et al 2024).

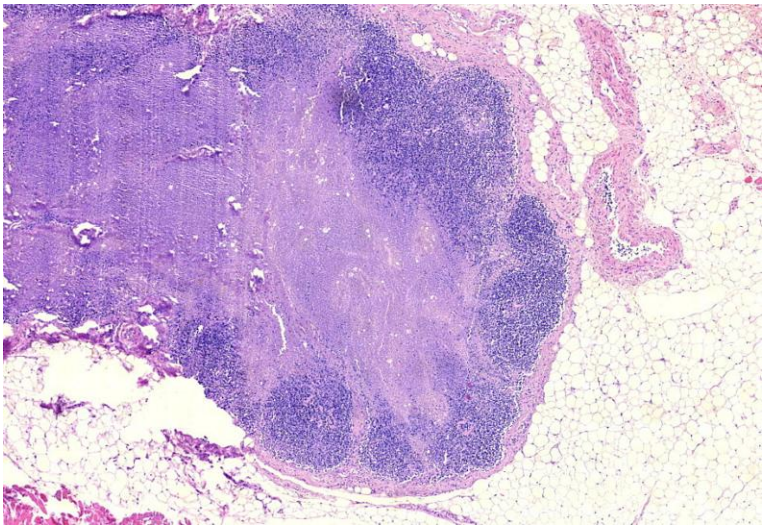

Figure 6. Case 15 Central necrosis in hyperplastic/neoplastic lymph node. From the *Pfizer Papers* (page 57) by A Burkhardt, 2024.

Case 15 is an example of a lymph node with "focal central infarct" (Figure 6) which Burkhardt said was "suggestive of neoplasia" due to the aggressive proliferation of lymphocytes that appears to have overpowered the blood supply leading to the infarct. Perhaps proliferation of activated lymphocytes is accompanied by production of monoclonal light chains. The deceased was a 70-year-old woman who died suddenly 57 days after her second COVID-19 vaccine (AstraZeneca and Pfizer). The cause of death was not determined.

COVID-19 vaccines induced spike protein production in multiple organs leading to inflammation, tissue destruction and unusual collections of lymphoid cells. The precise location, production output, and duration of these production sites is yet to be elucidated systematically. Free light chain analysis might be of value in these cases to help differentiate polyclonal inflammation from monoclonal reactions.

Clinical Patterns following COVID-19 Shots : An Analysis Framework

Clinical relevance of vaccine-induced foreign antigen persistence in two publications from a prospective cohort study of 195 cases (Semmler et al., 2023; Mundorf et al., 2024) identified immunological and inflammatory activity in patients with Post-Acute COVID-19 Vaccination Syndrome (PACVS). PACVS symptoms aggregated in three clusters (Mundorf et al., 2024, page 1):

> Overlapping clusters of (i) peripheral nerve dysfunction, dysesthesia, motor weakness, pain, and vasomotor dysfunction; (ii) cardiovascular impairment; and (iii) cognitive impairment, headache, and visual and acoustic dysfunctions were also frequently represented.

Specific patterns of inflammation and immunological biomarker response differentiated PACVS from normal vaccination response (Semmler et al., 2023, page 1):

> In PACVS, serological vaccination–response appeared significantly ($p < 0.0001$) altered, allowing discrimination from normal post-vaccination state (sensitivity = 90%, $p < 0.0001$) by increased Angiotensin II type 1 receptor antibodies... PACVS is thus indicated as a somatic syndrome delineated/detectable by diagnostic blood markers (bold added).

Two studies of light chain response in normal subjects, COVID-19 vaccinated subjects, hospitalized COVID-19 patients, COVID-19 ICU patients and non-ICU COVID-19 patients found statistically significant polyclonal responses with normal sFLCR kappa/lambda ratios differentiating these subgroups (Malecka-Gieldowska et al., 2021; Gudowska-Sawczuk et al., 2022). Normal subjects had the least response followed by COVID-19 vaccinated subjects and COVID-19 ICU patients having the largest response. The differences in sFLCκ and sFLCλ in the COVID-19 vaccinated and COVID-19 ICU subgroups were not statistically significant (Gudowska-Sawczuk, et al., 2022). Polyclonal elevation and normal ratios were accompanied by inflammatory biomarkers establishing a graded inflammatory response to both COVID-19 virus and vaccine. Out of reference range values were recorded for the COVID-19 and COVID-19 vaccine groups but specific cases were not discussed. Only the COVID-19 vaccine subgroup drove monoclonality to a limited degree as seen in the statistically significant elevation of the sFLCR compared with the COVID-19 and unvaccinated subgroups (Gudowska-Sawczuk, et al., 2022).

The current series of 25 cases from VAERS with out of reference range values of sFLCκ, sFLCλ, and sFLC kappa/lambda ratio in cases with severe response to either BNT162b2 or mRNA-1273 included cases of monoclonal response some in close temporal proximity to vaccination. Responses varied from subtle monoclonal response as in Monoclonal Gammopathy of Undetermined Significance, to reactivation of neoplasia in remission to *de novo* cases of overt malignancy. Six patterns of sFLC response were identified in this subset of 25 cases with quantitative data. The broader group of 75 cases 50 of which lacked complete quantitative data had frequent multisystem illnesses with cardiac, neurological and renal involvement including renal amyloid cases.

The basis for a sustained, unique, clinically relevant immune response with clinically identifiable disease clusters following COVID-19 vaccination has been demonstrated in PACVS and PVS. Clinically defined symptom clusters with unique biomarker profiles combined with unique patterns of histopathological and immunohistochemical findings could potentially elevate categorization of clinical syndromes following COVID-19 vaccination to disease status at least on a provisional basis. PACVS describes specific clinical groupings that can be included under the unifying concept of **CoVax Disease** that incorporates the clinically recognizable patterns such as those identified by Semmler and Mundorf with the neurological grouping of Samim et al. (2023), the renal grouping of Vudathaneni et al. (2023), and turbo cancer as defined histologically by Krüger (2024). Clinical findings, combined with laboratory determinations, tissue histology and special studies like immunohistochemistry and Raman spectroscopy can be employed to identify specific pathological processes (PP) involved in a particular clinical condition and which organs are involved (see Figure 7 showing a proposed Organ System-Pathological Process (OS-PP) spectrum for classification).

Conclusions

Prolonged immunological response to COVID-19 vaccination has been established by unique profiles of biomarkers, clinical disease clusters, destructive lymphocyte mediated histological and immunohistochemical findings. *Systematic linkage of biomarker profiles and clinical clusters to patterns of organ-specific and unique pathological findings under a unified concept from COVID-19 vaccination is a logical next step.* ***CoVax Disease*** *is proposed as a unifying concept for distinct disease clusters following COVID-19 vaccination.* Measurable increases in serum free light chains (sFLCs), particularly sFLCκ, as a marker of B-cell activation, have been demonstrated for SARS-CoV-2 infection and mRNA COVID-19 vaccines. Inflammatory responses as measured by traditional biomarkers like IL-6 accompany polyclonal elevations with normal sFLCR. A subset of cases reporting post-vaccination adverse events to VAERS have monoclonal gammopathies, including elevated sFLC kappa/lambda ratios, extremely high absolute FLC values, and, in some cases, clinical diagnoses of MGUS (Monoclonal Gammopathy of Undetermined Significance), multiple myeloma, or amyloidosis. Vaccination with mRNA COVID-19 injectables may induce or accelerate underlying plasma cell disorders in some individuals. Physicians should work up and monitor patients with out-of-range sFLC values, even when sFLCRs are within the reference range, as a spectrum of related medical conditions may emerge.

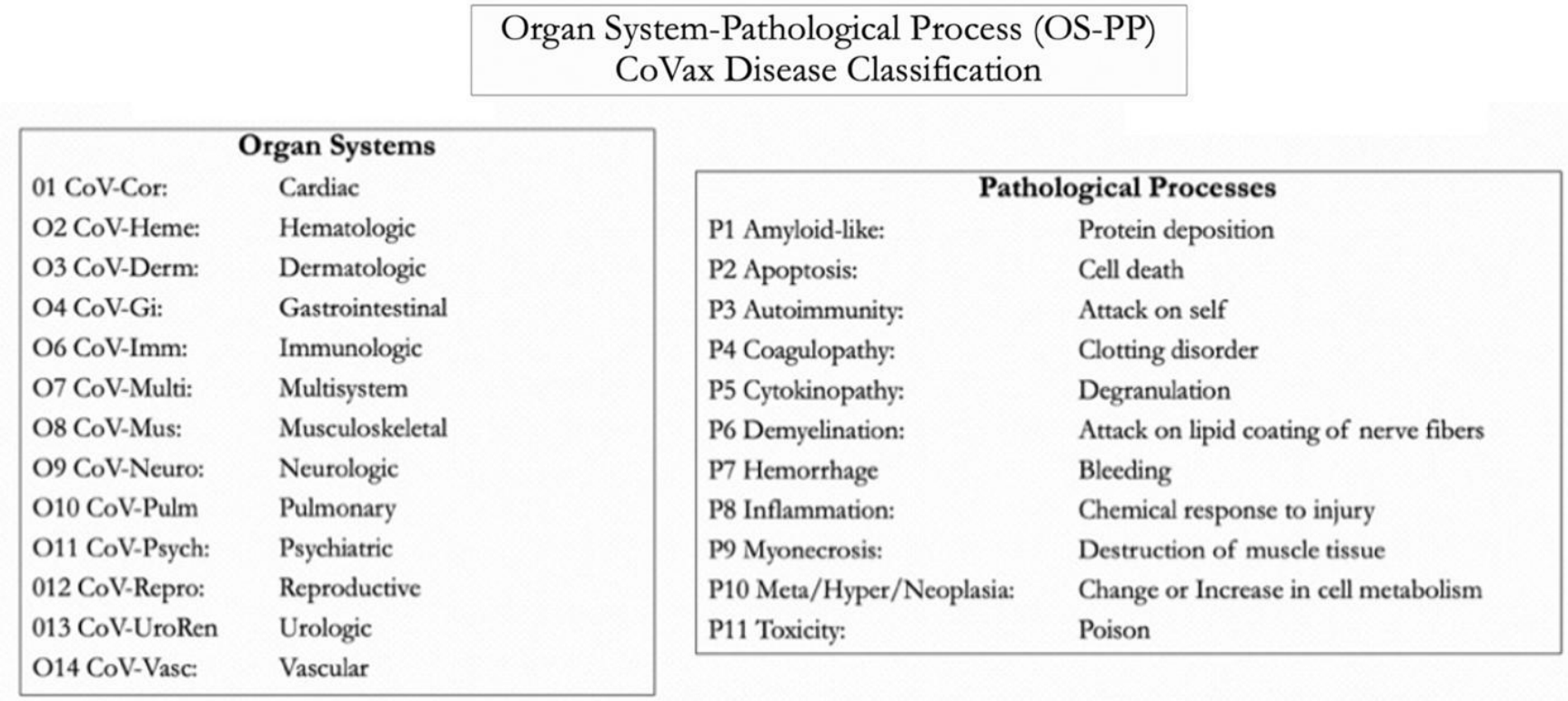

Figure 7. Proposed framework for tissue analysis of syndromes and disease states following COVID-19 vaccination.

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Institutional Review Board Statement

This study used publicly available data provided by the Centers for Disease Control and Prevention and the US Food and Drug Administration.

Data Availability Statement

Data are available on request.

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References

Aklaghi, K., Maclachlan, K., Korde, N., Mailankody, S., Lesokhin, A., Hassoun, H., Lu, S., Patel, D., Shah, U., Tan, C., Hultcrantz, M., Iyengar, N., Shah, G. L., Scordo, M., Lahoud, O. B., Chung, D. J., and Landau, H. J. (2025). Evaluating serum free light chain ratio as a biomarker in multiple myeloma. *Haematologica, 110*(1), 326–338. https://doi.org/10.3324/haematol.2024.285531

Aldén, M., Olofsson Falla, F., Yang, D., Barghouth, M., Luan, C., Rasmussen, M., & De Marinis, Y. (2022). Intracellular reverse transcription of Pfizer-BioNTech COVID-19 mRNA vaccine BNT162b2 in vitro in human liver cell line. *Current issues in molecular biology*, *44*(3), 1115–1126. https://doi.org/10.3390/cimb44030073

Basile, U., La Rosa, G., Napodano, C., Pocino, K., Cappannoli, L., Gulli, F., Cianfrocca, C., Di Stasio, E., and Biasucci, L. M. (2019). Free light chains: A novel biomarker of cardiovascular disease. A pilot study. *European Review for Medical and Pharmacological Sciences, 23*(6), 2563–2569. https://doi.org/10.26355/eurrev_201903_17405

Baumeier, C., Aleshcheva, G., Harms, D., Gross, U., Hamm, C., Assmus, B., Westenfeld, R., Kelm, M., Rammos, S., Wenzel, P., Münzel, T., Elsässer, A., Gailani, M., Perings, C., Bourakkadi, A., Flesch, M., Kempf, T., Bauersachs, J., Escher, F., & Schultheiss, H. P. (2022). Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series. *International journal of molecular sciences*, *23*(13), 6940. https://doi.org/10.3390/ijms2313694

BioNTech Manufacturing GmbH, 01 July 2020. Report No. 38166 (LPT): Repeat-dose toxicity study of three LNP-formulated mRNA platforms encoding for viral proteins by repeated intramuscular administration. https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/030123/125742_S1_M4_4.2.3.2+38166.pdf

BioNTech Manufacturing GmbH, & Pfizer Inc. (2021, February 8). *BNT162b2—Module 2.4: Nonclinical overview* [BLA STN 125742; FDA CBER submission]. PHMPT FOIA release. https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf

Bird, J., Behrens, J., Westin, J., Turesson, I., Drayson, M., Beetham, R., D'Sa, S., Soutar, R., Waage, A., Gulbrandsen, N., Gregersen, H., and Low, E. (2009). UK Myeloma Forum (UKMF) and Nordic Myeloma Study Group (NMSG): Guidelines for the investigation of newly detected M-proteins and the management of monoclonal gammopathy of undetermined significance (MGUS). *British Journal of Haematology, 147*(1), 22–42. https://doi.org/10.1111/j.1365-2141.2009.07807.x

Bracco, F., Gallo, P., Menna, R., Battistin, L., and Tavolato, B. (1987). Free light chains in the CSF in multiple sclerosis. *Journal of Neurology, 234*(5), 303–307. https://doi.org/10.1007/BF00314285

Burkhardt, A., Lang, W., and Schwarz, N. (2024). *Thorn in the flesh: How the corona vaccine-induced spike protein causes damage*. Tredition.

Burkhardt, A. (2024). Autopsy-histology-study on vaccination-associated complications and deaths. In N. Wolf (Ed.), *The Pfizer Papers* (pp. 56–57). Skyhorse. https://www.skyhorsepublishing.com/9781648210372/the-pfizer-papers/

Burkhardt, A., & Lang, W. (2023). *Burkhardt and Lang collection: Master documents* [Unpublished manuscript].

Cassano, R., Ferraro, S., Stella, A., Buda, G., Orciuolo, E., and Petrini, M. (2025). Light chain deposition disease: Pathogenesis, clinical characteristics, and treatment strategies. *Annals of Hematology, 104*(7), 2083–2093. https://doi.org/10.1007/s00277-024-05911-9

Davids, M. S., Murali, M. R., and Kuter, D. J. (2010). Serum free light chain analysis. *American Journal of Hematology, 85*(10), 787–790. https://doi.org/10.1002/ajh.21815

Debord, M. (2025, June 18). Les vaccins ARNm COVID peuvent induire le cancer de 17 manières distinctes selon plus de 100 études [The mRNA COVID vaccines can cause cancer in 17 distinct ways according to more than 100 studies]. *Le Point Critique*. https://lepointcritique.fr/2025/06/19/vaccins-arnm-anti-covid-peuvent-induire-cancer-de-17-manieres-distinctes-selon-plus-de-100-etudes/

Demortiere, S., Marignier, R., Bertheaume, N., Vukusic, S., D'Hardivilliers, F., and Lebrun-Frenay, C. (2025). Diagnostic utility of kappa free light chain index in adults with inaugural optic neuritis. *Neurology: Neuroimmunology and Neuroinflammation, 12*(1), e200386. https://doi.org/10.1212/NXI.0000000000200386

Dispenzieri, A. (2019). POEMS syndrome: 2019 update on diagnosis, risk-stratification, and management. *American Journal of Hematology, 94*(7), 812–827. https://doi.org/10.1002/ajh.25495

European Medicines Agency. (2020, December 21). *Comirnaty: EPAR—Public assessment report* (EMA/707383/2020; Corr. 2). https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

European Medicines Agency. (2021, January). *Spikevax (previously COVID-19 Vaccine Moderna): EPAR—Public assessment report* (EMA/15689/2021). https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf

Fend, F., Dogan, A., and Cook, J. R. (2023). Plasma cell neoplasms and related entities—evolution in diagnosis and classification. *Virchows Archiv, 482*(1), 163–177. https://doi.org/10.1007/s00428-022-03431-3

Gertz, M. A. (2024). Immunoglobulin light chain amyloidosis: 2024 update on diagnosis, prognosis, and treatment. *American Journal of Hematology, 99*(2), 309–324. https://doi.org/10.1002/ajh.27177

Emily R. Gordon, Oluwaseyi Adeuyan, Bradley D. Kwinta, Celine M. Schreidah, Lauren M. Fahmy, Dawn Queen, Megan H. Trager, Cynthia M. Magro, Larisa J. Geskin, Exploring Cutaneous Lymphoproliferative Disorders in the Wake of COVID-19 Vaccination, *Skin Health and Disease*, Volume 4, Issue 3, June 2024, ski2.367, https://doi.org/10.1002/ski2.367

Gudowska-Sawczuk, M., and Mroczko, B. (2023). Free light chains k and λ as new biomarkers of selected diseases. *International Journal of Molecular Sciences, 24*(11), 9531. https://doi.org/10.3390/ijms24119531

Gudowska-Sawczuk, M., Moniuszko-Malinowska, A., Pączek, S., Guziejko, K., Chorąży, M., and Mroczko, B. (2022). Evaluation of free light chains (FLCs) synthesis in response to exposure to SARS-CoV-2. *International Journal of Molecular Sciences, 23*(19), 11589. https://doi.org/10.3390/ijms231911589

Hegen, H., Arrambide, G., Gnanapavan, S., Kaplan, B., Khalil, M., Saadeh, R., Teunissen, C., Tumani, H., Villar, L. M., Willrich, M. A. V., and Zettl, U. K. (2022). Cerebrospinal fluid kappa free light chains for the diagnosis of multiple sclerosis: A consensus statement. *Multiple Sclerosis Journal, 29*(2), 182–195. https://doi.org/10.1177/13524585221134217

Hulscher, N. (2025, May 23). *17 ways mRNA shots may cause cancer, according to over 100 studies*. https://www.thefocalpoints.com/p/17-ways-mrna-shots-may-cause-cancer

Huang, S., Wasifuddin, M., Bellamkonda, A., Lee, P. S., Chaudhry, M. R., & Wang, J. C. (2024). Light-Chain Myeloma Presented as Osseus Tumors: A Case Report. *Journal of investigative medicine high impact case reports*, *12*, 23247096241307445. https://doi.org/10.1177/23247096241307445

Jenner, E. (2014). Serum free light chains in clinical laboratory diagnostics. *Clinica Chimica Acta, 427*, 15–20. https://doi.org/10.1016/j.cca.2013.08.018

Jones, H. B. (1848). On a new substance occurring in the urine of a patient with mollities ossium. *Philosophical Transactions of the Royal Society, 138*, 55–62. https://doi.org/10.1098/rstl.1848.0003

Kaplan, B., Livneh, A., & Sela, B. (2011). Immunoglobulin free light chain dimers in human diseases, *The Scientific World Journal*, 11, 901843https://doi.org/10.1100/tsw.2011.65

Katzmann, J. A., Clark, R., Abraham, R., Bryant, S., Lymp, S., Bradwell, A., and Kyle, R. (2002). Serum reference intervals and diagnostic ranges for free k and free λ immunoglobulin light chains: Relative sensitivity for detection of monoclonal light chains. *Clinical Chemistry, 48*(9), 1437–1444. https://doi.org/10.1093/clinchem/48.9.1437

Katzmann, J. A., Kyle, R. A., Benson, J., Larson, D. R., Snyder, M. R., Lust, J. A., Rajkumar, S. V., and Dispenzieri, A. (2009). Screening panels for detection of monoclonal gammopathies. *Clinical Chemistry, 55*(8), 1517–1522. https://doi.org/10.1373/clinchem.2009.126664

Krüger, U. and Lang, W. (2025). *Vaccinated – dead: Histopathological findings following COVID-19 vaccination*. Etica Media B.V. Swalman, Netherlands.

Krüger, U. (2024). Breast cancer specialist reveals increase in cancers and occurrences of 'turbo cancers' following genetic therapy vaccines. In N. Wolf et al. (Eds.), *The Pfizer papers* (pp. 127–138). Skyhorse Publishing. https://www.skyhorsepublishing.com/9781648210372/the-pfizer-papers/

Krumholz, H. M., Wu, Y., Sawano, M., Shah, R., Zhou, T., Arun, A. S., Khosla, P., Kaleem, S., Vashist, A., Bhattacharjee, B., Ding, Q., Lu, Y., Caraballo, C., Warner, F., Huang, C., Herrin, J., Putrino, D., Hertz, D., Dressen, B., and Iwasaki, A. (2023). Post-vaccination syndrome: A descriptive analysis of reported symptoms and patient experiences after COVID-19 immunization. Preprint (*medRxiv*). https://doi.org/10.1101/2023.11.09.23298266

Kyle, R. A., and Rajkumar, S. V. (2008). Multiple myeloma. *Blood, 111*(6), 2962–2972. https://doi.org/10.1182/blood-2007-10-078022

Kyle, R. A., Larson, D. R., Therneau, T. M., Dispenzieri, A., Kumar, S., Cerhan, J. R., and Rajkumar, S. V. (2018). Long-term follow-up of monoclonal gammopathy of undetermined significance. *New England Journal of Medicine, 378*(3), 241–249. https://doi.org/10.1056/NEJMoa1709974

Lan, M., Guo, Y., Wang, C., Wang, X., Li, J., and Wang, Y. (2024). Lambda light chain–restricted non-crystalline proximal tubulopathy with cast nephropathy in multiple myeloma: A case report and literature review. *BMC Nephrology, 25*(1), 325. https://doi.org/10.1186/s12882-024-03721-9

Lazarus, R., Klompas, M., and Bernstein, S. (2010). *Electronic support for public health-vaccine adverse event reporting system (ESP:VAERS)* (Grant Final Report). Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

Malecka-Gieldowska, M., Folta, M., Wisniewska, A., and Czyzewska, E. (2021). Cell population data and serum polyclonal immunoglobulin free light chains in the assessment of COVID-19 severity. *Viruses, 13*(7), 1381. https://doi.org/10.3390/v13071381

Marik, P., & Hope, J. (2025). COVID mRNA-induced "turbo cancers." *Journal of Independent Medicine*, *1*(3). https://10.71189/JIM/2025/V01N03A02

Martins, C., Gibier, J., Leroy, X., Bridoux, F., Touchard, G., Joly, D., Royal, V., Goujon, J. M., and Sirac, C. (2024). Non-myeloma light chain cast nephropathy: A multicenter retrospective study on clinicopathological characteristics. *Haematologica, 109*(8), 2557–2566. https://doi.org/10.3324/haematol.2024.285031

Matsumori, A., Shimada, T., Shimada, M., and Drayson, M. T. (2020). Immunoglobulin free light chains: An inflammatory biomarker of diabetes. *Inflammation Research, 69*(7), 715–718. https://doi.org/10.1007/s00011-020-01357-7

Mintoff, D., Scerri, L. and Betts, A. (2022), SARS-CoV-2 mRNA vaccine injection site pseudolymphoma. *J Eur Acad Dermatol Venereol,* 36: e20-e22. https://doi.org/10.1111/jdv.17680

Mundorf, A. K., Semmler, A., Heidecke, H., Schott, M., Steffen, F., Bittner, S., Lackner, K. J., Schulze-Bosse, K., Pawlitzki, M., Meuth, S. G., Klawonn, F., Ruhrländer, J., and Boege, F. (2024). Clinical and diagnostic features of post-acute COVID-19 vaccination syndrome (PACVS). *Vaccines, 12*(7), 790. https://doi.org/10.3390/vaccines12070790

Nakao, H., Koseki, T., Kato, K., Yamada, S., Tsuboi, N., Takahashi, K., and Mizuno, T. (2023). COVID-19 mRNA vaccination is associated with IgA nephropathy: An analysis of the Japanese adverse drug event report database. *Journal of Pharmacy and Pharmaceutical Sciences, 26*, 11453. https://doi.org/10.3389/jpps.2023.11453

Nance, K. D., & Meier, J. L. (2021). Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines. *ACS Central Science*, *7*(5), 748–756. https://doi.org/10.1021/acscentsci.1c00197

Nushida, H., Ito, A., Kurata, H., Umemoto, H., Tokunaga, I., Iseki, H., & Nishimura, A. (2023). A case of fatal multi-organ inflammation following COVID-19 vaccination. Legal Medicine, 63, 102244. https://doi.org/10.1016/j.legalmed.2023.102244

Nyström, S., & Hammarström, P. (2022). Amyloidogenesis of SARS-CoV-2 spike protein. *Journal of the American Chemical Society*, *144*(20), 8945–8950. https://doi.org/10.1021/jacs.2c03925

Park, K., and Kwon, S. (2024). Monoclonal gammopathy of renal significance from the perspective of nephrologists. *Blood Research, 59*(1), 28. https://doi.org/10.1007/s44313-024-00027-5

Pfizer, Inc. (2020). "A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals." https://doi.org/10.2215/CJN.0000000000000400

Pfizer, Inc., and BioNTech SE. (2020). *Pfizer-BioNTech COVID-19 vaccine (BNT162b2) VRBPAC briefing document*. U.S. Food and Drug Administration. https://www.fda.gov/media/144245/download

Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W., Jr., Hammitt, L. L., … Gruber, W. C. (2020). Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. *The New England Journal of Medicine, 383*(27), 2603–2615. https://doi.org/10.1056/NEJMoa2034577

Pratt, G., Pinney, J. H., & Cockwell, P. (2024). How I Treat Light Chain Cast Nephropathy. *Clinical journal of the American Society of Nephrology : CJASN*, *19*(5), 650–652. https://doi.org/10.2215/CJN.0000000000000400

Rosati, M., Terpos, E., Homan, P., Bergamaschi, C., Karaliota, S., Ntanasis-Stathopoulos, I., Devasundaram, S., Bear, J., Burns, R., Bagratuni, T., Trougakos, I. P., Dimopoulos, M. A., Pavlakis, G. N., & Felber, B. K. (2023). Rapid transient and longer-lasting innate cytokine changes associated with adaptive immunity after repeated SARS-CoV-2 BNT162b2 mRNA vaccinations. Frontiers in Immunology, 14, Article 1292568. https://doi.org/10.3389/fimmu.2023.1292568

Röltgen, K., Nielsen, S., Silva, O., Pinsky, B. A., Nadeau, K. C., and Boyd, S. (2022). Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination. *Cell, 185*(6), 1025–1040. https://doi.org/10.1016/j.cell.2022.01.018

Salama, M. E. and Hoffman, R. (2023). Progress in the classification of hematopoietic and lymphoid neoplasms: Clinical implications. In R. Hoffman (Ed.), *Hematology: Basic principles and practice* (8th ed., pp. 800–812). Elsevier. https://doi.org/10.1016/B978-0-323-56738-1.00051-0

Samim, M., Dhar, D., Arshad, F., Anudeep, D. D. S., Patel, V. G., Neeharika, S. R., Dhamija, K., Ravindranath, C. M., Yadav, R., Raja, P., Netravathi, M., Menon, D., Holla, V. V., Kamble, N. L., Pal, P. K., Nalini, A., and Vengalil, S. (2023). Co-VAN study: COVID-19 vaccine associated neurological diseases—An experience from an apex neurosciences centre and review of the literature. *Journal of Clinical Neuroscience, 108*, 37–75. https://doi.org/10.1016/j.jocn.2022.12.015

Santiago, D., & Oller, J. W. (2023). Abnormal Clots and All-Cause Mortality During the Pandemic Experiment: Five Doses of COVID-19 Vaccine Are Evidently Lethal to Nearly All Medicare Participants. *International Journal of Vaccine Theory, Practice, and Research*, *3*(1), 847–890. https://doi.org/10.56098/ijvtpr.v3i1.73

Semmler, A., Mundorf, A. K., Kuechler, A. S., Schulze-Bosse, K., Heidecke, H., Schulze-Forster, K., Schott, M., Uhrberg, M., Weinhold, S., and Lackner, K. J. (2023). Chronic fatigue and dysautonomia following COVID-19 vaccination is distinguished from normal vaccination response by altered blood markers. *Vaccines, 11*(11), 1642. https://doi.org/10.3390/vaccines11111642

Snozek, C. L. H., Kinard, T. N., & Adamski, J. (2018). Rapid reduction of extremely high kappa free light chains in a patient with myeloma cast nephropathy. *Journal of clinical apheresis*, *33*(3), 439–443. https://doi.org/10.1002/jca.21619

Therapeutic Goods Administration. (2021, January 8). *Non-clinical evaluation of BNT162b2 [mRNA] COVID-19 vaccine (Comirnaty)* (FOI 2389, Document 6). https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf

Thomas, S. J., Moreira, E. D., Jr., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Polack, F. P., Zerbini, C., Bailey, R., Swanson, K. A., Xu, X., Roychoudhury, S., Koury, K., Bouguermouh, S., Kalina, W. V., Cooper, D., Frenck, R. W., Jr., … Jansen, K. U. (2021). Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine through 6 months. *The New England Journal of Medicine, 385*(19), 1761–1773. https://doi.org/10.1056/NEJMoa2110345

US Food and Drug Administration. (2021). *Summary basis for regulatory action – Comirnaty (BNT162b2 (COVID-19 vaccine, mRNA)): Clinical review* (BLA 125742/0). https://doi.org/10.1056/NEJMoa2110345

Verdaguer-Faja, J., Valdivieso, L., Fabregat-Pratdepadua, M., Melendo, G. T., Quer, A., Carrascosap, J. M., & Boada, A. (2024). Cutaneous Pseudolymphoma after COVID-19 Vaccine Injection. *Indian journal of dermatology*, *69*(3), 269–272. https://doi.org/10.4103/ijd.ijd_420_22

Vudathaneni, V. K. P., Nadella, S. B., Hema, D., and Boyapati, R. (2023). Renal complications following COVID-19 vaccination: A narrative literature review. *Indian Journal of Community Medicine: Official Publication of Indian Association of Preventive and Social Medicine, 48*(2), 214–219. https://doi.org/10.4103/ijcm.ijcm_654_22

Walsh, E. E., Frenck, R. W., Jr., Falsey, A. R., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Neuzil, K., Mulligan, M. J., and Bailey, R. (2020). Safety and immunogenicity of two RNA-based COVID-19 vaccine candidates. *New England Journal of Medicine, 383*(24), 2439–2450. https://doi.org/10.1056/NEJMoa2027906

Xu, K., Kamuriwo, L., Anderson, C., & Jasani, P. (2022). IgG kappa multiple myeloma with isolated central nervous system relapse. *EJHaem*, *3*(3), 1082–1083. https://doi.org/10.1002/jha2.469

Zamfir, M. A., Moraru, L., Dobrea, C., Scheau, A. E., Iacob, S., Moldovan, C., Scheau, C., Caruntu, C., & Caruntu, A. (2022). Hematologic Malignancies Diagnosed in the Context of the mRNA COVID-19 Vaccination Campaign: A Report of Two Cases. *Medicina (Kaunas, Lithuania)*, *58*(7), 874. https://doi.org/10.3390/medicina58070874

Zhao, L., Jin, S., Wang, S., Zhang, Z., Wang, X., Chen, Z., Wang, X., Huang, S., Zhang, D., & Wu, H. (2024). Tertiary lymphoid structures in diseases: immune mechanisms and therapeutic advances. *Signal transduction and targeted therapy*, *9*(1), 225. https://doi.org/10.1038/s41392-024-01947-5

Zhu, L., Hu, Q., Zhang, L., and Li, A. (2024). The role of minimal residual disease and serum free light chain ratio in the management of multiple myeloma. *Discover Oncology, 15*(1), 229. https://doi.org/10.1007/s12672-024-01090-1

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