Expert report

Probable side effects to vaccination with Gardasil

Jesper Mehlsen, MD

Frederiksberg, Denmark

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QUALIFICATIONS

I graduated as a medical doctor from the University of Copenhagen, Denmark in 1979. As part of my training to become a specialist in Clinical Physiology and Nuclear Medicine, I did 11 years of postgraduate work in different specialties such as neurology, endocrinology, rheumatology, and urology.

After achieving my certification as a specialist in 1990, I primarily worked in the Department of Clinical Physiology and Nuclear Medicine at hospitals associated with the University of Copenhagen, becoming head of the Department at Frederiksberg Hospital in 1995. In that position, I developed a special interest in clinical and scientific work with patients having dysfunction of the autonomic nervous system. I helped establish tilt test procedures and teaching staff in several hospitals around Denmark. More than 8,500 tilt-tests with analysis of the autonomic, cardiovascular control have been performed by me or under my supervision. Working with Ph.D. students and their professor at the Department of Mathematics, North Carolina State University, I have developed mathematical models of autonomic cardiovascular control [1,2,3,4,5].

In 2010, I was asked to lead a Coordinating Research Center at Frederiksberg Hospital, where the focus was on collaboration with the pharmaceutical industry. I continued to see patients with autonomic nervous system dysfunction at the Syncope Center.

Prior to this appointment, I was Principal Investigator and headed steering committees in studies on hypertension, prevention of cardiovascular disease, and peripheral vascular disease. The main studies in the Coordinating Research Center were on Merck's HPV vaccines - primarily on Gardasil-9, with a few smaller studies on Gardasil 4. In total, the center had included 3,000+ patients in Gardasil studies. I acted as principal investigator in most and as National Coordinator in some of the studies on Gardasil in close collaboration with Merck´s Danish Division (MSD Denmark).

In 2015, as a result of a dramatic increase in post-Gardasil vaccination injuries, the Danish Government established five regional centers to assess and treat patients with possible side effects to Gardasil vaccination. I was appointed to lead the "Unit for Patients with Unexplained Symptoms Possibly Related to HPV-vaccination" in the Capital Region of Denmark. A total of 845 patients were then referred to the clinic as well as others that had been referred to the Syncope Centre before 2015. In total, by 2016, the Danish Medicines Agency had received >2,300 reports on suspected adverse events among approximately 600,000 HPV-vaccinated women. From these reports, >1,000 were categorized as serious.

I left Frederiksberg Hospital (now Bispebjerg Frederiksberg Hospital) in January 2019 and have continued my scientific work at the National Hospital (Rigshospitalet), seeing patients in my private clinic. The clinical and scientific work is still focused on autonomic, cardiovascular dysfunction – in relation to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) – a diagnosis most of our patients in the "Unit for Patients with Unexplained Symptoms Possibly Related to HPV-vaccination" were given based on the International Consensus Criteria [6].

I was appointed President of the Danish Society of Clinical Physiology and Nuclear Medicine, 1996-99. I was Vice-president of the Danish Organization of Laboratory Medicine from 1995-98. I was a Member of the Board in the Danish Hypertension Society, 1994-2000. I am currently chairman of the European ME Clinician's Council and co-chairing the European ME Research Group.

According to Google Scholar, I have 333 publications of which 170+ are in peer-reviewed scientific journals. I have 20,000+ citations and my H-factor is 50 (an index based on the most cited papers and the number of citations received in other publications).

BACKGROUND

a. HPV in general

After being appointed to lead the Coordinating Research Center in 2010, I studied intensively human papilloma virus and the research showing the connection between HPV and cervical cancer of the uterus. I studied the development of cervical cancer through Denmark's unique screening program reducing the incidence of cervical cancer from 40 to 14 per 100,000 from 1960 to 2014 and the mortalities from 15 to 4 pr 100,000 in the same period.

b. HPV vaccines

As Principal Investigator in Merck's studies on the quadrivalent and the nonavalent Gardasil vaccines (Gardasil4 and Gardasil9), I was familiar with the background for the studies and the previous publications. This knowledge was further enhanced when I coauthored publications related to the studies run in the Coordinating Research Center [7,8,9,10].

c. Background on autonomic nervous dysfunction

By coincidence, I had become an expert on autonomic cardiovascular control while leading the Syncope Center at Frederiksberg Hospital, University of Copenhagen. That expertise was particularly useful when I served as a principal investigator in several of Merck's Gardasil4 and -9 studies.

I have worked clinically and scientifically with dysfunction of the autonomic nervous system for over 35 years. I coauthored my first publications in 1985 and have authored/coauthored 30+ scientific publications in the last 10 years related to autonomic nervous dysfunction.

I have therefore been able to observe firsthand, study, and describe the autonomic dysfunction suffered by patients following vaccination against HPV.

METHODOLOGY

Because of my professional experience and my prior research and publications as described above, I came to this task with a considerable amount of knowledge and understanding of the scientific issues surrounding Gardasil already. I am aware of much of the medical literature, both supporting and opposing viewpoints, and have necessarily kept up to date on the science in this area. For this assignment, I reviewed my own prior research, and I also conducted further research using a database called PubMed applying various search terms such as "Gardasil," "human papillomavirus," "autoimmune," "POTS," "orthostatic intolerance," and "dysautonomia." I analyzed the papers retrieved from my searches by focusing on: 1. the study type and objective; 2. the study population, including its size; 3. the outcome measures and

methods used to assess them; 4. the results, including consideration of risk and odds ratios to understand the strength of any associations found; 5. the conclusions by the authors; 6. the studies' limitations, including potential biases, methodological constraints, or issues with generalizability. I paid particular attention to opposing views (e.g. studies concluding Gardasil does not pose a risk) to ensure a balanced review of available evidence.

Using differential diagnoses in my practice treating dysautonomia patients following HPV vaccination, applying Bradford Hill criteria to studies finding an association between Gardasil and autoimmune conditions, dysautonomia and POTS, lab results, positive rechallenge and observations from my clinical experience and education, I analyze and arrive at conclusions to a reasonable degree of medical and scientific certainty. This process is consistent with the methodologies I have employed for decades in writing and publishing peer-reviewed medical journal articles, preparing briefings for regulatory bodies such as the EMA and the Danish Health Authority, and summarizing results from clinical trials, including those for Gardasil, in which I was a principal investigator.

Studies on post-Gardasil adverse events

In 2011, we saw the first patients complaining about symptoms starting shortly after their first, second, or third HPV vaccination. Their primary symptoms were orthostatic intolerance (lightheadedness, palpitations, fatigue, blurred vision, dizziness, nausea, chest discomfort, cognitive impairment, and near-fainting spells/syncope). As the number of patients with a similar history grew, we started to systematically collect data by questionnaires, standard blood tests, tests for autoimmunity, analyses of mitochondrial function, analyses of the immune system and measurements of autonomic cardiovascular control. The specialized analyses were performed by leading researchers in molecular biology and immunology from Denmark and Germany. We were funded for this work by a grant from the Danish Government.

In our 2015 publication on the first 53 referred patients, we concluded: *"We found consistency in the reported symptoms as well as between our findings and those described by others. Our findings neither confirm nor dismiss a causal link to the Q-HPV vaccine, but they suggest that further research is urgently warranted to clarify the pathophysiology behind the symptoms experienced in these patients and to evaluate the possibility and the nature of any causal link and hopefully establish targeted treatment options"* [11].

The National Board of Health reported on September 15th, 2015, to the Danish Parliament that regional clinics would be started to handle the possible side effects to HPV-vaccination [12]. In June 2015, I was appointed by the hospital administration to lead the clinic – "One Entry" Subtitled: "Investigation and possibly treatment of patients with unexplained symptoms that have occurred in temporal relation to an HPV vaccination" [13] – in the Capital Region of Denmark.

Our follow-up publication on 839 referred patients including control groups was published in a high-impact medical publication, the Journal of Autoimmunity, in 2022 [14]. The analyses lead to the conclusion that: *"This study has shown that girls and young women with probable side effects to HPV-vaccination have symptoms and biological markers compatible with an autoimmune disease closely resembling that seen in ME/CFS and subsets of long-COVID. Together with previous studies,*

demonstrating increase morbidity in this group of patients preceding vaccination, this raises the probability that prior disease may precondition some individuals for vaccine related adverse events. The HPV-vaccine possesses a strong immunogenicity, and it is suggested that possible vulnerability should be further investigated and considered when counselling for such vaccines."

Autoimmune conditions and Gardasil vaccines

In developing vaccines there is always a trade-off regarding safety versus efficacy as expressed by the World Health Organization [15]: "*Vaccine efficacy refers to the ability of a vaccine to bring about the intended beneficial effects on vaccinated individuals in a defined population under ideal conditions of use. The potential benefits of an effective vaccine – e.g., promotion of health and well-being, and protection from illness and its physical, psychological, and socioeconomic consequences – must be weighed against the potential risk of an adverse event following immunization (AEFI) with that vaccine. Vaccine-associated risk is the probability of an adverse or unwanted outcome occurring, and the severity of the resulting harm to the health of vaccinated individuals in a defined population following immunization with a vaccine under ideal conditions of use"*.
Gardasil4 and -9 are very potent vaccines based on non-infectious recombinant type-specific L1 capsid proteins assembled into virus-like particles as immunogens that present an exterior surface closely mimicking the HPV virions. It is this multiplicity of L1 domains that confers the VLP antigen with substantial immunogenicity, which is further enhanced by concomitant immune modulators (adjuvants). Vaccine adjuvants are molecules or compounds that have intrinsic immunomodulatory properties and when administered in conjunction with an antigen, effectively potentiate the host antigen-specific immune responses compared to responses raised when antigen is given alone. Vaccination with Gardasil has a very high efficacy for generating potent antibodies to the vaccine's included strains of HPV due to the combination of the VLP antigen and the aluminum containing adjuvant. Vaccines stimulate the immune system and activate first the non-specific (innate) system which subsequently converts to a specific immunity – in this case - against HPV. Stimulating the immune system activates the cell danger response resulting in the well-known symptoms of fatigue, low grade fever, headaches, and musculoskeletal pain. In most people, this response subsides within a day or two but in some cases, the danger response does not resolve [16]. The energy poducing mitochondria change their function from producing the energy needed for normal bodily functions to a production of signaling molecules and reactive oxygen species designated to defend the body. Symptoms from muscle and nerve tissue are affected as they strongly depend on carbohydrate metabolism, which is diminished. Lactate stemming from anaerobic carbohydrate metabolism causes inflammation in muscle and nerve tissue accounting for muscle pain, headaches and probably also for brain fog. Part of the danger response is a lowered threshold for sensory information increasing the light and sound sensitivity, causing abnormal sensation like tingling, and increasing pain perception. Also, a part of the danger response is an imbalance in the normal autoantibodies directed at G-protein couple receptors [17] and in the Danish cohort, we found abnormal levels of autoantibodies directed against the adrenergic beta-2- and the muscarinic M-2-receptors in 92 per cent of the patients. These autoantibodies interfere with the normal autonomic control of internal

organs and are the probable cause of dysfunction of cardiovascular reflexes and blood pressure control, of gastrointestinal motility, of visual adaptation, and of exogenous glands. It is our opinion that postural tachycardia syndrome (POTS) is likely the result of the imbalance in cardiovascular control caused by the antibodies found in our cohort. The antibody pattern found in our cohort are like those found in other cohorts of HPV vaccinated and in POTS patients using different laboratories and different techniques [18,19,20]. I summarized and presented these analyses to Merck [20], Sanofi MSD and the Danish Health Authority [21]. (See Appendix 1)

Improprieties by Merck or EMA regarding their investigation of Gardasil induced autoimmune conditions.

To the best of my knowledge neither the producer – Merck - nor the European Medicines Agency (EMA) have properly conducted research into the relation between Gardasil vaccination and side effects such as POTS. As I was engaged in studies of Gardasil4 and -9 in close collaboration with Merck, I tried – December 2nd, 2014 - to draw the attention of Peter Aurup, MD, then Vice President and Head Global Clinical Trial Operations in Merck by e-mail to the fact that: "*Since late spring 2013, we have received a small number of referrals regarding patients with possible adverse reaction to HPV-vaccination. The background for referral has been signs and symptoms of autonomic dysfunction ...".* Merck Denmark were receptive, but Merck USA, specifically Alain Luxembourg, discarded my concerns.

Based on literature reviews, data from the producers (Sanofi and Merck), and expert opinions, EMA declared in 2015 that there was no link between HPV vaccination and serious autoimmune or neurological adverse events. For some reason EMA ignored data provided by the WHO collaborating center in Uppsala, Sweden [23] and the subsequent safety concern with HPV vaccine [24] as well as other reports linking Gardasil to these adverse events.

I have personal knowledge concerning cases of POTS in the Gardasil clinical trial programs that an investigator working under my supervision attempted to report, but Merck would not accept the reports as adverse events.

Meanwhile, according to Gotzsche and Jorgensen, the reporting for Sanofi MSD to EMA was misleading [25] They wrote:

> "On 15 May 2017, EMA Executive Director Guido Rasi explained to the EU Ombudsman that 'all studies submitted for the marketing authorization application for Gardasil were placebo controlled'. EMA's official report on POTS and CRPS also gives readers this impression and uses the term 'placebo cohorts' for the Gardasil trials.
>
> "This is not true. None of the trials were truly placebo (ie, saline) controlled. In one trial, 597 children received a so-called 'placebo', which included all the excipients in the carrier solution. In another trial, of the nine-valent Gardasil 9, 306 participants received a saline placebo, but as they had all been vaccinated with the quadrivalent Gardasil earlier, those who did not tolerate the original HPV vaccine were likely not enrolled into the study. In the remaining trials, the control group received another vaccine, for example, against hepatitis A or B, which contain an

adjuvant similar to that in the HPV vaccines. EMA did not address this fundamental problem in its official report."

"The use of active comparators may make it impossible to detect serious harms of the HPV vaccines in the randomized trials if the comparators cause the same or similar harms. This problem was criticised by two doctors external to EMA's expert group in the briefing note, but it was not mentioned in EMA's official report."

Epidemiological studies on adverse events to Gardasil vaccination

a. Studies based on registers

i. The first major study was by Arnheim et al 2013 [26] and included 997 585 girls aged 10-17, among whom 296 826 received a total of 696 420 HPV-4 vaccine doses. Main outcome measures were incident hospital diagnosed autoimmune, neurological, and venous thromboembolic events (53 different outcomes) up to 180 days after each HP-4V vaccine dose. At least five vaccine exposed cases occurred in 29 and these were analyzed further. Whereas the rate ratios for 20 of 23 autoimmune events were not significantly increased, exposure to HPV-4 vaccine was significantly associated with Behcet's syndrome, Raynaud's disease, and type 1 diabetes. However, when they used their own "strength criteria," these events were disregarded. They did not evaluate any symptoms of orthostatic intolerance, autonomic dysfunction or postural tachycardia – the latter being the most common form of orthostatic intolerance in young women [27] Although Denmark and Sweden are alike in many respects, including having similar healthcare systems and universal access to healthcare, differences in diagnostic coding practices might have influenced the ascertainment of cases. The vaccine coverage was 49% in Denmark and 18% in Sweden.

ii. Hviid et al published in 2020 [28] a study based on a nationwide cohort of Danish female participants aged 10-44 years in 2007-16 to evaluate the association between the quadrivalent human papillomavirus vaccine and chronic fatigue syndrome, complex regional pain syndrome, and postural orthostatic tachycardia syndrome in a self-controlled case series analysis. The register used to analyze the association between HPV vaccination and syndromes with autonomic dysfunction cannot be regarded as reflecting the true incidence of these syndromes. The validity of this study is questionable as the authors have lumped diagnostic codes thus mixing post-viral disease – such as mononucleosis which is prevalent in adolescents – with ME/CFS and including supraventricular tachycardia of any kind with POTS. The proper conclusion would be that they "failed to establish the reality of the effect under investigation."

iii. Thomsen et al published in 2020 [29] a partly symptom-based register study using the Danish registry system and included data from 314,017 girls who were HPV-vaccinated at ages 11–17 years between 2008 and 2014. From all 442,229 girls aged 11–17 years in the source population, we sampled 177,724 unique girls who served as 314,017 matched unvaccinated comparators. These girls had not received an HPV vaccine on the index date of the HPV-vaccinated girls (56% of the 177,724 girls acted as an unvaccinated comparator to 1 vaccinated girl only, 25% to 2 vaccinated girls, and 19% to 3 or more vaccinated girls). A slight "healthy vaccinee effect" was observed; that is, girls who were vaccinated against HPV had a slightly lower prevalence of prior hospital-diagnosed comorbidity than unvaccinated girls. The main

study outcomes were the following types of hospital records, predefined in the protocol: a first hospital contact with abdominal pain, nonspecific pain, headache, malaise or fatigue (including CFS), tachycardia (four different ICD10 codes one of which was POTS), and hypotension or syncope. In absolute numbers they identified 10 cases of POTS in the group of unvaccinated girls and 6 in the vaccinated. They identified 9 cases of CFS in in the group of unvaccinated girls and so few in those vaccinated that they could not be reported due to data protection regulation (risk of being identifiable). The 95% confidence levels were 0.19 to 1.50 for POTS and 0.02 to 0.99 for CFS.

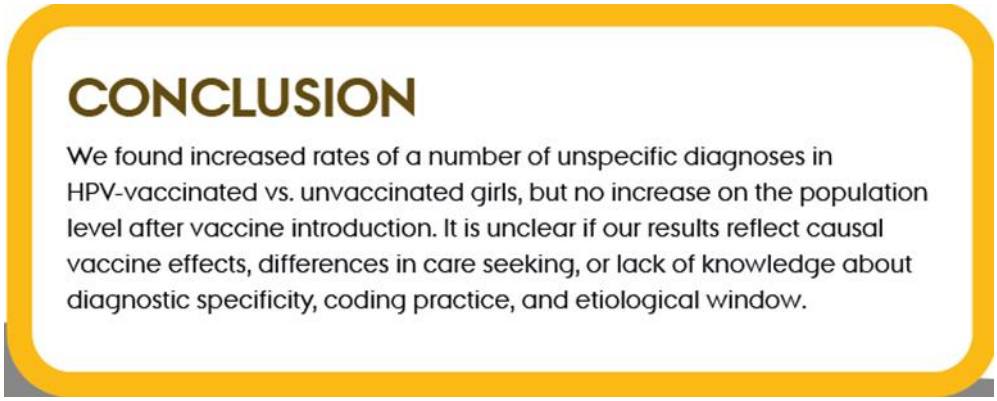
Interestingly, the same group of authors published data [30] on the same study as a poster and the results were quite different. In the poster they report on "all 184,597 HPV-vaccinated girls aged between 11 and 18 years in 2008-2014 in Denmark and 44,038 age-matched girls who did not receive HPV vaccine. All girls entered the study population at age 11." They found significant differences between vaccinated and unvaccinated girls in the incidence rates of 6 different symptoms associated with POTS and ME/CFS – abdominal pain, unspecific pain, headache, hypotension/syncope, tachycardia, and malaise/fatigue:

TABLE 2. Incidence rates and adjusted incidence rate ratios of hospital contacts with selected diagnoses in girls exposed versus non-exposed to HPV vaccination

Outcome	HPV vaccine non-exposed		HPV vaccine exposed		Crude IRR (95% CI)	Adjusted* IRR (95% CI)
	n	Incidence rate /1.000 pyrs	n	Incidence rate /1.000 pyrs		
Abdominal Pain	2772	8.21	6423	10.36	1.07 (1.02-1.13)	1.08 (1.03-1.14)
Unspecific pain	337	0.95	920	1.39	1.18 (1.03-1.35)	1.26 (1.08-1.46)
Headache	513	1.45	1352	2.05	1.25 (1.12-1.40)	1.36 (1.21-1.54)
Hypotension/syncope	725	2.05	2458	3.75	1.42 (1.29-1.55)	1.39 (1.26-1.53)
Tachycardia	108	0.30	429	0.65	1.60 (1.28-2.02)	1.59 (1.24-2.04)
Malaise/fatigue	106	0.30	506	0.76	1.56 (1.24-1.96)	1.60 (1.25-2.04)
Chronic fatigue syndrome	11	0.03	6	0.01	0.17 (0.06-0.49)	0.20 (0.06-0.63)
Trauma	12330	92.4	14996	75.6	0.94 (0.92-0.96)	0.89 (0.87-0.92)
Diabetes	166	0.47	233	0.35	0.89 (0.72-1.11)	0.88 (0.70-1.10)
Cancer	41	0.12	85	0.13	1.00 (0.67-1.51)	0.94 (0.61-1.44)
Pneumonia	194	0.57	411	0.65	0.83 (0.69-1.01)	0.82 (0.67-1.00)
Asthma	577	1.72	1047	1.67	1.00 (0.89-1.12)	0.92 (0.82-1.04)
Appendicitis	683	1.94	1374	2.10	1.05 (0.95-1.16)	0.96 (0.86-1.07)

*Adjusted by Cox regression for: year of entry (2008-2014), history of asthma, diabetes, infections, or mental disorders, frequency of GP contacts, previous psychometric tests or talk therapy at GPs, previous psychologist or psychiatrist visit, education of parents (primary, secondary, higher), employment of parents (none, one, both), income of parents in DKR (<=490,000, 490,000-650,000, 650,000-840,000, >840,000), marital status of parents (married, other), and ethnicity (non-Danish, Danish)

They concluded this based on their results:



Comments: The girls were their own controls and thus appear both as unvaccinated and vaccinated, 177,724 were identified but the number of patients used in the analysis was 314,017 not 355,448 which would have been more logical (2 x 177,017), and the publication offers no explanation for this discrepancy. The age group included did not represent the total population of HPV vaccinated within the time frame used for the study as a catch-up vaccination program for adolescent girls and women up till the age of 27 years was running in that period. As has been pointed out by our group, the mean age of those seeking help in our unit for possible side effects to HPV-vaccination was 23.5 years and less than 6 per cent were in the original target age-group of 12 to 14 years [14]. This is a serious bias in their cohort selection.

In a somewhat larger and mostly overlapping group of vaccinees they found significant differences in six symptoms compared to an unvaccinated control group [30; copy of the poster in Appendix 3]. The results in terms of diagnoses were based on the Danish National Patient Registry but as pointed out earlier, the diagnoses of ME/CFS and POTS are almost non-existing in this registry. This is evident from the very small number of patients found by the study with these two diagnoses. The result – in statistical terms – is confidence intervals of such a width that they preclude meaningful analysis and the result being the so-called "error of the second kind" – in standard terms the chance of finding no difference between groups is almost 100 percent.

General comments on diagnosis-based register studies

The Danish Medicine Agency has in general discarded the epidemiological studies based on registers in their report to the European Medicine Agency and the rapporteurs on HPV vaccination [31]: "The data from these safety studies including a large number of women and with no evidence of increased risk of diseases are reassuring. However, a limitation in the studies is that the use of registers to identify outcome measures is highly dependent on diagnoses. The syndromes suspected as reactions to HPV-vaccination are often difficult to diagnose and has overlap in symptoms between diagnoses. Also, many cases report symptoms without a diagnosis. Such cases would not be identified in the currently published register studies."

b. Studies based primarily on symptoms

i. Yaju and Tsubaki [32] are statisticians, and they reanalyzed data for a Japanese cohort of 30,793 women were included, comprising 21,034 vaccinated cases, 9,245 unvaccinated

controls (subtotal: 30,279). Data were originally obtained from a self-completed mail survey of 24 symptoms considered adverse events experienced in 70,000 girls/young women conducted in September 2015. Due to the change in policy regarding HPV-vaccinations in Japan the relation between age of the girls and vaccination status with the proportion of vaccinated girls varied from 14,6 per cent in the 15-year-old group to 70 percent in the 18-year-old group. This shift in proportion of vaccinated participants.

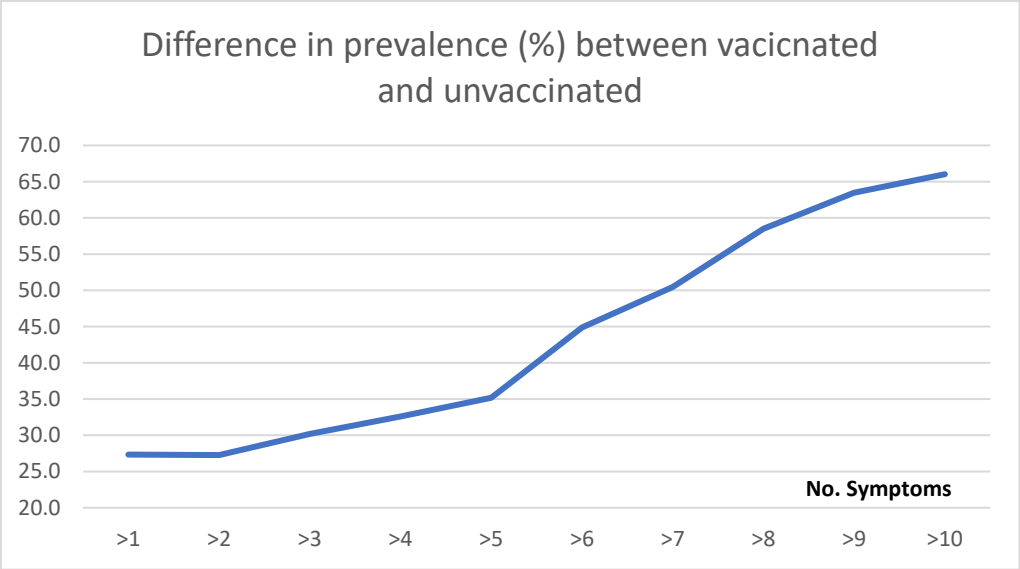
First, one possible explanation for these findings is the healthy vaccine effect bias [33]. These common symptoms are more prone to the healthy vaccine effect. For instance, young women in better health might be more likely to be vaccinated and women in worse health might be less likely to receive HPV vaccination. Therefore, events in the vaccinated group might be underestimated, whereas those in the unvaccinated group might be overestimated.

Second, the mean study period for the vaccinated cases was shorter than that for the unvaccinated controls. As a result of this difference, the event rates of the vaccinated cases were expected to be relatively under-estimated, compared to those of the unvaccinated controls.

They concluded [32] that: “Based on this analysis using data from the Nagoya Survey, a possible association between HPV vaccination and distinct symptoms, such as cognitive impairment or movement disorders, exists. A consistent causal relationship between HPV vaccination and these symptoms remains uncertain. However, given the seriousness of the symptoms, the authors believe that a more comprehensive and large-scale study is essential to confirm the safety of HPV vaccination.

ii. The study by Fukushima [34] is a descriptive, nationwide epidemiological survey to estimate the prevalence and incidence of diverse symptoms among Japanese adolescents without HPV vaccination. Participants were 11,037 medical departments in hospitals selected nationwide by stratified random sampling. Eligible patients had to satisfy four criteria: aged 12–18 years upon visiting hospital; having at least one of four symptoms pain or sensory dysfunction, motor dysfunction, autonomic dysfunction, or cognitive impairment); symptoms persisting for at least 3 months; and influence attendance at school or work. They extracted data of patients with diverse symptoms like those after HPV-vaccination while considering opinions of doctors in charge. Of the18,302 departments selected for the first-stage survey, 11,037 (60.3%) responded. The 6-month period prevalence of diverse symptoms was 19.8 per 100,000 for boys and 40.1 per 100,000 for. The prevalence for “never vaccinated” was 20.2 per 100,000, for those with symptoms following HPV vaccination 27.8 per 100,000. The prevalence among those with unknown vaccine status could not be estimated. Fukushima et al concluded that adolescent Japanese girls without HPV vaccination also visited hospitals with diverse symptoms similar to those following HPV vaccination.

Comments: Including girls with only one or very few symptoms in the group would lead to a skewed distribution which they do not discuss. In our cohort 80 per cent of the included had more than 10 symptoms and looking at Fukushima’s data will reveal a more than doubling of the relative difference between vaccinated and unvaccinated of having > 1 symptom to > 10 symptoms (see below)



c. Studies based on adverse event reports

i. The study by Chao C et al [35] included 189,629 women of all ages who received at least one dose of HPV4 between 08/2006 and 03/2008. The majority (99%) of these women were in the indicated age range (9–26 years). Women in the autoimmune surveillance were followed up to 180 days (referred to as the risk period, excluding day of vaccination) after each dose of HPV4. Autoimmune conditions of interest were prespecified and composed of three groups: (i) rheumatologic/autoimmune disorders, including immune thrombocytopenia (ITP), autoimmune hemolytic anemia, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA) and juvenile rheumatoid arthritis (JRA), (ii) autoimmune endocrine conditions, including type 1 diabetes, Hashimoto's disease and Graves' disease, and (iii) autoimmune neurological/ophthalmic conditions, including multiple sclerosis (MS), acute disseminated encephalomyelitis, other demyelinating diseases of the central nervous system, vaccine-associated demyelination, Guillain-Barré syndrome, neuromyelitis optica, optic neuritis and uveitis. 1014 potential new-onset cases were electronically identified; 719 were eligible for case review; 31–40% were confirmed as new onset. This result in a group of 223 – 288 individual confirmed cases and except for Hashimoto's disease none of the estimated incidence risk ration were significant. They did not analyze autoimmune autonomic dysfunction in general or POTS and syncope. In the study Chao et al want to show the prevalence of specific autoimmune disease in subjects vaccinated with Gardasil-4. They prespecified three groups of autoimmune diseases and carefully revied the new onset cases in the vaccinated group.

To attain an estimate of new-onset cases within the unvaccinated control group they used a mathematical model often applied to account for non-responders. To build the model they apparently used data from the vaccinated and evaluated group and applied the model both to unvaccinated controls and for those not sampled, vaccinated, potential cases. This approach has a high risk of *circulus in probando*, which is a logical fallacy in which the reasoner begins with what they are trying to end with. When combined with the fact that the project was financed by the producer of the vaccine invalidates the results obtained.

ii. In the study by Felicetti et [36] al, all spontaneous reports of vasculitis following immunization between January 2003 and June 2014 were retrieved from Eudravigilance (EV), the Vaccine Adverse Event Reporting System (VAERS), and VigiBase®. A Standard MedDRA Query (SMQ) for vasculitis was used and vaccine types were categorized using the Anatomical Therapeutic Chemical classification system. They retrieved 1797 reports of vasculitis in EV, 1171 in VAERS, and 2606 in VigiBase®. Vasculitis was predominantly reported in children aged 1–17 years. The generic term "vasculitis" was the most frequently reported AEFI in this category across the three databases (range 21.9% to 27.5% of all reported vasculitis for vaccines). For the more specific terms, Henoch–Schoenlein Purpura (HSP) was most frequently reported, (19.1% on average), followed by Kawasaki disease (KD) (16.1% on average) and polymyalgia rheumatica (PMR) (9.2% on average). Less frequently reported subtypes were cutaneous vasculitis (CuV), vasculitis of the central nervous system (CNS-V), and Behcet's syndrome (BS). BS was most frequently reported after hepatitis and HPV vaccines and CNS-V after HPV vaccines.

iii. The study by Chandler et al [24] aimed at exploring global reporting patterns for HPV vaccine for subgroups of reports with similar adverse event (AE) profiles. All individual case safety reports for HPV vaccines in VigiBase® until 1 January 2015 were identified. A statistical cluster analysis algorithm was used to identify natural groupings based on AE profiles in a data-driven exploratory analysis. Clinical assessment of the clusters was performed to identify clusters relevant to current safety concerns. Fifty-four clusters containing at least five reports were identified. The four largest clusters included 71 % of the analyzed HPV reports and described AEs included in the product label. Four smaller clusters were identified to include case reports relevant to ongoing safety concerns (total of 694 cases). In all four of these clusters, the most reported AE terms were headache, dizziness, and fatigue or syncope; three of these four AE terms were described in >50 % of the reports included in the clusters. These clusters had a higher proportion of serious cases compared with HPV reports overall. Furthermore, only a minority of reports included in these clusters included AE terms of diagnoses to explain the symptoms. Using proportional reporting ratios, the combination of headache and dizziness with either fatigue or syncope was found to be more commonly reported in HPV vaccine reports compared with non-HPV vaccine reports for females aged 9-25 years. This disproportionality remained when results were stratified by age and when those countries reporting the signals of CRPS (Japan) and POTS (Denmark) were excluded. They concluded that the study revealed additional reports of AEs following HPV vaccination that are serious in nature and describe symptoms that overlap those reported in cases from the recent safety signals (POTS, CRPS, and CFS), but which do not report explicit diagnoses.

iv. Geir and Geir undertook two epidemiological studies to evaluate concerns about the potential for HPV4 vaccination to induce serious autoimmune adverse events (SAAEs) [37,38]. In the first study [37], the vaccine adverse event reporting system (VAERS) database was examined for adverse event reports associated with vaccines administered from January 2006 through December 2012 to recipients between 18 and 39 years old with a listed residence in the USA and a specified female gender. It was observed that cases with the SAAE outcomes of gastroenteritis, arthritis, systemic lupus erythematosus, vasculitis, alopecia, or CNS conditions were significantly more likely than controls to have received HPV4 vaccine. Cases with the outcomes of Guillain-Barre syndrome, thrombocytopenia, infection, conjunctivitis, or diarrhea

were no more likely than controls to have received HPV4 vaccine. Cases with the general health outcomes were no more likely than controls to have received HPV4 vaccine.

v. In their second study [38], Geir and Geir extended their first study by expanding the study period (2006 to 2014) and the age interval 6–39-year-old recipients. In this study, they found cases with the serious autoimmune adverse event (SAAE) outcomes of with syncope, gastroenteritis, rheumatoid arthritis, thrombocytopenia, systemic lupus erythematosus, vasculitis, alopecia, CNS demyelinating conditions, ovarian damage, or irritable bowel syndrome were significantly more likely than controls to have received HPV4 vaccine. Cases with the outcome of Guillain-Barre syndrome were no more likely than controls to have received HPV4 vaccine. Cases with Guillain-Barre syndrome, infection, conjunctivitis, diarrhea, or pneumonia were no more likely than controls to have received HPV4 vaccine.

d. Studies based on clinical studies by vaccine producers

i. Jorgensen et al [25] showed that careful analyses of the data from clinical studies conducted by the vaccine producers would have revealed possible side effects. Joergensen et al published a review study aimed at assessing the benefits and harms of the human HPV vaccines [39]. They obtained 24 clinical study reports of 58,412 pages from EMA/Merck and GlaxoSmithKline for 22 industry trials and 2 industry follow-up studies - 17 Cervarix™, 5 Gardasil™, 1 Gardasil 9™ and 1 monovalent Merck HPV type 16 vaccine with a total of 95,670 participants (79,102 females and 16,568 males aged 8–72 years). Two researchers extracted data and judged risk of bias with the Cochrane tool. Risk ratio (RR) estimates were pooled using random-effects meta-analysis. Clinically relevant outcomes in intention to treat populations—including serious and general harms.

Twenty-four of 50 eligible clinical study reports were obtained with 58,412 pages of 22 trials and 2 follow-up studies including 95,670 participants: 79,102 females and 16,568 males age 8–72; 393,194 person-years; and 49 months mean weighted follow-up. Serious harms were incompletely reported for 72% of participants. Nearly all (99%) control participants received active comparators. No clinical study report included complete case report forms.

The HPV vaccines did not significantly increase fatal (RR 1.19 (95% CI 0.65 to 2.19)) or serious harms (RR 1.01 (95% CI 0.94 to 1.08)), and no individual fatal or serious harm classified with a MedDRA-preferred term was significantly increased or decreased by the HPV vaccines.

The HPV vaccines increased new onset back pain RR 1.15 (95% CI 1.00 to 1.33). The HPV vaccines increased general harms RR 1.07 (95% CI 1.03 to 1.11) — especially myalgia RR 1.41 (95% CI 1.24 to 1.60), fatigue RR 1.13 (95% CI 1.08 to 1.18), and headache RR 1.06 (95% CI 1.02 to 1.11). The HPV vaccines increased serious nervous system disorders grouped in the MedDRA system organ class RR 1.49 (95% CI 1.02 to 2.16) and decreased new onset vascular disorders grouped in the MedDRA system organ class RR 0.80 (95% CI 0.67 to 0.94).

Cases of anaphylaxis and syncope were evenly distributed. There were no cases of chronic fatigue syndrome (CFS), complex regional pain syndrome (CRPS), Guillain-Barré syndrome (GBS) or postural tachycardia syndrome (POTS), but there was one case of premature ovarian failure (POF) in the HPV vaccine group. Post hoc exploratory analyses of harms of special interest yielded the following results: “The serious harms that were judged ‘definitely associated’ with POTS or CRPS by the blinded physician were increased by the HPV vaccines,

both for POTS (56 vs. 26, RR 1.92 [95% CI 1.21 to 3.07], NNH 1073, P = 0.006, I2 = 0%) and CRPS (95 vs. 57, RR 1.54 [95% CI 1.11 to 2.14], NNH 906, P = 0.010, I2 = 0%). The new onset diseases that were judged 'definitely associated' with POTS were also increased by the HPV vaccines (3675 vs. 3352, RR 1.08 [95% CI 1.01 to 1.15], NNH 144, P = 0.03, I2 = 29%).

Bradford Hill criteria applied to post-Gardasil vaccination autoimmune conditions including POTS.

a. Strength: A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal. *An association between HPV-vaccine and symptoms of chronic inflammation has been found in at least three cohorts [14,34,35] – one in Denmark and two in Japan. The systematic review by Joergensen et al [39] showed autoimmune conditions such as POTS and CRPS were significantly associated with HPV-vaccination*.
b. Consistency: Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect. *POTS associated with HPV-vaccination has been reported in case reports [18,40,41*], *The findings in the two large cohorts were observed by independent observers and cases reported by other observers [42,43] show similar findings.*
c. Specificity: Causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship. *Adverse events are reported from a specific population of girls and young women vaccinated against HPV [14,34,35,42,43].*
d. Temporality: The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay). *There is a time delay between the cause (HPV-vaccination) and the effect (occurrence of symptoms). [14,32,35]*
e. Biological gradient: Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence. *Adverse events were more likely after the second and third dose of the vaccine. [12]*
f. Plausibility: A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism is limited by current knowledge). *Vaccines containing adjuvants have been linked to an increased risk of autoimmune/-inflammatory adverse events following immunization [36]. The review by Guimarães et al [44] stated: "there is evidence of vaccine-induced autoimmunity and adjuvant induced autoimmunity in both experimental models as well as human patients" [50]*
g. Coherence: Coherence between epidemiological and laboratory findings increases the likelihood of an effect. However, Hill noted that "... lack of such [laboratory] evidence cannot nullify the epidemiological effect on associations." *Epidemiological findings cohere [37,38] with the clinical observations.*
h. Experiment: "Occasionally it is possible to appeal to experimental evidence." *Experimental evidence for a risk of cross-reactivity have been published [45].*

i. Analogy: The use of analogies or similarities between the observed association and any other associations. *Other types of vaccines have caused long-term adverse events in other populations [46,47].*

Summary and conclusion

Cohort and case studies have shown probable connection between HPV vaccination and autoimmune conditions and Postural Tachycardia syndrome as well as other generalized inflammatory conditions.

Epidemiological studies based on data derived from national registers are not useful in detecting such conditions as expressed by the Danish Medicine Agency: "a limitation in the studies is that the use of registers to identify outcome measures is highly dependent on diagnoses. The syndromes suspected as reactions to HPV-vaccination are often difficult to diagnose and has overlap in symptoms between diagnoses."

Epidemiological studies based on symptoms are not useful when reporting on single symptoms as autoimmune conditions, and POTS, result in several symptoms and because single symptoms in a cohort of adolescents are very common hampering the probability of detecting any differences between vaccinees and their controls is very low.

Epidemiological studies based on adverse event reports have shown clear signals of autoimmune conditions associated with HPV vaccination. Reexamining the protocols of HPV vaccines prior to approval for general use have supported the independent analysis of adverse event reports.

As expressed by Chandler, et al [48]: "The randomized controlled trials upon which licensure is based and the observational epidemiological studies by which post-marketing signals are investigated provide only population-based estimations of risk. No epidemiological study can answer the question "Did this vaccine cause this event in this patient?" [48]. The Committee to Review Adverse Effects of Vaccines stated in 2011: "Epidemiologic analyses are usually unable to detect an increased or decreased risk that is small and epidemiologic analyses also cannot identify with certainty which individual in a population at risk will develop a given condition" [49]. In a more recent analysis [5], Gvozdenović et al stated that as "many epidemiological studies are observational in their design, and unlike randomized controlled trials where similarity of groups can be experimentally attained, comparability of groups can be difficult or even impossible to demonstrate. This renders causal inference in these cases challenging and conditional on unverifiable assumptions."

Based on my education, experience, research, investigation, analyses, a review of the literature, and the material identified in this report, it is my opinion to a reasonable degree of medical and scientific certainty that Gardasil has been the probable cause of POTS and an autoimmune condition resembling myalgic encephalomyelitis (ME/CFS) and Post-COVID-19 syndrome. Dysfunction of the autonomic nervous system induced by Gardasil is prominent in these syndromes with manifestations of severe orthostatic intolerance i.e. POTS.

Frederiksberg, September 9th 2024

Jesper Mehlsen

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Appendix 1:

Informationsmøde for patienter mistænkt for bivirkninger til HPV-vaccine

Torsdag den 7. maj 2015

Kl. 19:30 - 21:00

Appendix 3

Unspecific ICD-10 Hospital Discharge Diagnoses After HPV Vaccination: A Nationwide Matched Cohort And Time Series Study

Reimar W Thomsen[1], Buket Öztürk[1], Lars Pedersen[1], Sia K Nicolaisen[1], Irene Petersen[2], Kim Varming[3], Jørn Olsen[1] and Henrik T Sørensen[1]

1 Aarhus University Hospital, Aarhus, Denmark
2 University College London, London, United Kingdom
3 Aalborg University Hospital, Aalborg, Denmark

Background

Since inclusion of HPV vaccination in pediatric care in the late 2000s, diffuse autonomic symptoms have emerged among vaccinated girls, which undermine public confidence in the vaccine.

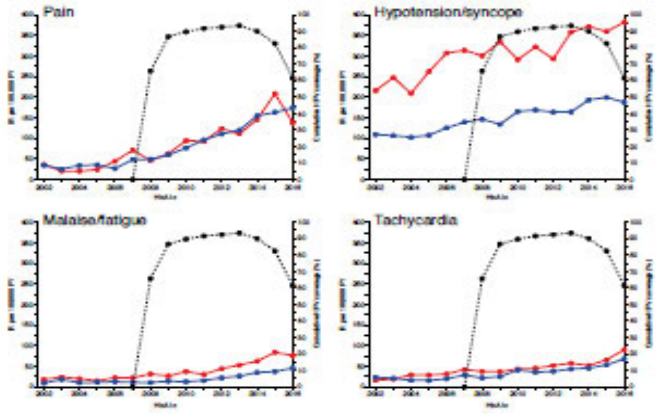
Aim

To examine the risk of unspecific ICD-10 discharge diagnoses in HPV-vaccinated vs unvaccinated girls made during hospital contacts (outpatient clinics, emergency departments, or inpatient admissions), including pain, malaise/fatigue, hypotension/syncope, and tachycardia. We also examined nationwide time trends in these diagnoses in Danish girls and boys.

Methods

Cohort outcome analysis and time series study based on the Danish Civil Registration System, National Patient Registry, Health Insurance Service Registry, Prescription Registry, and labour market databases. The study included all 184,597 HPV-vaccinated girls aged between 11 and 18 years in 2008-2014 in Denmark and 44,038 age-matched girls who did not receive HPV vaccine. All girls entered the study population at age 11. Exposure to the HPV vaccine was a time-varying variable. Incidence rates of discharge diagnoses were assessed, using Cox regression to adjust for comorbid conditions, prior healthcare contacts, ethnicity, and parental education, employment, income, and marital status.

FIGURE 1. Time trends in nationwide incidence per 100,000 person-years of hospital contacts with selected diagnoses among 12-15 year old girls (red line) and 12-15 year old boys (blue line). Black line shows annual coverage of HPV vaccination in girls.



CONCLUSION

We found increased rates of a number of unspecific diagnoses in HPV-vaccinated vs. unvaccinated girls, but no increase on the population level after vaccine introduction. It is unclear if our results reflect causal vaccine effects, differences in care seeking, or lack of knowledge about diagnostic specificity, coding practice, and etiological window.

Results

Between 2008 and 2012, more than 85% of 11-year-old girls received the HPV vaccine, usually before they turned 13 (94%). By 2014 only 28% of girls received this vaccine. HPV vaccinated girls had slightly less comorbidity at baseline, had socioeconomically better off parents, and were less likely to be immigrants (TABLE 1). Adjusted incidence rate ratios (IRRs) in HPV vaccine-exposed vs unexposed girls were increased, as follows: 1.08 (95% CI 1.03-1.14) for abdominal pain, 1.26 (1.08-1.46) for unspecific pain, 1.36 (1.21-1.54) for headache, 1.39 (1.26-1.53) for hypotension/syncope, 1.59 (1.24-2.04) for tachycardia, and 1.60 (1.25-2.04) for malaise/-fatigue (TABLE 2). The IRR for death was clearly decreased at 0.39 (0.23-0.65). IRRs for negative control outcomes (trauma, cancer, diabetes, pneumonia, asthma, appendicitis) were close to 1.0 (TABLE 2). In population time-trend analyses, we observed a steady increase in the above diagnoses in both girls and (largely HPV-unvaccinated) boys between 2002 and 2016, unrelated to HPV vaccination introduction in 2008 (FIGURE 1).

TABLE 1. Characteristics of HPV vaccinated and non-vaccinated girls at age 11 years and their parents

	HPV non-vaccinated girls (N=44,038)	HPV vaccinated girls (N=184,597)
Girls at age 11 years:		
Asthma	5.6%	5.2%
Previous severe infection	8.2%	8.0%
Mental disorder	6.9%	5.6%
Diabetes	0.33%	0.26%
Previous psychologist or psychiatrist visit	1.2%	1.0%
>25 previous GP contacts	52.7%	49.6%
Parents of the girls:		
Higher education (university)	17.9%	15.1%
Both parents employed	62.5%	71.7%
Annual income of parents >490,000 DKR (>65,700 EUR)	69.8%	76.9%
Parents = married	62.8%	66.4%
Non-Danish ethnicity	13.8%	9.9%

TABLE 2. Incidence rates and adjusted incidence rate ratios of hospital contacts with selected diagnoses in girls exposed versus non-exposed to HPV vaccination

Outcome	HPV vaccine non-exposed		HPV vaccine exposed		Crude IRR (95% CI)	Adjusted* IRR (95% CI)
	n	Incidence rate /1.000 pyrs	n	Incidence rate /1.000 pyrs		
Abdominal Pain	2772	8.21	6423	10.36	1.07 (1.02-1.13)	1.08 (1.03-1.14)
Unspecific pain	337	0.95	920	1.39	1.18 (1.03-1.35)	1.26 (1.08-1.46)
Headache	513	1.45	1352	2.05	1.25 (1.12-1.40)	1.36 (1.21-1.54)
Hypotension/syncope	725	2.05	2458	3.75	1.42 (1.29-1.55)	1.39 (1.26-1.53)
Tachycardia	108	0.30	429	0.65	1.60 (1.28-2.02)	1.59 (1.24-2.04)
Malaise/fatigue	106	0.30	506	0.76	1.55 (1.24-1.95)	1.60 (1.25-2.04)
Chronic fatigue syndrome	11	0.03	6	0.01	0.17 (0.06-0.49)	0.20 (0.06-0.63)
Trauma	12330	92.4	14996	75.6	0.94 (0.92-0.96)	0.89 (0.87-0.92)
Diabetes	166	0.47	233	0.35	0.89 (0.72-1.11)	0.88 (0.70-1.10)
Cancer	41	0.12	86	0.13	1.00 (0.67-1.51)	0.94 (0.61-1.44)
Pneumonia	194	0.57	411	0.65	0.83 (0.69-1.01)	0.82 (0.67-1.00)
Asthma	577	1.72	1047	1.67	1.00 (0.89-1.12)	0.92 (0.82-1.04)
Appendicitis	683	1.94	1374	2.10	1.05 (0.95-1.16)	0.96 (0.86-1.07)

*Adjusted by Cox regression for year of entry (2008-2014), history of asthma, diabetes, infections, or mental disorders, frequency of GP contacts, previous psychometric tests or talk therapy at GPs, previous psychologist or psychiatrist visit, education of parents (primary, secondary, higher), employment of parents (none, one, both), income of parents in DKR (<=490,000, 490,000-650,000, 650,000-840,000, >840,000), marital status of parents (married, other), and ethnicity (non-Danish, Danish)

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AARHUS UNIVERSITY
DEPARTMENT OF CLINICAL EPIDEMIOLOGY

midt
Central Denmark Region

CV

Curriculum Vitae – November 2023 Jesper Mehlsen

Personal data
Name: Jesper Mehlsen. Date of birth: 26-06-1952. Home address: Folkets Alle 2, DK-2000 Frederiksberg

Education/academic degrees
1979 MD, University of Copenhagen. 1990 Specialist in Clinical Physiology & Nuclear Medicine

Recent positions
2019 - Senior Researcher, Section of Surgical Pathophysiology, Rigshospitalet (National Hospital), University of Copenhagen
2019- Private Practice, Diakonissestiftelsen, Frederiksberg – home page:klinikmehlsen.com (Danish)
2016-2019 Senior Consultant, Syncope Centre, Department of Cardiology, Bispebjerg & Frederiksberg Hospitals
2010-2016 Director of Research, Coordinating Research Centre, Frederiksberg Hospital, University of Copenhagen

Previous clinical positions in the following medical specialties:
Neurology, Endocrinology, Rheumatology, Urology.

National and International collaboration
Dept. Neuro-anesthesiology, Rigshospitalet, University of Copenhagen – collaboration with prof. Kirsten Møller on autonomic dysfunction in patients with traumatic brain injury.
Institute of Mathematics, North Carolina State University – collaboration with prof Mette Olufsen on mathematical models of autonomic cardiovascular control.
Dept. of Science, Systems, and Models, Roskilde University – collaboration with prof Johnny T Ottesen on mathematical modelling of cardiovascular control
Max-Delbrück-Centrum für Molekuläre Medizin, Berlin – collaboration with ass. prof. Gerd Wallukat on antibodies against receptors in the autonomic nervous system

Supervision of Student (Master, PhD and Postdocs)
Supervisor for Postdocs, Ph.D.-students and medical students on scholarships in Denmark (University of Copenhagen) and USA (North Carolina State University).
Supervisor for Master students at Technical University of Denmark and at Roskilde University Centre.

Experience in management of clinical studies
Member of the International Steering Committee and Danish Principal Investigator for the Anglo-Scandinavian. Clinical Outcomes Trial (ASCOT), a Phase IV GCP-study in hypertensive patients.
Head of the Steering Committee and Principal Investigator in GEPARD, a Phase IV non-interventional trial in peripheral arterial disease.
Head of the Steering Committee and Principal Investigator in PAPAGENO, a Phase IV non-interventional trial in prevention of cardiovascular disease.
Principal Investigator in Parallel, a phase III GCP-trial testing a triple combination of Olmesartan Medoxomil, Amlodipine Bensylate, and Hydrochlorothiazide in subjects with hypertension.
Principal Investigator in V501-01- follow-up, V503-001, V503-003, V503-006, V503-007, V503-010, all phase III-trials in vaccination with Gardasil 4 or 9 against HPV including a total of 3,200 participants at our centre.
National Coordinator in V503-003 a phase III-trial in vaccination against HPV.

Data on publications
Peer-reviewed scientific articles: 175.
Google Scholar, Juni 2023: Total publications: 332. H-index: 51. Sum of citations: 20,384.

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5. P Fernandez-Guerra, AC Gonzalez-Ebsen, SE Boonen, J Courraud, et al. Bioenergetic and proteomic profiling of immune cells in myalgic encephalomyelitis/chronic fatigue syndrome patients: an exploratory study. Biomolecules 2021 11 (7), 961
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5. MN Frandsen, L Huang, RH Petersen, NB Foss, J Mehlsen, H Kehlet Continuous perioperative heart rate variability monitoring in video-assisted thoracoscopic surgery lobectomy—a pilot study. Journal of Clinical Monitoring and Computing, 2023, 1-9.
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