

DENMARK: PUSHING BACK IN EUROPE

The epicenter of the HPV vaccine controversy in continental Europe is the Kingdom of Denmark. A small country with a population of approximately 6 million people, it is the smallest of the Scandinavian countries. Unfortunately, around 100 Danish women die from cervical cancer annually.¹

Denmark, as we know from Kesia and Sesilje's story in Chapter 2, was a clinical trial center during the development stages of both Gardasil and Cervarix and continues to support an "extension study" location at Frederiksberg Hospital under the supervision of Dr. Jesper Mehlsen. Schools do not administer the vaccine as in Ireland and the UK, but the National Medicines Agency recommends it, as does the Danish National Cancer Society. The vaccine is available in drugstores and fitness centers around the country.²

Kesia's and Sesilje's story starts later in the Danish chronicles. They made the connection between their illness and the clinical trials in 2016, long after the vaccine was introduced in Denmark. Before this, many families had begun to report injuries following the vaccine in Denmark. One such family was the Viborg family.

Karsten Viborg was a typical family man enjoying life with his wife and two teenage children. He had no idea when he and his wife consented to the Gardasil vaccine for their 12-year-old daughter in 2010 that their lives would never be the same. Their daughter Rikke did not react immediately to the vaccine. Her symptoms crept up on her over time. First she experienced headaches, pain and flu-like symptoms. As time went on, and with each subsequent vaccine dose, her symptoms became more severe. Following the third dose in 2011, she had severe and chronic headaches, frequent fainting without any warning, paralysis from her hips down, and insomnia. She experienced more than 30 different symptoms in all, although she was only twelve years old. When she was healthy, she was an active scuba diver, played handball, and was very athletic. Following the vaccine, she was absent from school 70% of the time from 2011 to 2014. A few doctors were starting to admit to Karsten that his daughter's symptoms were related to the Gardasil vaccine, but they said there was nothing they could do.

That didn't sit well with Karsten since he could not accept that his young daughter would be sick for the foreseeable future. She needed medical help. He began researching Gardasil side effects and came across stories of other girls with similar symptoms. He came across the work of Drs. Chris Shaw and Lucija Tomljenovic rather quickly. Karsten wrote to Dr. Shaw, and to his surprise, Dr. Shaw wrote back right away. Dr. Shaw could not help with treatment protocols but

put Karsten in touch with Dr. Yehuda Shoenfeld in Israel, a world-renowned autoimmune disease specialist.

Dr. Shoenfeld kindly put Karsten in touch with a doctor in Scandinavia, Professor Vera Stejskal in Stockholm. Little did Karsten know at the time that, in his first toe-dipping into the world of HPV vaccines, he had just made contact with some of the most prominent trailblazers in this controversial arena. Professor Stejskal suggested Karsten travel to an autism conference in Edinburgh, Scotland, where she would be speaking.³ He was confused as to why this would be relevant to his daughter's case, but he went because he trusted Professor Stejskal's perspective.

Despite the conference's focus on recovery from autism, Karsten quickly understood its relevance to his daughter's plight. He learned all he could about biomedical healing and what the body can do to heal once one addresses root causes of illness. This was profoundly inspiring to Karsten. As an engineer, he was not familiar with such ideas, but he saw the value in using natural approaches to rebuild Rikke's immune system and to change her diet to lower inflammation. It couldn't hurt, and she was so sick that he had to try. Professor Stejskal died on September 27, 2017, to the sadness of the Viborg family. Karsten knew that without her guidance, his daughter would never have gotten the help she needed.

Karsten was motivated and began to see significant improvements in Rikke as soon as he made the changes he learned about in Edinburgh. Karsten began studying and reading journals to learn all he could about autoimmune disorders and recovery. He read over 700 scientific papers and became an expert in HPV vaccine injury, specifically side effects from Gardasil. He travelled to Germany, Switzerland, France, and Scotland to find answers and treatment protocols. With the help of an enormous team of doctors and specialists, Rikke gradually recovered from her illnesses and resumed a relatively normal life. It wasn't easy, and without the hundreds of scientific tests and treatment protocols, it would not have happened. And the cost was great. Karsten discovered that Rikke's treatment in local hospitals cost around DKK250,000 (about \$40,000), which is a large sum of money, especially when there is no clear diagnosis. And this doesn't include the personal expenses Karsten incurred to travel to doctors and clinics around Europe. Recovery from autoimmune illness is expensive and time consuming, he learned.

Through this journey, Karsten discovered that there were many more "Rikkes" in Denmark. He formed the patient group "HPV Victims Denmark" in early 2015 with other parents of children with similar issues. As in other countries, Danish families were thrown into this controversy because they could not receive the help they needed for their sick children. Doctors could find no medical explanation for their conditions and routinely recommended psychological testing. The government repeatedly denied any association with the vaccine. If there was no diagnosis and doctors believed the symptoms were psychosomatic, then families held out little hope for their children's recovery. Karsten shared his daughter's story to inspire others that recovery was possible. Soon he became more directly involved in advocacy as people began sharing this information on social media.

As social media stories were shared widely, media attention grew. It wasn't long before a TV station, TV2 Denmark, approached some injured girls and their families about taking part in a documentary called "The Vaccinated Girls." It would be about the controversy brewing around the vaccine. The documentary featured many of the girls in Karsten's patient support group, and raised the alarm about the side effects of the vaccine, in particular in athletic girls. The documentary screened on March 26, 2015 and quickly took off on social media.⁴

The documentary featured Dr. Louise Brinth, a physician at the Danish Syncope Unit in Frederiksberg Hospital, known as the Syncope Centre. Dr. Brinth voiced her concerns that most of the girls at the Centre reported that their symptoms started shortly after receiving Gardasil. She said in the film that in 1997, the Centre saw two POTS cases; in 2014, there were 57. By 2017, the Centre had seen over 400 girls who sought treatment after receiving Gardasil. It has become one of the only specialist clinics in the world, specializing in diagnosing and treating girls with symptoms potentially linked to HPV vaccines.

Dr. Brinth's colleague Dr. Jesper Mehlsen, with 30 years' experience of diagnosing and treating autonomic dysfunction and POTS, also appeared in the film, saying that the girls had virtually the same spontaneous stories and didn't know each other before they arrived at the Centre. Throughout his career, Dr. Mehlsen has published 125 scientific papers in peer-reviewed journals; six of those focus on HPV vaccination. Ironically, he was a principal investigator in some early clinical trials on HPV vaccines in Denmark. He is regarded as an expert in his field.

Both doctors would become pivotal to the HPV vaccine controversy in Denmark. Together they published three peer-reviewed scientific articles relating to the HPV vaccine and its side effects.⁵ They began to report all cases of suspected vaccine reactions to the Danish Health and Medicines Authority, as they were legally required to do. The first case was referred to their Center in 2011, over a year after the vaccine was introduced. By 2013, they had seven more cases. Word spread in Denmark that their Center was not dismissing the girls' reactions as psychosomatic, and they were one of the few places that offered a treatment plan, at least for some of the symptoms related to a POTS diagnosis.

Over the next few years, they received more and more case referrals. The Danish Health Authority cooperated with Dr. Brinth and her colleagues and took the situation seriously. By 2013, as more cases kept coming in, the Health Authority requested Drs. Brinth and Mehlsen to draft a formal report on their findings. Their report to the Health Authority was the first such report, detailing 35 post-HPV vaccine cases. The Health Authority immediately forwarded the report to the EMA for review.⁶ Of the 35 cases, the report noted:

Twenty-five had a high level of physical activity before vaccination and irregular periods were reported by all patients not on treatment with oral contraception. Serum bilirubin was below the lower detection limit in 17 patients. Twenty-one of the referred patients fulfilled the criteria for a diagnosis of POTS (60%, 95% CI 43-77%). All patients had orthostatic intolerance, 94% nausea,

82% chronic headache, 82% fatigue, 77% cognitive dysfunction, 72% segmental dystonia, 68% neuropathic pain.⁷

Since Dr. Brinth was a POTS specialist and 60% of the girls had this diagnosis, POTS became the focus. Dr. Brinth repeatedly asked the EMA and other health authorities to note the significance of other symptoms in their report. The EMA did not take these into consideration, however, and concluded in December 2014 that the relationship between POTS and Gardasil could be “neither confirmed nor denied.”⁸ The Danish Health Authority posted a statement on their websites following the EMA decision, saying that even if POTS was classified as an adverse reaction to the vaccine, they would not withdraw it from the vaccine schedule as the benefit of preventing hundreds of cases of cancer each year would still outweigh the suspected reported adverse reactions.⁹

Despite their continued support of the HPV vaccine program following the EMA review, the Health Authority responded to increased media and public pressure to look into the growing number of girls who were becoming ill, whatever the cause. There was also some political pressure. The HPV Victims group, including Karsten Viborg, met with members of Parliament throughout this time to try to obtain support and recognition for their girls’ chronic illnesses.

From this grassroots advocacy effort, an unlikely ally appeared. Liselott Blixt of the Danish People’s Party was one of the first politicians to push for Denmark to adopt the HPV vaccine. Ironically, she became the first to seek its removal from the national recommended vaccine schedule. After her own daughter fell ill following the vaccine, she campaigned strenuously for the vaccine to be removed. Blixt is the chairperson of Parliament’s Health Committee;¹⁰ her opponents criticize her stance on the vaccine as “grossly irresponsible.”¹¹

Despite opposition, Blixt eventually secured 7 million Danish kroner (around \$1 million), for an independent investigation into the vaccine’s side effects in October 2015. The funds have gone to three institutions: 4 million Kroner to Frederiksberg Hospital under the direction of Dr. Jesper Mehlsen, 1.5 million Kroner to the Statens Serum Institut and the remaining 1.5million to Aarhus University under the direction of Dr. Kim Varming.¹² The world eagerly awaits the outcome of these studies.



In March 2015, amid growing pressure, the health departments of the five “regions,” or states, in Denmark announced that they would open five new “HPV Clinics,” in addition to the one in Frederiksberg Hospital. This would help alleviate Drs. Brinth and Mehlsen of their growing caseload. Over 1,300 cases flooded the HPV clinics shortly after opening.¹³ The response was much higher than expected; waiting lists of six to nine months were normal.¹⁴ Each clinic was to institute an intake process to collect data on the girls’ symptoms and some medical tests were to be performed. From a request on social media, we were able to gather from those that sought

treatment, that the clinics did not actually perform even basic laboratory work and they mostly referred girls for psychological examination. We cannot confirm these reports but to date, no official information has been published on any data collected at these clinics.

Over 2,300 adverse events from the HPV vaccine have been reported officially in Denmark; over 1,000 of those reports were considered *severe*.¹⁵ The Statens Serum Institute reported 150 adverse events per 100,000 shots sold in 2015, including POTS, CRPS and “medically unexplained physical symptoms.”¹⁶

Many HPV vaccine proponents blame the publicity around the documentary for the spike in reported adverse events. Danish health authorities implied that the reports were not related to the HPV vaccine and that the girls who would have succumbed to autonomic disorders anyways may have been swayed by what they saw on TV.¹⁷ They attributed the mistaken association with the vaccine as unfortunate yet mere coincidence. In 2018 both the English subtitled version and TV2’s Danish version of the documentary has been removed from the internet.

The documentary may well have raised awareness about HPV vaccine injury and may have alerted people who experienced similar temporal reactions following the HPV vaccine to report them. This does not explain away, however, the physical pain girls are reporting to the centers after HPV vaccination. Danish psychologist Dr. Peter La Cour saw many girls who suspected their reactions were from the vaccine. He believes that they experience both physical and psychological pain, with the latter made worse by the “blame the victim” phenomenon. In a presentation he gave to the Danish Society for Medical Philosophy, Ethics and Method in November 2016 (a presentation Karsten Viborg attended),¹⁸ Dr. La Cour explains that while they have no diagnosis in psychiatry for what the girls are experiencing, and there are no biomarkers to look for, they must adopt a more modern model in approaching their diagnosis and treatment. He believes that the unfiltered debate in the media and online does not go unnoticed by the girls, which is harmful to their rehabilitation. He does not believe that social media has had an impact on the proliferation of their symptoms. In other words, he does not believe that social media is responsible for a kind of mass hysteria or reaction to vaccination. In his experience with Facebook groups for all kinds of illnesses, HPV vaccine patient groups on social media are not different. Patients want acknowledgement, support, and help in coping with their daily symptoms. Dr. La Cour believes that patient groups online “reflect the level of symptom burden, they do not invent symptom burden.”¹⁹

In 2015, Drs. Brinth and Mehlsen published their second article on 53 patients, entitled “Suspected side effects to the quadrivalent human papilloma vaccine.”²⁰ The results were alarming:

52 out of 53 patients (98%) reported that their activities of daily living were seriously affected and 40 (75%) had had to quit school or work for more than two months due to their symptoms.

Headache: 53 (100%)
Orthostatic intolerance: 51 (96%)
Syncope: 24 (45%)
POTS: 28 (53%)
Fatigue: 51 (96%)
Cognitive dysfunction: 47 (89%)
Disordered sleep: 45 (85%)
Visual symptoms: 37 (70%)
Blurring of vision: 44 (83%)
Gastrointestinal symptoms: 48 (91%)
Neuropathic pain: 35 patients (66%)
Motor symptoms: 35 (66%)
Dyspnoea: 35 (66%)
Skin disorders: 34 (64%)
Voiding dysfunction: 31 (59%)
Limb weakness: 30 (57%)
Vascular abnormalities: 27 (51%)
Irregular periods: 15/31 not on pill (48%)
Sicca symptoms: 21 (40%)
Hyperventilation: 18 (34%)

Dr. Brinth and her colleagues sent this new information to the Health Authority once again, and again, Denmark requested the EMA to conduct a safety review. Despite Dr. Brinth's objections, the EMA again focused its review on POTS and, unexpectedly, CRPS, even though CRPS was not part of Dr. Brinth's research. Nevertheless, the EMA issued a draft assessment report a few months later, on November 29, 2015.²¹ The EMA dismissed Dr. Brinth's findings and now rejected their previous conclusion that they could not "confirm or deny" a causal link, and replaced it with a more resolute position that there is no causal link with the vaccine, which we discussed in Chapter 17. Immediately issuing a detailed 50-page response, Dr. Brinth harshly criticized the Agency's assessment of her cases.²² She asserted that the EMA unfairly criticized her work, clinical expertise, and judgment.²³

The EMA also criticized a 2015 pharmacovigilance study from the Uppsala Monitoring Centre in Uppsala, Sweden.²⁴ The Danish Medicines Agency contacted the Uppsala Centre in 2014 for assistance so that it could compare Dr. Brinth's data to that from Uppsala.²⁵ The Health Authority wanted to understand if this was a true signal using Uppsala's passive adverse event reporting system Vigibase, which the WHO sponsors. The Uppsala Centre is the most highly respected pharmacovigilance center in the world.²⁶ Uppsala agreed to look at Dr. Brinth's data, specifically related to POTS, and Uppsala published its findings.²⁷ Dr. Rebecca Chandler, a physician and

research scientist originally from the US, headed up the Uppsala team.

Dr. Chandler's research identified gaps in the monitoring and reporting of adverse events following the HPV vaccine due to inconsistent diagnostic criteria for conditions such as POTS, CRPS, and fatigue-related symptoms. Her analysis also found inconsistencies in the way doctors categorize clusters of symptoms as serious or non-serious. Dr. Chandler's team used a new technique called "cluster analysis" to delve deeper into the data to achieve a better understanding. They found cases in four small clusters, which they analyzed further. All the cases they analyzed were from before January 2015, so any possible reporting bias following the release of the "Vaccinated Girls" documentary in March 2015 could not affect the study.²⁸

Dr. Chandler concluded that a disproportionate number of adverse events, both expected adverse events and unconfirmed ones, followed HPV vaccination compared to other vaccinations. Her article hypothesized that the adverse event reports suggested an association with fatigue-like symptoms, which could include POTS and other disorders. The article described this "signal":

A causal association with the HPV vaccine remains uncertain; however, we believe that a more thorough investigation of this signal is required to ensure continued public trust in both vaccination programmes and regulatory authorities.

The EMA did not agree with Dr. Chandler's findings or the call for further investigation, however. Ignoring Dr. Chandler's observations based on data from the WHO database, it stated that no link existed between the HPV vaccine with POTS and CRPS.²⁹ Dr. Chandler criticized the EMA's assessment of her work. In an interview with Medscape she said, "I was disappointed by the poor quality of the document."³⁰

The Danish Health Authority embraced the EMA decision and continues to recommend the HPV vaccine. The EMA report coincided, however, with the Health Authority's unexpected decision in January 2016 to replace Gardasil with GSK's Cervarix.³¹ The government tender for HPV vaccine supply included criteria for "efficacy, adverse reactions, additional effects ... and price."³² Unfortunately, no international media covered this major supplier switch given the controversial association between Gardasil and adverse events over the previous three years. Despite reassurance from the EMA and the Danish Health Authority, uptake of the HPV vaccine declined from the high of 80% when the vaccine was first introduced in 2009 to 15% in 2016.³³ Uptake is currently on the rise, however, due to a public awareness campaign by the Health Authority called "Stop HPV, Stop Cervical Cancer."³⁴

THE CONTROVERSY CONTINUES

The controversy with the EMA and the Cochrane Nordic Centre has only increased the public's resistance to the vaccine. Despite this, there is still a push to give the HPV vaccine to as many

girls, and now boys, as possible. Cervarix was indicated by the EMA to prevent anal cancer in 2016, and this paved the way for promotion of this vaccine to boys in Denmark.³⁵

The Danish Cancer Society, Kræftens Bekæmpelse, joined the Danish Medicines Agency in a joint information campaign to improve uptake rates. Merck Sharp and Dohme entered into several partnership agreements with the Cancer Society until 2024, worth almost 17 million Kroner (about \$2.6 million) for follow up research relating to the FUTURE II and FUTURE 9 (Gardasil 9) studies.³⁶

Since parent groups like Karsten's are still seeking answers about what happened to their daughters, the controversy is unlikely to end any time soon. Vaccine promotion campaigns will do little to ease 2,500 girls' suffering. Denmark is the only European country to date where the HPV vaccine program has essentially collapsed. Therefore, like Japan, the spotlight will remain on Denmark for some time as to what happened and why. Also like Japan, Denmark has a group of doctors studying the suspected side effects of the HPV vaccine. The scientific community eagerly awaits the outcome of Dr. Mehlsen's study on more than 800 girls in his clinic at Frederiksberg Hospital, the goal of which is to examine the "biological and pathophysiological factors in girls/women experiencing symptoms suspected to be adverse reactions from HPV vaccination."³⁷

Whatever the outcome, the work of Drs. Brinth and Mehlsen, and their colleagues deserves close examination, as does Vigibase data on adverse events. Epidemiological studies, currently cited to dispel associations with side effects, are alone insufficient. More basic science research is needed. Dr. Chandler has criticized the usefulness of epidemiological studies that rely on a single-diagnosis concept to detect safety signals.³⁸ The HPV controversy has become an "elephant in the room" in Denmark and elsewhere. But as long as Drs. Brinth, Mehlsen, and Chandler can continue their research in this area, there is hope to unlock this scientific mystery.

¹ Cervical cancer statistics Denmark, <http://www.hpvcentre.net/statistics/reports/DNK.pdf>.

² HPV vaccine available Matas cosmetic store, Denmark, <https://www.matas.dk/danish-vaccination-service>.

³ Amet L, *et al.*, "Changing the course of autism: The science and intervention," *OA Autism*, 2(1):1, January 10, 2014, <http://www.oapublishinglondon.com/article/1138>.

⁴ "The Vaccinated Girls" – since removed from the internet, formerly available at <https://www.youtube.com/watch?v=GO2i-r39hok>.

⁵ Brinth L, *et al.*, "Suspected side effects to the quadrivalent human papilloma vaccine," *Dan Med J*, 62(4):A5604, April 6, 2015, <https://www.ncbi.nlm.nih.gov/pubmed/25872549>. Brinth L, *et al.*, "Orthostatic intolerance and postural tachycardia syndrome as suspected adverse effects of vaccination against human papilloma virus," *Vaccine*, 33(22):2602-2605, May 21, 2015, <https://www.ncbi.nlm.nih.gov/pubmed/25882168>. Brinth L, *et al.*, "Is chronic fatigue syndrome/myalgic encephalomyelitis a relevant diagnosis in patients with suspected side effects to human papilloma virus vaccine?" *Int J Vaccines Vaccin*, 1(1):00003, June 15, 2015.

⁶ Danish Health Authority "Our cooperation with EMA and the Syncope Centre at the Frederiksberg Hospital," <https://www.sst.dk/en/news/2015/emas-new-assessment-of-the-hpv-vaccine-the-benefits-outweigh-the-risks/2-our-cooperation-with-ema-and-the-syncope-centre-at-frederiksberg-hospital>.

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- ⁸ Cooperation with EMA, note 6 above.
- ⁹ “EMA’s New Assessment of the HPV Vaccine: The Benefits Outweigh the Risks,” April 17, 2015, <https://www.sst.dk/en/news/2015/emas-new-assessment-of-the-hpv-vaccine-the-benefits-outweigh-the-risks>.
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- ¹¹ “Massive criticism: Liselott Blixt is grossly irresponsible in HPV cases,” *Altinget*, December 8, 2015 (translated), <https://translate.google.com/translate?hl=en&sl=da&u=https://www.alinget.dk/artikel/massiv-kritik-liselott-blixt-er-groft-uansvarlig-i-hpv-sag&prev=search>.
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- ¹³ “Chronic Symptoms After HPV Vaccination: Danes Start Study,” *Medscape*, November 13, 2015, <https://www.medscape.com/viewarticle/854469>.
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- ¹⁶ *Ibid.*, 9-10.
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- ²⁰ Brinth Suspected side effects, note 5 above.
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- ²⁴ *Ibid.*, 29.
- ²⁵ *Ibid.*, 26.
- ²⁶ Uppsala Pharmacovigilance, <https://www.who-umc.org>.
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- ³⁸ Chandler, note 27 above.