Valproate Victims

Newsletter October 2019

Engagement, EUExit, History,

IMMDS Review

(Independent Medicines and Medical Devices Safety Review)

Timeline, history and PIP

In September we attended a Timeline review meeting where all groups apart from INFACT sat round the table to discuss the controversial history. Steve Pollard attended to represent our group. Steve had been working with OACS during our litigation against Sanofi and his work was fully appreciated.

We have also been included to attend meetings on the subject of PIP assessments. We will contact you in due course as we learn more.

We have been informed that the Review has been held back and is unlikely to be published until February. We believe that this will be to accommodate Brexit.

Some of the young people affected gathered to discuss their issues which have been forwarded to the Review Team in anticipation of a meeting. It's important to us that all voices are heard.

Back in May Valproate Victims submitted oral evidence to the Review along with academic Trish Greenhalgh and Josephine

Tapper, a Patient Engagement professional.
It has now been added to the website.

IMMDS Review Evidence Hearings

Please contact the Review Team if you have any concerns

Reviewteam@kcl.ac.uk

Family Futures Survey

This has now been submitted to the Review Team. You may fill out the survey as the information may be useful in future.

Our survey showed that around half of our members wanted to be part of a group compensation scheme and half wanted to organise their own funds in individual Trusts run by people of their own choosing.

These results have guided our policy and we now no longer prioritise a Public Inquiry in favour of prioritising compensation with an option for an individual scheme.

We have discussed alternatives with solicitors and have run it past professionals in the areas of law. We have confirmed this in writing to the Review Team following an internal discussion. Although this is contradictory to previous statements, the Review has become a "PI-Lite" and covers a PI scope. We would welcome a PI but right now, redress and relief in the firm of compensation and support, is what's essential to our members.

The survey is still taking responses, please do fill it in.

Family Futures Survey

Legal Actions

If your child was born after 2004 you may be eligible for compensation under a medical negligence claim. Please do find a local solicitor to get advice. We have used Leigh Day for many cases but the choice of solicitors is yours.

We have also been hearing that some patient groups present legal opportunities and may imply that you need to be a member of their group to claim. This would be unethical practice and is unfortunately sometimes encouraged by law firms to gain control of numbers by exclusivity.

CONFERENCES AND ENGAGEMENT EVENTS

Patient Safety and Engagement

We attended the MHRA Patient Group engagement event and have been working hard to share our views on best practice for engagement.

Jeremy Hunt has set up an arm's length body which is currently run as a charity. It aims to carry out investigations into serious flaws in the health system, it's the result if a number of patient groups and will assist the NHS and wider services to make changes based on evidence that is often swept aside in out of court settlements.

"*Our investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. The recommendations we make aim to improve healthcare systems and processes in order to reduce risk and improve safety.*

Our organisation values independence, transparency, objectivity, expertise and learning for improvement."

Back in August, Bridgette York and Susan Cole presented to the IMMDS Review Team our views on patient engagement and safety. We suggested the idea that a safety authority is required that has real powers to make change.

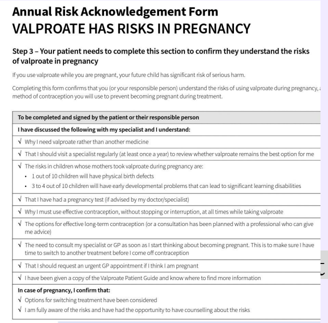
Oxford Nuffield Centre for Evidence Based Medicine

As mentioned in the last newsletter I was given the opportunity to speak at the CEBM at their three day conference at University of Oxford. I spoke on a panel alongside Kath Sansom of the Mesh Campaign and Marie Lyon of the Primodos campaign and the event was hosted by Carl Heneghan. Carl produced a cumulative meta-analysis of the history of valproate research which is a key document for legal purposes. This was a great privilege and I hope I did well. There was so much more that could have been said.

We met many interesting people and as a result have several projects to take forward.

Josie attended with me, it was a long hot day and she was a great support. I was also supported by some of the mesh campaigners in the run up in preparation for the talk.

Valproate Consent Forms



Annual Risk Acknowledgement Form

VALPROATE HAS RISKS IN PREGNANCY

Step 3 – Your patient needs to complete this section to confirm they understand the risks of valproate in pregnancy

If you use valproate while you are pregnant, your future child has significant risk of serious harm.

Completing this form confirms that you (or your responsible person) understand the risks of using valproate during pregnancy,
method of contraception you will use to prevent becoming pregnant during treatment.

To be completed and signed by the patient or their responsible person
I have discussed the following with my specialist and I understand:
√ Why I need valproate rather than another medicine
√ That I should visit a specialist regularly (at least once a year) to review whether valproate remains the best option for me
√ The risks in children whose mothers took valproate during pregnancy are: • 1 out of 10 children will have physical birth defects • 3 to 4 out of 10 children will have early developmental problems that can lead to significant learning disabilities
√ That I have had a pregnancy test (if advised by my doctor/specialist)
√ Why I must use effective contraception, without stopping or interruption, at all times while taking valproate
√ The options for effective long-term contraception (or a consultation has been planned with a professional who can give me advice)
√ The need to consult my specialist or GP as soon as I start thinking about becoming pregnant. This is to make sure I have time to switch to another treatment before I come off contraception
√ That I should request an urgent GP appointment if I think I am pregnant
√ I have been given a copy of the Valproate Patient Guide and know where to find more information
In case of pregnancy, I confirm that: √ Options for switching treatment have been considered √ I am fully aware of the risks and have had the opportunity to have counselling about the risks

MHRA are currently looking at the effect of the new Pregnancy Prevention plans and the valproate toolkit. One of the priorities of their plan was to ensure women now fully understand the risks of valproate in pregnancy. Epilepsy Action, SUDEP Action and Young Epilepsy are running a new survey on this.

We have developed a survey looking into what happened historically regarding what we understood by this.

LINK

I attended conference run by Leigh Day, who often take on human rights cases. I was lucky to meet Nadine Montgomery, whose legal battle against Lanarkshire HealthTrust altered the statute books to ensure that women consent must be fully informed. Her child has cerebral palsy following a bad decision made by her midwife, without fully agreeing the process with her first. I believe that if Nadine's case had been won 20 years ago womens healthcare would be in a very different place now.

How will the EU Exit affect us and our cause?

As the government is having such a difficult time planning anything we can only go with what we know.

1. The European Medicines Agency has moved offices from London to Amsterdam. They did this soon after the referendum result. It's an indication of how precious a resource it is.
2. Scientists and health experts have been moving abroad, emptying our universities and institutions if talents.

3. UK Regulation has the opportunity to change quickly to accommodate global regulatory changes.
4. There may be medicines shortages
5. Employment and legal rights for people with epilepsy and people with disabilities may change. Food prices are going up.
6. Health and social care Services are being outsourced rapidly and there is gathering momentum for bringing in new Apps and Digital solutions.
7. Access to internet pages is changing due to data protection and access conflicts.

SUPPORT

Specialist Centres

We hope that some specialist centres will be set up to support children affected by FVSD. .

This is a significant document for our families and now it's published it would be great if you as families could take a look at this and respond with your thoughts in case you think anything's been missed.

Once again I've done this in a survey format (it makes filing easier) so please do submit your thoughts to us as soon as possible. This is a significant piece of work and will affect the future care of our families.

[Care and Diagnostic Pathway for Fetal Valproate Spectrum Disorder]

Research Participants

Some members have been concerned about studies they've been part of. **If you've been part of a study and have not been happy with** the way it went or are unsure about what you were involved in we would like to hear your views and experiences and can point you in the right direction.

OACS Charity Trustees have asked me to organise their volunteers. I'm pleased to do this as it makes things less complicated for families who will have just one main Charity to engage with and we will also avoid covering same ground.

I have many years of training and experience in charity work. We will be working in regional teams and if you'd like to join up please contact me on valproatevictims@gmail.com

OACS Board has been extremely stretched. Please give an indication of the type of work you wish to do, our Facsjustice/ValproateVictims group has always collaborated with OACS and continue to do so.**FINALLY**

Please note that if you have concerns or need further information to help you and your family OACS has a helpline on their website, www.oacscharity.org

and the IMMDS Review Team also have supporters. If you'd like to speak to the Review Team please email them with your details on reviewteam@kcl.ac.uk.

It can be extremely difficult running a household as a person with epilepsy and where children have disabilities. Asking for help is sometimes hard. A problem shared on one of the closed Facebook groups (OACS Charity or Valproate Victims) may also be of help so please do try.

These are difficult times when our friends and family will see us through. Please do join the Facebook groups to support each other.

Private Facebook Group

Valproate Victims

Private Facebook OACS