

Second Clerk
Tanwen Summers,
Children, Young People and Education Committee
National Assembly for Wales
Cardiff Bay
CF99 1NA

November 20th

Dear Second Clerk,

Thank you for the opportunity to provide evidence to the Children, Young People and Education Committee session on 16th October in support of the Inquiry into Children's Rights in Wales on behalf of Noah's Ark, Children's Hospital for Wales. Further to the written and oral evidence¹ we submitted to the Committee, we would like to thank you for the further opportunity to reiterate that paediatric clinical research in Wales has a history of being underrepresented and resourced and to respond to the Deputy Minister for Health and Social Services oral evidence as part of this inquiry on November 6th.

From 2010-2015 children's paediatric research was included in the Welsh Health Infrastructure through the Children and Young People's Research Network; however, the change from the old infrastructure to the new Centres and Units in 2015 resulted in a loss of focus on paediatric research. The creation of a Clinical Research Facility for children was one of the National Centre for Population Health and Wellbeing's objectives, however no funding was made available for this and Cardiff and Vale University Health Board moved forward with this as a solo project. Since 2015 paediatric research across Wales has been supported in two ways: a) through the Children's Speciality Lead and b) through Activity Based Funding (ABF). This is wholly inadequate; the Speciality Lead (currently held at the Noah's Ark Children's Hospital for Wales by Dr Phillip Connor (NACHfW)) is funded for one session of consultant time (3.75 hours) a week to encourage and increase paediatric research across Wales and the ABF model does not compensate for the complexity of paediatric trials and the fact that numbers will always be a very small proportion of adult studies.

We believe that the lack of spending on clinical paediatric research in Wales creates an environment where children are not being offered the same opportunities as adults and indeed children in the rest of the UK to participate in clinical research. This includes children with cancer who having exhausted their conventional treatment options, who are not

¹ <http://senedd.assembly.wales/ielssueDetails.aspx?Ild=25724&Opt=3>

provided with the opportunity to participate in early phase clinical research in Wales. Early phase trials have the potential to prolong the lives of children. It is discriminatory and not in the best interests of these children that they are not gaining the benefits of good quality clinical research. This is a breach of their human rights as laid out in most globally ratified human rights treaty the United Nations Convention on the Rights of the Child (UNCRC) and concurrently our own domestic legislation the Rights of Children and Young Person's Wales Measure 2011.

We are also concerned that there is still a lack of visibility of children in the Welsh Government health research budget. The lack of transparency in public expenditure on paediatric research means that it is currently not possible to tell without more detailed analysis, whether the Welsh Government is using sufficient levels of expenditure to fulfil children's human right to the highest attainable standard of health. Under article 4 of the UNCRC, Ministers have a clear obligation to demonstrate whether it is fulfilling children's economic, social and cultural rights 'to the maximum extent of available resources'. We believe that transparent evidence of spending on children in relation to health research is an essential tool in both meeting this obligation and evidencing how planned spending and indeed spending cuts are impacting on the outcomes for children and young people in the enjoyment of their human rights.

We are concerned that health policy and decision making around access to medicines and paediatric research has not incorporated the accountability framework of children's human rights. Given that the UK could be about to leave the European Union and the protections that the EU Regulation currently offers, a clear framework of accountability for children is even more essential.

In addressing the Deputy Minister for Health and Social Services' oral evidence on November 6th, we would like to make the following points:

1. Dr Philip Connor's role of Speciality Lead for Child Health. We acknowledge that Dr Connor's role is an important one, however as indicated in our written evidence, a 3.75 hour a week role for a single consultant is not sufficient to stimulate and support clinical paediatric research across Wales. The Speciality Lead posts are based on similar posts in England, where there are several Speciality Leads for Child Health across the English regions all lead by Prof. Paul Dimitri who is based in Sheffield. The English system also provides opportunities for NHS Trusts to apply for funding which specifically funds clinical research. One such example is the funding for Clinical Research Facilities, such as the one based in the Alder Hey Children's Hospital. These funding streams provide resource to employ the staff needed, such as paediatric research nurses, to support delivery of studies stimulated by the work of the Speciality Leads. Unfortunately, Wales does not offer a similar funding stream. There are a number of paediatric clinical research facilities situated throughout the regions in England. As earlier mentioned, Wales has one, based at the Noah's Ark Children's Hospital for Wales, which is funded purely from research funding allocated to Cardiff and Vale University Health Board. Much of the funding

used to support the Children's Research Facility in Cardiff is funding generated by the adult medicine departments at the University Hospital of Wales, funding which is subsidising paediatric clinical research because of the issues with the ABF formula and its discriminatory impact on clinical paediatric research.

We do not know how much is spent on supporting paediatric research elsewhere in Wales because when we requested the information from Health and Care Research Wales, they were not able to provide us with it.

2. Review of the ABF Model and request for a CRIA: In paragraph 1 we mentioned that the Children's CRF in Cardiff (CYARU) is being subsidised by other Clinical Boards in Cardiff and Vale UHB. This is because of the current Activity Based Funding model that we explained in depth during our oral evidence on 16th October, has a discriminatory affect against children due to the one off payment it offers for recruitment in clinical research. In the Deputy Minister's evidence, she stated that recommendations were forthcoming which would propose a *"more agile approach to distributing research delivery funding, particularly for children."*

It was as part of this policy change on ABF that we requested Welsh Government and Health and Care Research Wales to consider the relevant obligations under the Measure and that a CRIA be completed. The request was made at the start of the process change in March 2019 but found that we had to remind colleagues of their obligations again in September 2019 once the process of change was almost complete. We share concerns with other colleagues who have given evidence that CRIA's may be being completed at the end of the stage of policy development or may be an afterthought when decisions have already been made.

Transparency and evidence of the CRIA decision making process

3. At this point we believe it is important to draw on the evidence given by Karen Cornish on 6th November. When the Deputy Minister was asked about our CRIA requests Karen, at paragraph 93 of the transcript suggested at a pre-CRIA stage that officials can decide that they do not need to complete a full children's rights impact assessment. We accept that she could not say if it was applicable to the review of the ABF from the perspective of the officials involved at the time of formulating the policy.

We would like to make it clear that the ABF formula and any subsequent change to it has impact on the lives of children and young people in Wales. There is no other funding stream for children's clinical research in the current system. As we have not yet seen the CRIA for this policy change or any evidence of due regard being paid we believe that the evidence should be made available. As we alluded to in our oral evidence we have serious concerns that the changes to the ABF will not lift paediatric clinical research Wales out of its poverty cycle and we feel that it is vital that Welsh Government are able to 'show us their workings'.

Health infrastructural funding neglects paediatric clinical research

4. Finally, we would like to address the Deputy Minister's announcement on the Health and Care Research Infrastructure Groups. She announced two new groups CASCADE and DECIPHer. Both groups show the current focus of their research on their websites: DECIPHer (<http://decipher.uk.net/>) and CASCADE (<http://sites.cardiff.ac.uk/cascade/>). Whilst we congratulate both groups on their success in securing funding, they do not address the infrastructure gaps that we identified in both our oral and written evidence regarding clinical paediatric research.

The final group mentioned is the National Centre for Population Health and Wellbeing Research (<https://ncphwr.org.uk/>). This Centre was originally established in 2015, however, as we have previously mentioned no funding was made available for one of its objectives to establish a Clinical Research Facility and Cardiff and Vale University Health Board pursued this project alone. Unfortunately the NCPHWR work does not fill the infrastructure gaps in clinical paediatric research.

We would appreciate seeing a copy of the CRIA that was completed as part of the infrastructure change process. The Noah's Ark Children's Hospital for Wales in 2018 informed Health and Care Research Wales and Welsh Government, through a response to a consultation process, that the 2015-2020 infrastructure was not providing support for clinical paediatric research. We would appreciate support in accessing evidence of whether this concern was considered as part of the process of commissioning the new 2020-2025 infrastructure.

Sending children out of Wales to participate in clinical trials

5. In the Deputy Minister's oral evidence she cited paediatric cardiac surgery as an example of a clinical service that required a critical mass of patients to enable quality standards to be met [and so cardiac surgery cases are sent to Bristol]. This is not applicable to the case of research and development in children. Firstly, as outlined in our oral evidence, we cannot send children out of Wales to enrol in trials as the cost to the families is prohibitive and not covered by the Welsh Government. Secondly, the critical mass required in children's interventional studies is much lower. One study can save one child's life and we believe it is reasonable to have small numbers of studies open to take care of the small numbers of children with these complex conditions in Wales. We also believe that children should have the same opportunities as adults to participate in clinical trials in Wales.

In conclusion it is difficult to determine whether due regard to the Convention on the Rights of the Child has been paid without accessing additional information. We would appreciate the Committee's support in helping us to:

- access transparent evidence on the Welsh Government's spend on clinical paediatric research support and delivery;
- access to the CRIA decision making process for the change in activity based funding policy for research delivery; and
- access to the CRIA decision making process for the new health and social care research infrastructure funded by Welsh Government.

Many thanks,

Yours sincerely,

Dr Phillip Connor,

Rhian Croke,

Rhian Thomas-Turner