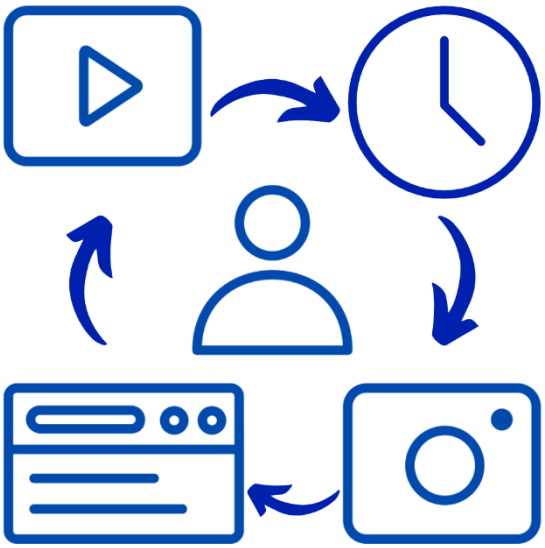
Digital dosing – what's the right exposure?

Random thoughts by Elin Haf Davies

Digital devices are pervasive in children's lives today! Children's photos are captured digitally, uploaded to the cloud and shared on social media within hours of birth – if not as a bump during pregnancy and delivery even! Each step of their development captured by hundreds and thousands of photos and videos.

By the age of thee their digital engagement and footprint is likely to exceed most 70-year-olds. 'Footprints' imply leaving a natural and healthy trail on our planet, whereas exhaust implies a more toxic trail of destruction. Our digital footprint may indeed already be a digital exhaust.

Children's cartoons and programmes are available 24 hours a day through live streaming on smartphones and tablets. Continuous learning from carefully choregraphed children's programmes on demand 24/7. Children ask questions to *Alexa* more frequently than their own parents and Grandparents in some homes. All awhile, the adults in their world are also digitally distracted.



But is there anything we can learn from our experience exposing children to medicines that apply to the digital age?

Years of off-label and unlicensed prescribing of medicines to children because they were merely an after-thought to pharmaceutical funded studies, have led to sub-optimal prescribing and over-dosing leading to poor clinical outcomes, side effects and serious adverse events despite effective medicines.

Knowing the right dose of the right medicine to be prescribed at the right time is still a challenge for many paediatricians, as the licensed indications do not include the necessary data on the dosing and exposure. Organ maturation in the developing child doesn't ensure that allometric scaling* alone enables safe prescribing.

Thalidomide and Phenytoin are clear examples that safe prescribing to a female adult does not ensure safe exposure for the foetus.

The Paediatric Regulation was implemented in 2007 with the objective to improve the health of children in Europe by facilitating development and availability of medicines for children. The Regulation aims to ensure that medicines for use in children are of **high quality**, **ethically researched** and **authorised appropriately** and to improve the availability of information on the use of medicines for children. It aims to achieve this without subjecting children to unnecessary trials or delaying the authorisation of medicines for use in adults.

The regulation mandated that pharmaceutical companies identified the right dose and formulation for safe exposure and effective prescribing. But while change has been slow, we do now see more Marketing Authorisations of new medicines include the necessary pharmacokinetic, pharmacodynamic and dosing data for children.

Do we face the same challenge for identifying the amount of digital exposure that is safe and effective for our children? Does their organ maturation in childhood mandate different exposure to that which is safe for adults?

Too much – and our children may grow to be addicted to dopamine and live in a constant state of anxiety from producing too much cortisol and being stimulated too much too often.

Too little – and our children lose out on learning opportunities, digital skills and digital literacy which will keep them on the same learning trajectory as their peers.

Should digital interactions be classified as we do with the mechanism of action of medicines? How do we define that two hours of Peppa Pig a day is safe and effective for 2 year old child development but that two hours of gaming at 8 years old may not be?

Is it the combination effect of Facebook and gaming or is it the absence of other physical outdoors activity to counteract the impact that is the issue? Polypharmacy and drug-to-drug interactions in neonates and children cause increasing challenges, is it the same for digital exposure.

Parental control of screen time is either not implemented or becomes a constant source of friction and arguments in the family home. Continuous learning from digital and engagement with devices potentially lead to a missed opportunity to form a family bond and an emotionally and psychologically healthy child.

Regulatory frameworks to mandate the responsibility of big Pharmaceuticals to explore the needs of children have worked for the most part, but regulatory framework for big tech company is lacking across the board, including that for the protection of adults. Much like we currently lack the legal remit to prohibit the food giants from marketing fizzy drink and high calorie sweets to toddlers and children of all ages.

Government control for tobacco sales was achieved eventually, and similarly alcohol tax initiatives are starting to make inroads. The data for the damage of tobacco, alcohol, junk food and unlicensed or off label medicines were clear and enabled regulatory changes - despite effective lobbying to the contrary by the big corporates. How will we effectively navigate the regulatory landscape when the data for what's digitally safe and effective for babies, toddlers, children, and adolescence is currently missing?

The exposure of vaccines and medicine in the right format and right dose (timing and frequency) is one of our strongest tools to protect the health of children. How can we equally ensure that digital exposure is in the right format and right amount (timing and frequency) to protect the health of children? Ironically – the answer will be in the data of their digital exhaust. Only with access and analysis of that data will we enable effective policy influences and regulatory frameworks to protect and promote child health.

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*Allometric scaling is a very important concept in toxicology and health risk assessment. It is commonly used for **inter-species dose extrapolation and establishing a safe dose for humans based on animal toxicology data**.