

Editorial; medical practice driven by legislators rather than by regulators.

When I counsel women with babies born with congenital CMV infection, common questions include: "why wasn't I told about this infection before I became pregnant? If CMV damages so many babies each year, why don't we have a screening programme?"

Bodies responsible for deciding if there should be screening for a new condition lay down strict criteria. Consistent application of these criteria is designed to ensure that screening is only done if it can be shown that benefits will be produced that outweigh the financial and opportunity costs that are inevitably incurred.(1) It is also important to show that the benefits outweigh the parental anxiety that any screening program should be expected to induce. Congenital CMV meets all the criteria required except for one: treatment of asymptomatic infection.(2, 3) Treatment of neonates has been shown to be effective, but the cases recruited were all identified because they had symptoms at birth.(4, 5) Although we know that many cases with symptoms are not recognised in routine clinical practice, a screening programme should not be created simply to compensate for inadequacies in diagnostic skills.

The absence of a screening test means that other linked public health initiatives, such as providing information to those at risk, can be left on the back burner. Professional bodies can review the issue and conclude, not unreasonably from their point of view, that they should only take action once an intervention, like treatment or screening, becomes available. This creates a Catch-22, where regulators will not allow screening to begin until the treatment of asymptomatics has been shown to be safe and effective, while children who are asymptomatic cannot be identified in the absence of a screening programme (or an unrealistically large research grant). The resulting stalemate has led to some frustration, especially as conditions considered more newsworthy, such as Zika in pregnancy, seem to acquire immediate support, despite their lower propensity for damaging babies in temperate climates.(6)

This impasse has now been disturbed by the birth of Daisy in 2012 who has had an effect on public health out of all proportion to her low birth weight. Her parents, like many before them, were shocked to discover that a virus able to damage large numbers of babies is circulating in our communities without women of childbearing age being alerted to the risks and being offered the potential to take steps to reduce those risks. The difference in the case of Daisy is that her grandmother is a legislator in the US state of Utah. Instantly recognising an injustice, she set about framing legislation that would require the provision of information about CMV. A bill passed rapidly into law on 1 July 2013 directs the Utah Department of Health to take two actions. Firstly, to create a public education program to inform women of childbearing age about CMV and its transmission, the birth defects it can cause, methods of diagnosis, and available preventative measures. Secondly, it requires medical practitioners to

test infants who fail newborn hearing screening tests for the presence of congenital CMV. If this can be done rapidly enough, treatment with valganciclovir can be started within the first month of life, which is the time cut-off studied in the randomised controlled trials that showed clinical benefit.(4, 5) Similar, but not identical, laws in Connecticut, Hawaii, Illinois, Texas and Tennessee followed this initiative. An additional 8 states now have legislation pending.(7) The message is clear; if medical practitioners sit in their professional silos and refuse to take an initiative until a cognate professional group makes the first move, then parents will see the bigger picture and force change by exerting their constitutional rights to have their concerns addressed.

Where does this leave us in Europe as we observe the tide turning in the USA towards selective screening of those who fail their newborn hearing tests and, potentially, universal screening of all babies? Many innovations that start in North America end up reaching these shores along with the prevailing winds. European screening committees appear to hold to an overly rigid interpretation of the criteria and decline to countenance assessments of whether children and their families might benefit from linking laboratory testing for congenital CMV with that for newborn hearing screening. This is despite preliminary results indicating both efficacy and cost-effectiveness.(8-10) It would equally be possible to interpret the prevention of further hearing loss in the randomised controlled trials as adequate proof that early treatment can delay or prevent future loss of hearing.(4, 5) This would then allow committees to justify initiating a pilot study in one region of a country whose results would guide whether nationwide screening could be justified. In the absence of such an initiative, screening committees may be accused of not doing enough for the ordinary people who have recently unleashed a wave of anti-establishment populism in the USA. Thus, committee members need to keep an eye on the weather coming from the West lest, like King Canute, they soon find themselves left looking somewhat damp.

PD Griffiths

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