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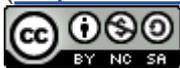
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# Will the Eastern Mediterranean Region be the first to prevent all of folic acid-preventable spina bifida and anencephaly?

Godfrey P. Oakley Jr., MD, MSPM, Vijaya Kancherla, MS, PhD.

The global total prevention of folic acid preventable-spina bifida and anencephaly (FAP SBA) is long overdue. It has been 24 years since the publication of findings from the randomized clinical trial by the Medical Research Council proving unequivocally that folic acid taken shortly before and during early pregnancy will prevent a large proportion of spina bifida and anencephaly.<sup>1</sup> Within this same time period, vaccine programs have assured that almost every child in the world is receiving newly developed conjugate vaccines, leading to remarkable global improvements in associated child mortality and child health. Unlike the expansive global support achieved for preventing vaccine-preventable diseases, no country or donor organizations has provided sufficient resources to build the global program for the total prevention of FAP SBA. Due to lack of support, the current level of global prevention for FAP SBA has stalled at approximately 25%.<sup>2</sup> The bottom line is that we are collectively failing children globally by letting FAP SBA to occur, which is associated with high risk of death and disability, including orthopedic, motor, neurologic, and learning and developmental deficits.

Global total prevention of FAP SBA requires implementing effective prevention programs in each country. Experience with infectious disease prevention programs suggests that total prevention is achieved through country-by-country and World Health Organization (WHO) region-by-region efforts. For example, we know that rubella infection during early pregnancy causes a cluster of severe birth defects termed

as congenital rubella syndrome. There is a strategic plan for the global total prevention of rubella. Recently, the Pan American Health Organization (PAHO) announced that there had been no cases of rubella and congenital rubella syndrome for the last 5 years in their region. The PAHO became the first of WHO regions to achieve total prevention of this vaccine preventable-birth defect. Given that FAP SBA is just as preventable as the congenital rubella syndrome, we ask, which will be the first WHO region to achieve and to demonstrate total prevention of FAP SBA? Perhaps it will be PAHO, as national mandatory folic acid fortification programs are widespread in the region. In the United States, where folic acid fortification has been implemented country-wide as a mandatory policy since January 1, 1998, FAP SBA has reached a near-total prevention.<sup>3</sup>

The Pan American Health Organization may not be the first to achieve total prevention of FAP SBA. It could be the Eastern Mediterranean Region (EMR). We hope that this editorial will spark the Kingdom of Saudi Arabia (KSA) to provide the leadership and resources to prevent all FAP SBA in the EMR. In 1996, during a workshop for developing a common standard for micronutrient fortification for the EMR, Oman, which at the time had a single flour mill, elected to begin folic acid fortification, and became the first country in the world to successfully implement a country-wide folic acid fortification program. In 2003, KSA required flour to be fortified with folic acid at 1.5 part per million (ppm), similar to the 1.4 ppm adopted by United States, and exactly the concentration used

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by Canada. A few hospital-based studies in Oman and KSA have reported reductions in FAP SBA post-fortification. Nevertheless, new and larger studies in KSA and Oman could determine whether or not total prevention of FAP SBA has actually occurred. Such studies could be the foundation, upon which to develop policies and programs to provide total prevention, and demonstrate that total prevention is possible and has occurred.

The global public health community has yet to set the standard for demonstrating total prevention of FAP SBA. As promotion of prevention is occurring, standards for demonstrating total prevention will likely be agreed upon. Studies in Oman and KSA could provide critical parts of the evidence needed to develop protocols for assessing the total prevention of FAP SBA. There are several possible approaches to demonstrate total prevention. First, excellent spina bifida and anencephaly surveillance programs, either as free standing surveillance programs or as a part of a broader birth defects surveillance program, could monitor the induced abortions and newborn prevalence of the two birth defects. We have learned in recent years that the non-folic acid preventable spina bifida rate is approximately 0.5 per 1000 births. If current prevalence rates, in well-conducted surveillance programs, are reduced to approximately 0.5 per 1000 births, it will demonstrate total prevention, or near total prevention of FAP SBA.<sup>3</sup> Second, case-control studies can be conducted to show that folic acid containing supplements no longer offer a protective effect for spina bifida and anencephaly where mandatory folic acid fortification programs are effective. Third, and a more timely approach, can be based on the recent WHO issued guideline using red blood cell folate concentration as a reliable and fast way to estimate the prevalence of FAP SBA in the community.<sup>4</sup>

Both Oman and KSA are excellent countries to use these 3 approaches to determine how close each country is to total prevention of FAP SBA. Scientists conducting these studies would not only make important contributions to the public health in their own country, but also provide data of interest to other countries and to scientists trying to develop standardized protocols that can be used in every country to demonstrate the total prevention (or lack of it) of FAP SBA.

In conclusion, the total prevention of FAP SBA represents an urgent opportunity to improve the lives of children by preventing perinatal, infant, and under-five year mortality and disability globally. In 2014, Salih wrote that “prevention of neural tube defects can gain a faster momentum if ... countries adopted fortification of the staple food in their communities”.<sup>5</sup> The Teratology Society has recently recommended the urgent global implementation of mandatory folic acid fortification as the cornerstone of global prevention of FAP SBA.<sup>6</sup> We hope this editorial will motivate those with the resources to set the goal of total prevention of FAP SBA, and to provide the logistics to ensure that it is achieved and documented. We also hope that soon we will read papers in this journal, demonstrating the total prevention of FAP SBA in KSA, and perhaps all of ERM. This result would be a major achievement for the children in the Region and provide an example for other countries and regions to follow the lead.

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