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ALL DOSES ARE NOT THE SAME: POTENTIAL ROLE OF VACCINE QUALITY IN VACCINE ADVERSE REACTIONS

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Vaccine adverse reaction investigations typically focus on the commonalities of all doses of a vaccine, such as excipients. The possibility that some adverse reactions may be caused by defective doses is difficult to investigate due to lack of data on the quality of individual doses. Here, a defective dose means its critical quality attributes are outside the acceptable range. It is unrealistic to expect zero defect rate when a vaccine is administered; defects may occur during manufacturing, which is not very precise, or during distribution, where mishandling such as cold chain breaches may happen. Manufacturing errors and product mishandling will lead to a few defective doses among many quality doses. Unless the defect rate of a vaccine at vaccination sites is known to be markedly lower than the adverse reaction rate, the possibility that some adverse reactions are caused by defective doses cannot be excluded.

Quantitatively inspecting every dose of a vaccine at vaccination sites may prevent adverse reactions caused by defective doses. But inspecting every dose before injection has multiple challenges, one of which is lack of suitable analytical technologies for quantitative inspection. Current analytical technologies are *ex situ* and invasive, as they require transferring the vaccine drug substance out of its primary container for data collection. Inspecting vaccines with invasive analytical technologies destroys product integrity. We have been developing a noninvasive analytical technology, $wNMR$, which stands for water proton nuclear magnetic resonance. $wNMR$ can be performed in an *in situ* and noninvasive fashion on sealed vials, using inexpensive benchtop instruments. $wNMR$ relies on the water proton (1H_2O) signal for analysis. Because of the high concentration of water, $wNMR$ data collection typically takes seconds. $wNMR$ may be used as either an in-line process analytical technology for vaccine production or a QC technology to inspect every vial of a vaccine before release and then before injection.

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