CLOSER LOOK

MEMORANDUM

Research from Dr. Lutz Heinemann finds highly-variable, below-threshold insulin concentrations in U100 regular and NPH vials - January 26, 2018

The Journal of Diabetes Science and Technology recently published stirring results on insulin quality from Drs. Lutz Heinemann and Alan Carter. Among 18 randomly-purchased vials of insulin (U100 regular and NPH samples, from Lilly and Novo Nordisk), none met FDA's minimum concentration requirement of 95 U/ml to leave the manufacturer. Dr. Heinemann first presented these findings at DTM 2017, and the data generated a worried buzz among conference attendees as well.

All nine regular insulin samples hovered between 13.9-28.7 U/ml, suggesting someone could be injecting 1/8 as much insulin as he/she thought. Equally concerning, the nine NPH samples were much more variable, ranging from 35.1-94.2 U/ml, suggesting even more guesswork for the patient as to how much insulin is actually entering the bloodstream. Across all 18 vials, average insulin concentration was 40 U/ml, with only one sample >80 U/ml.

Insulin concentration was measured via basic mass spectrometry. Importantly, the authors attribute this problem to a break in the cold supply chain between manufacturer and pharmacy, rather than manufacturers sending below-par insulin into the market.

There was some open skepticism at DTM about how sample handling and analysis might have impacted results; Dr. Heinemann himself called for others to repeat these measurements. A key takeaway from this now-published study is that below-threshold insulin concentrations may be a serious issue in the real world, putting patients in danger at worst, or delivering suboptimal diabetes management at best. It's worth noting that insulin analogs weren't studied, and we'd be interested to see that analysis. If this is a genuine problem - if there's even a small chance - we'd like to see the conversation and research continue, given the patient implications.

These findings also call to mind recent DTS research indicating a lack of accuracy in BGMs: It's clear that more market surveillance and consumer protection is needed across multiple facets of diabetes care.

-- by Megan Clyne, Ann Carracher, Abigail Dove, Payal Marathe, and Kelly Close