Correspondence

NOVEL EPINEPHRINE AUTO-INJECTOR (NEA): SHARPS INJURY PREVENTION VALIDATION AND COMPARABLE ANALYSIS WITH EPIPEN AND TWINJECT

To the Editor: Guerlain et al[1] concluded that "the sharps injury prevention feature was verified for the novel epinephrine auto-injector (Intellijject), and health care professionals experienced in the use of EpiPen and Twinject for allergic emergencies perceived Intellijject to be a safer and preferred alternative."[1] However, this conclusion is flawed.

Although this study was intended to obtain feedback on, and evaluate preference for, features of Intellijject compared with those of Twinject and EpiPen, it was poorly designed and employed methods that were biased toward Intellijject. The selected participants were practicing nurses who had trained patients on EpiPen and Twinject in the previous 12 months, rather than patients or caregivers who would represent typical users of epinephrine auto-injectors (EA) in the real world. Moreover, participants underwent extensive training and testing for Intellijject. In the training phase, each participant was required to read the instructions and successfully demonstrate the use of the device 3 times consecutively. In the testing phase, each participant was required to inject 18 Intellijject devices—a different orange and a new Intellijject device were used for each injection. However, participants did not undergo equivalent training and testing for EpiPen or Twinject. In the comparative evaluation step, participants were asked to rate the 3 EA devices based on preference for size/shape, ease of use, ease of training patients in use, perceived safety, and overall preference, but these features were not equally tested or reported for all 3 devices, which is not reflective of a true comparator trial. Participants were also asked to recall instances during which an EA was used incorrectly. Although participants listed a retractable needle as a beneficial feature of Intellijject (potentially preventing exposure to a needle already contaminated with a blood product), participants' reports of their least favorite features of Intellijject—the shape for gripping/holding, the difficulty in removing both the outer case and safety cap, and the tendency of the device to become slippery when wet (features that are critical during stressful emergency situations[2])—suggest that Intellijject may be potentially hazardous in real-world settings.

Overall, flawed methodology and comparisons raise substantial questions about the validity of the authors' conclusion. This study's use of an EpiPen device not available in the United States and since replaced by a newer version (with needle protection)[3] rendered any findings for the comparison with EpiPen clinically irrelevant.

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2. Simons FER, Lieberman PL, Read EJ Jr, Edwards ES. Hazards of unintentional injection of epinephrine from autoinjectors: a systematic review. *Ann Allergy Asthma Immunol.* 2009;102:282–287.
3. EpiPen [package insert]. Napa, CA: Dey Pharma, L.P.; 2008.

Author's response: The conclusion with which Dr. Chipps takes issue—that subjects preferred the NEA (Intellijject, Richmond, Virginia) to EpiPen (Mylan Inc, Canonsburg, Pennsylvania) or Twinject (Shionogi Inc, Florham, New Jersey)—is not flawed, but is, rather, a summary of the results.[1] Our study design was based on Food and Drug Administration (FDA) Guidance[2]: "... the evaluators should include a variety of health care professionals who routinely use the type of device you are testing ..." and, "... minimize bias by selecting a sufficient number of evaluators to each use a large enough sample of devices ... to allow them to gain familiarity with the device and thus provide objective opinions."

Chipps is also concerned that we did not test "patients and caregivers" when in fact we have done exactly that—published as a previous study that we cited.[3] In that study, most subjects also preferred the NEA over TwinJect and EpiPen. Perhaps more importantly, there was a propensity for subjects to inject the existing devices upside down, whereas no such instances occurred with the NEA.

Chipps also states that our study used an EpiPen device "not available in the United States"; this is incorrect. The "old EpiPen" was commercially available at the time of our studies. Indeed, it is reasonable to assume, given shelf life and the fact that devices are often retained past their expiry date, that there could be millions of them still in circulation. It is true that a new EpiPen has subsequently become available, but there are continued reports of errors and accidental injections even with the latest version.[4,5] The new EpiPen is even larger than before, making it less likely to be carried at all times.

Finally, Chipps makes a fallacious leap from the fact that study participants were asked to list their least favorite aspect of the study device to claiming that it "may be potentially hazardous in real-world settings." The point of rigorous usability testing required for devices, and completed for Intellijject's NEA, is to ensure that their successful use has been established. For example, despite this being listed as a least favorite feature, there was no difference in time taken to inject the NEA with wet vs dry hands.

As it appears from the available data that none of the currently commercially available products has demonstrated usability in a controlled study, a more logical conclusion would be that it is the currently marketed products that carry a question mark over their ease of use in real life.

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