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Cover Story

Improving the reach of vaccines to low-resource regions with a needle-free vaccine delivery device and long-term thermostabilization

More than 17 million people die every year from infectious diseases — most of these in developing countries. Many of the diseases could be prevented by vaccination, but vaccines are underutilized in low-resource regions. With all vaccines being sensitive to heat, the "cold-chain" is essential for maintaining their quality during transport and storage. This is a huge burden in vaccination campaigns. The cold-chain alone can contribute up to 80% of the financial cost of vaccination programs in developing countries. Advances are being made to improve vaccine thermal stability, but they primarily still rely on the needle and syringe for delivery. This hinders safe and effective vaccination, particularly in the developing world. Vaccination using needle and syringe is tied to the potential need for high doses (because the immune "sweet spot" of skin is largely missed by needles putting vaccine into muscle), the need for qualified medical practitioners, needle-stick injuries, needle phobia and disposal costs.

The paper from Professor Kendall and his co-workers in this issue [1] introduces a new concept to help address these social/medical problems that affect so many people in low-resource regions. First, they designed their Nanopatch "from the ground up" for the purpose of meeting the urgent need for a new vaccine delivery device that is long-term thermostable, efficient, needle-free, simple and affordable. The Nanopatch contains very small and densely packed projections (21,025 projections/cm^2), dry-coated with vaccine and applied to the skin for rapid release (just two minutes), achieving targeted vaccine delivery. With the concept in hand, the team then set about testing the Nanopatch in practice. They focused on confirming both vaccination dose-sparing (compared to the needle and syringe) and thermostabilization. Using a conventional influenza vaccine as a relevant test case (although the Nanopatch is versatile, applicable to the classes of vaccines [2]), the team advanced their previously reported jet-coating method [3] to invoke a 5 fold increase the relative amount of vaccine delivered into the skin, thereby significantly reducing vaccine wastage. The resultant immune responses in mice confirmed an equivalent protective immune responses as intramuscular injection (with the needle and syringe), but with only 1/30th of the actual dose. Also, in separate experiments, the team also showed the vaccine coated Nanopatches are stable for at least 6 months at 23 °C, inducing comparable immunogenicity with freshly coated patches. Importantly, these collective results are achieved with a device that is simple, and conceptually suited to fabrication of a large number of units at a low cost.

Overall, the study by Professor Kendall's group shows that the Nanopatch has key and unique attributes in ultimately meeting the medical need in certain low-resource regions with low vaccine affordability and difficulty in maintaining "cold-chain" for vaccine storage and transport. There is still much to be done now in proving the Nanopatch in human use. However, looking ahead, the Nanopatch has the potential to replace the needle and syringe not only in the low resource regions but also globally.

It is interesting to note that in May 2011 the FDA approved Sanofi's Fluzone Intradermal vaccine designed for adults 18 through 64 years old. Unlike the traditional flu shots using a needle 25 mm or longer, the new intradermal vaccine has a needle of only a 1.5 mm length. The short needle is attached to a pre-filled syringe. The clinical study showed that the immunological response was the same between the intradermal and intramuscular routes. The dermis is known to have a high concentration of the dendritic cells that are critical to generating an immune response. Although the needle was shorter, the new vaccine was as painful as the bigger needles, with equal, if not more, adverse reactions to the vaccine. Thus, the only benefit of this intradermal microinjection is that it appears to be patient-friendly because of the absence of a long, intimidating needle. Patients would feel very comfortable if the vaccine delivery devices do not even have needles at all. The Nanopatch system, when it is introduced clinically, is expected to become the ultimate patient-friendly formulation for vaccine delivery.

References

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