Update on 2D Vaccine Barcode Scanning

National Vaccine Advisory Committee (NVAC)
New Vaccine Technologies

September 13, 2018

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Immunization Services Division, CDC

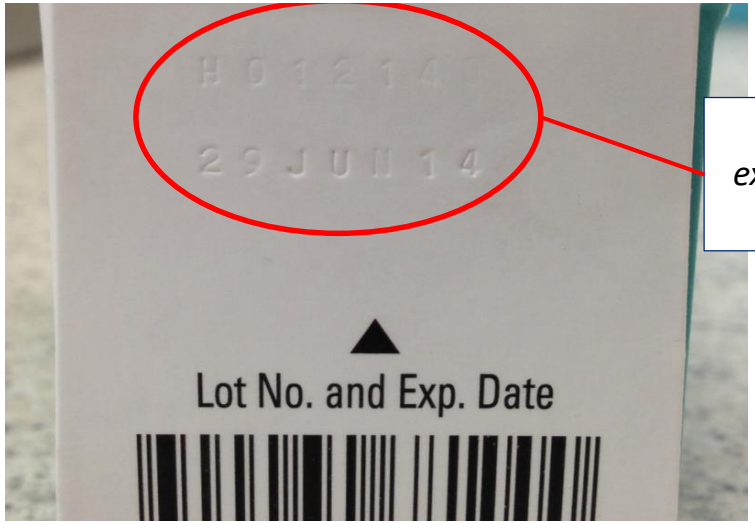
Outline

2D Barcoded Vaccines Timeline & Pilots Overview
Recent Pilot Findings
Next Steps

2D Barcoded Vaccines Timeline **& Pilots Overview**

“The Problem”

“The lot number and expiration date are hard to read on some of the vaccines we get. When those vaccines get barcodes we can scan, it will be a huge help.”

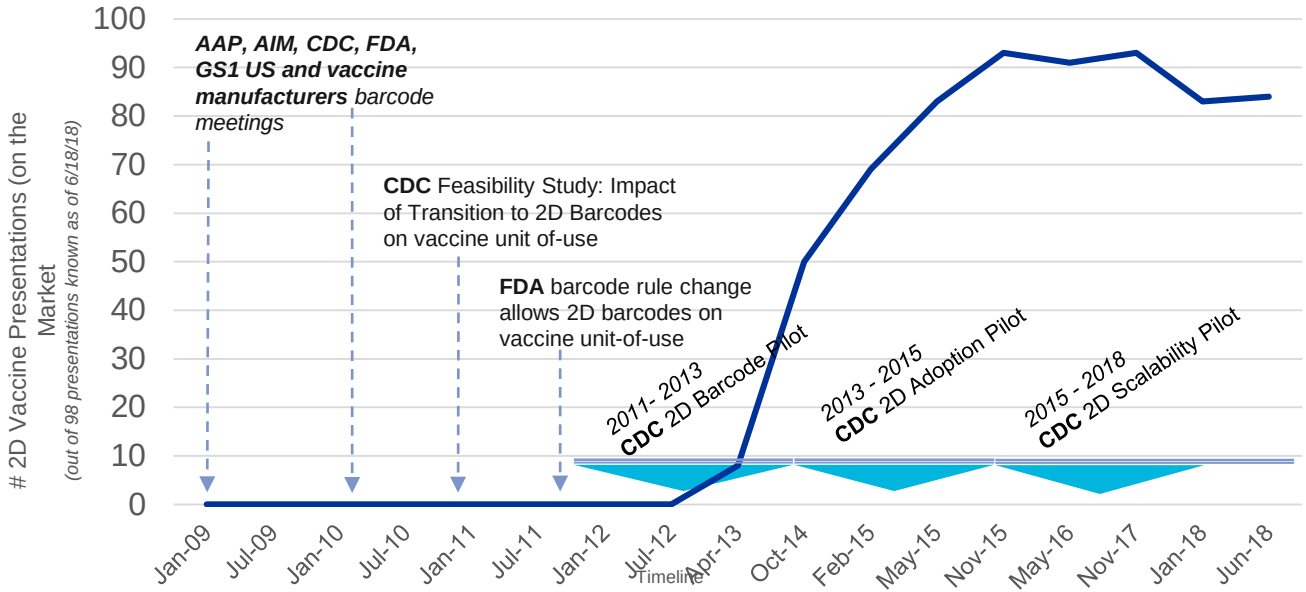


Lot number and expiration date stamped on M-M-R package

“I often see transcription errors where eight (8) and “B” or zero (0) and “O” have been mixed up. Scanning will fix these issues and reduce the number of times I can’t find the lot I’m looking for in our inventory.”

2D Barcoded Vaccines Timeline

Number of 2D Barcoded Vaccine Presentations (Vial/Syringe), US Market



Unit of Use Two-Dimensional (2D) Barcoded Vaccine Presentations – August 2018

	Total 2D Shipping / Total Products	% of Vaccine Portfolio 2D Barcoded	Total VFC and 2D / Total VFC	% of VFC Price List2D Barcoded
GSK	28 / 28	100%	21 / 21`	100%
Merck	31 / 31	100%	23 / 23	100%
Sanofi Pasteur	19 / 23	83%	13 / 13	100%
Wyeth A Subsidiary of Pfizer	2 / 2	100%	2 / 2	100%
Medimmune	0 / 4	0%	0 / 0	0%
Seqirus	0 / 8	0%	0 / 8	0%
Dynavax	1 / 1	100%	0 / 0	0%
Totals	81 / 97	84%	59 / 68	88%

Information is obtained directly from the manufacturers through regular outreach

CDC 2D Barcode Scanning Pilots

*2D Pilot (2D): Assess Impact (2011 – 2013)**	*2D Adoption: Facilitate Adoption (2013 – 2015)*	**Recent Pilot** ***2D Scalability (2015 – 2018)***
Objectives • Assess 2D impact on vaccination data quality & workflow impact • Identify 2D scanning opportunities and challenges • Implement 2D barcodes	**Objectives** • 2D Pilot Objectives • Broaden observations of the initial pilot • Facilitate the adoption of 2D barcode scanning	**Objectives** • Assess 2D scanning in a large health system • Assess compliance with scanning • Identify and develop solutions to address challenges
Participants • 217 healthcare practices • 10 Immunization Awardees • 2 Vaccine manufacturers	**Participants** • 87 Diverse practices • 7 Immunization Awardees • 3 Vaccine manufacturers	**Participants** • 1 large healthcare system • 27 care centers • 4 Vaccine manufacturers

Ongoing Work with Vaccine Community Members:
Vaccine Manufacturers, EMR Vendors, Practitioners, Health Systems, Scanner Vendors

***** Periods of primary data collection and project activities provided

2D Adoption: Compliance … or lack thereof

Determining whether a 2D barcoded vaccine was actually scanned by the user

Unanticipated Findings:

- Variance between self-reported scanning rates and system-tracked scanning (50+% for self-report vs. ~20% for system-tracked)
- Compliance to using scanners decreased over time and differed by vaccine type and time of year

Needs Identified:

To realize the most benefits from 2D scanning the ***technology needs to work as expected*** *and* ***immunizers need to scan regularly (high compliance)***

Recent Pilot (2015-2018): Selection of System, Sites, and Timeline

Piloting 2D barcode scanning implementation within one health care system

Selection of Health Care System

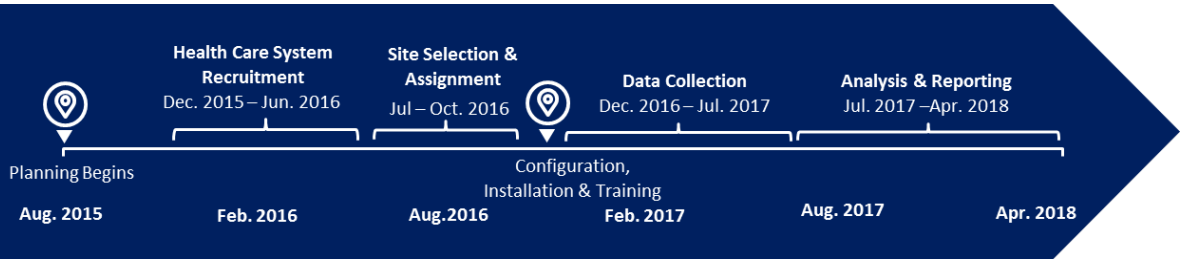
- Recruitment Criteria for Health Care System
  - Sutter Health selected based on criteria, including:
    - Interest and willingness to participate
    - Use of a single EMR systemwide that supported scanning
    - Ability to confirm whether vaccine record scanned or not

Sutter Health
Sutter Medical Foundation

Selection of Sites

- Selection of 27 Sites within the Health Care System
  - Sites selected based on:
    - Interest and willingness to participate
    - Diversity of centers administering vaccines (e.g., pediatrics, vaccine clinic, internal medicine)
    - Agreement to installation and use of scanners
    - Agreement to data collection and assigned adherence strategy group

Pilot Timeline



New: Seeking to "Nudge" Practitioner Behavior with Strategy Groups

Sites were stratified and randomly assigned to an adherence strategy group

Training Only

Training on use of 2D scanners and protocol for scanning

Training *+ No other steps*

Commitment Card

Written personal rationale for scanning/signed commitment to scanning

Training *+*
Commitment Card
(below left)

Scanning Report

Posted report – compares individuals at center and center to other centers

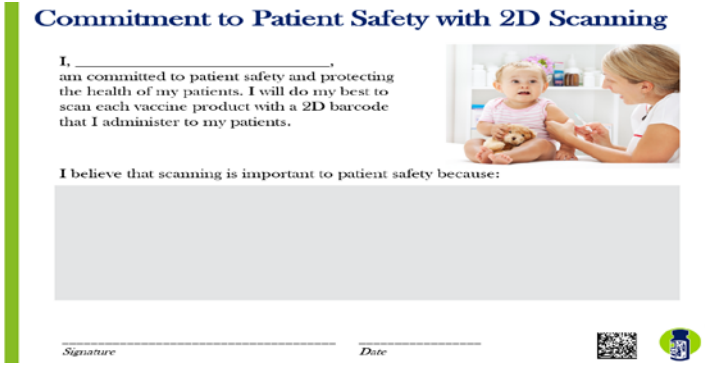
Training *+*
Scanning Report
(below right)

Combination

Combination of all previous strategies

Training *+*
Commitment Card *+*
Scanning Report

Commitment Card



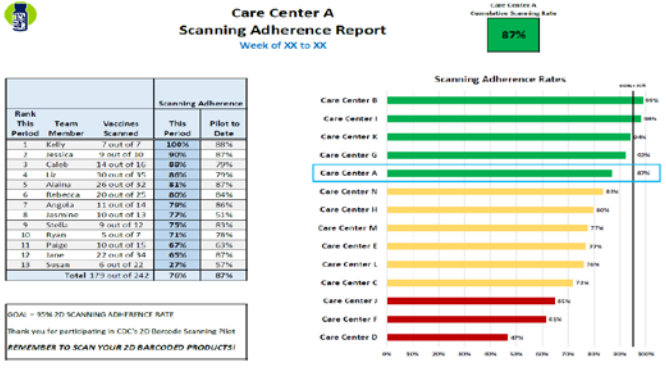
Commitment to Patient Safety with 2D Scanning

I, _____,
am committed to patient safety and protecting the health of my patients. I will do my best to scan each vaccine product with a 2D barcode that I administer to my patients.

I believe that scanning is important to patient safety because:

_____ _____
Signature Date

Sample Scanning Report



Care Center A
Scanning Adherence Report
Week of XX to XX

87%

Scanning Adherence Rates

Rank This Period	Team Member	Vaccines Scanned	Scanning Adherence This Period	Scanning Adherence Pilot to Date
1	Kelly	7 out of 7	100%	88%
2	Jessica	9 out of 10	90%	87%
3	Caleb	14 out of 16	88%	79%
4	Liz	30 out of 35	86%	79%
5	Alaina	26 out of 32	81%	87%
6	Rebecca	20 out of 25	80%	84%
7	Angela	11 out of 14	79%	86%
8	Jasmine	10 out of 13	77%	51%
9	Stella	9 out of 12	75%	83%
10	Ryan	5 out of 7	71%	78%
11	Paige	10 out of 15	67%	63%
12	Jane	22 out of 34	65%	87%
13	Sarah	6 out of 22	27%	57%
		Total 179 out of 242	70%	82%

GOAL = 95% 2D SCANNING ADHERENCE RATE
Thank you for participating in CDC's 2D Barcode Scanning Pilot
REMEMBER TO SCAN YOUR 2D BARCODED PRODUCTS!

Recent Pilot Findings

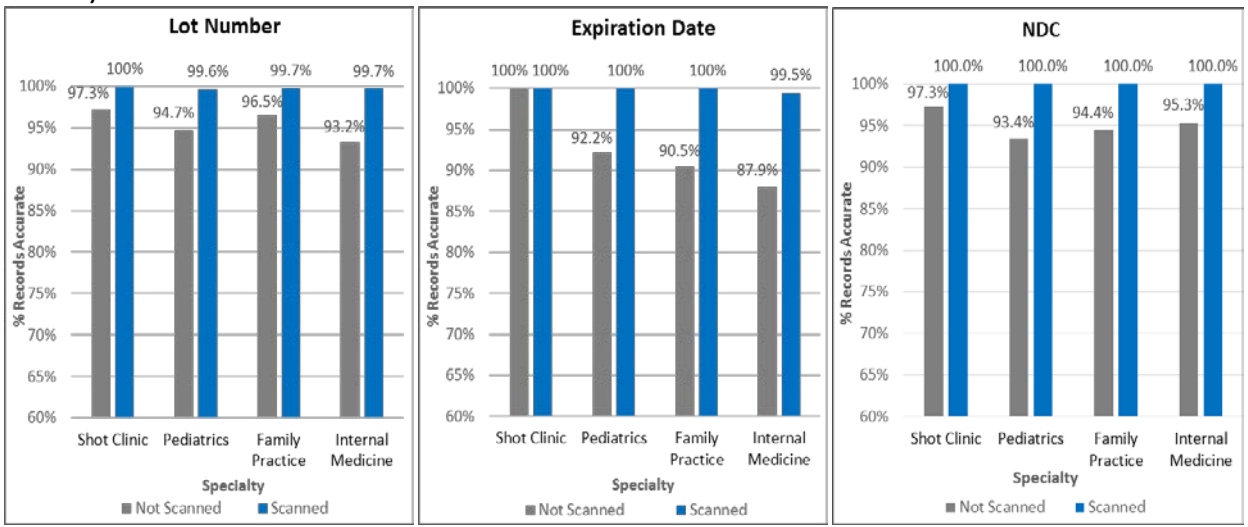
Summary Findings from the Recent Pilot

Accuracy Increased	Accuracy: lot number improved 4.6%, expiration date improved 9.2%, and product identifier (NDC) improved 5.7% when scanned
Time Savings Observed	21 seconds saved per vaccine entered when scanned (average 7.04 seconds when scanned, 28.19 seconds when not scanned)
Scanning Rates	Most vaccines administered were scanned - 94% - (~68,000), Rates varied by specialty, volume, adherence strategy group, site
Strategies Worked	Scanning rates higher with use of scanning rate reports and commitment cards – plus unplanned strategies (leader visits)
Staff Survey	Reduced eye strain, reduced hand / joint-related problems, disposing of syringes in room instead of carrying for later entry (safety)
Challenges Existed	Roadblocks to consistent scanning included: scanning difficulties, scanner location, limited buy-in, and unclear expectations/ protocol

Accuracy Improvements Varied by Data Element and Specialty

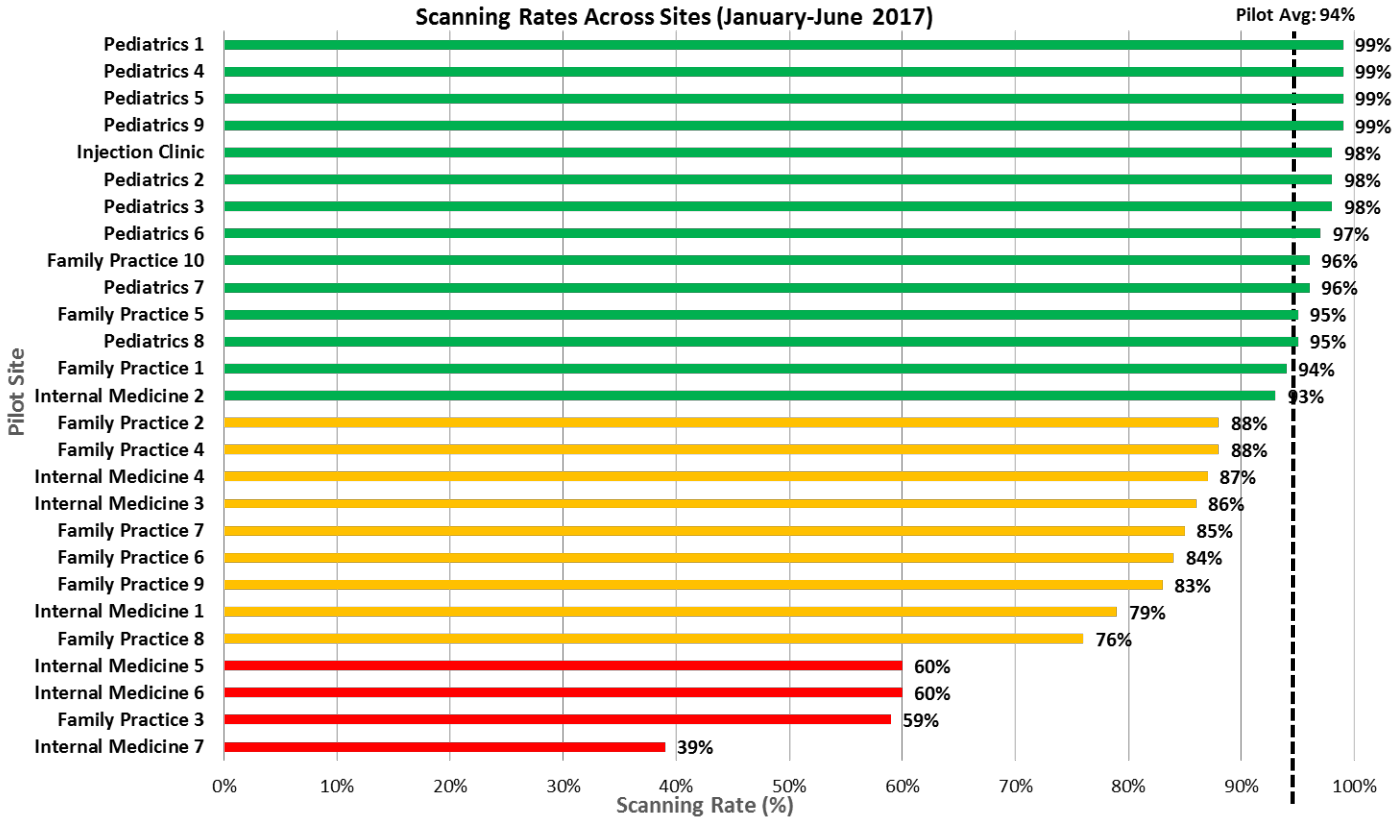
- Improvements to record accuracy when vaccines scanned (compared with not scanned) ranged from 2.7%-6.5% for lot number; 0%-11.6% for expiration date; and 2.7%-6.6% for product identifier (NDC)

- Differences when scanned or not scanned statistically significant (except where noted)*



*Statistically significant difference (p<.01) between scanned and not scanned accuracy of vaccine records for each specialty, within each data element, with the exception of the expiration date field comparison for the shot clinic.

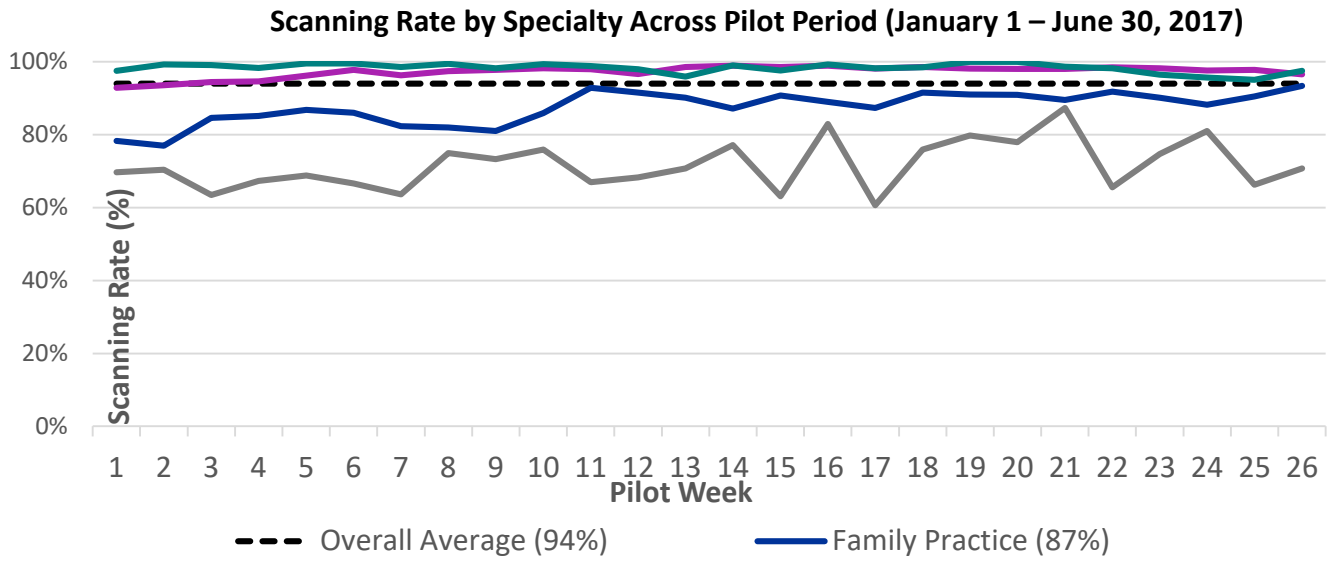
Scanning Rates Ranged from 39% to 99% Across Pilot Sites



Significant Variation in Scanning Rates by Specialty*

Highest rates = **Pediatric** sites (97%) and a **Shot Clinic** (99%)

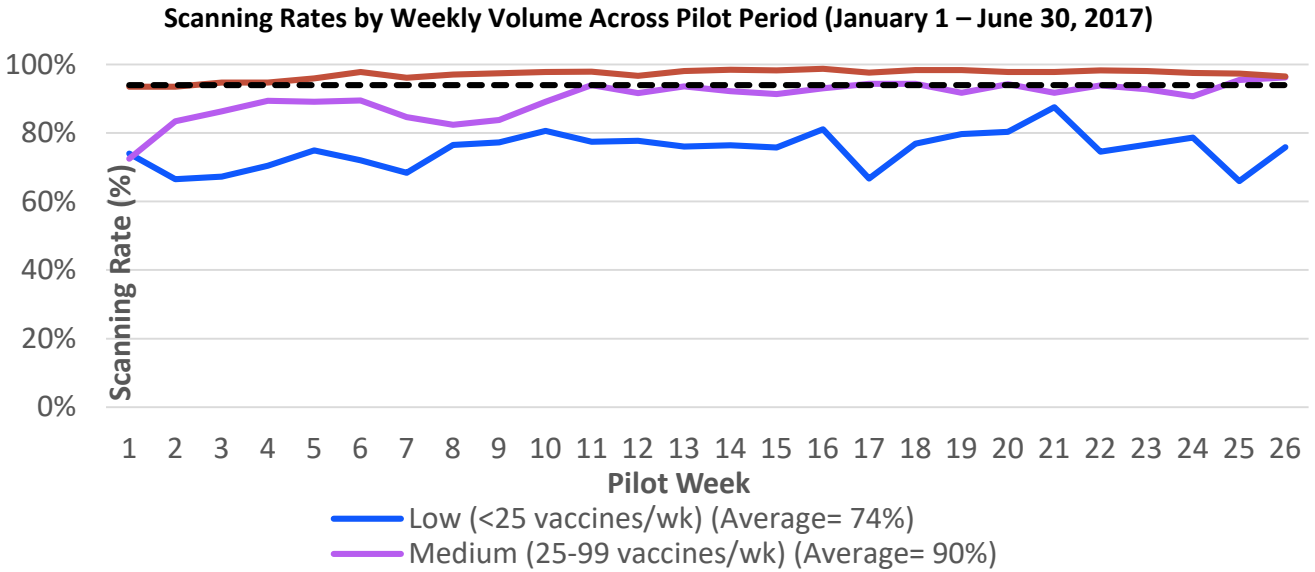
Lowest rates = **Internal Medicine** sites (71%)



*Significant at p < .0001 level

Scanning Rates Increased as Weekly Volume Increased

Significant difference in scanning rates by volume,* from
74% for low-volume sites to **97% for high-volume sites**



*Significant at p < .0001 level

Adherence Strategies Significantly Improved Scanning Rates

Training-only group had the **lowest average scanning rate**

Groups with an **additional strategy had significantly higher scanning rates***

Training Only	Commitment Card	Scanning Adherence Report	Combination (Card + Reports)
		
92% scanning rate	**96%** scanning rate	**94%** scanning rate	**96%** scanning rate

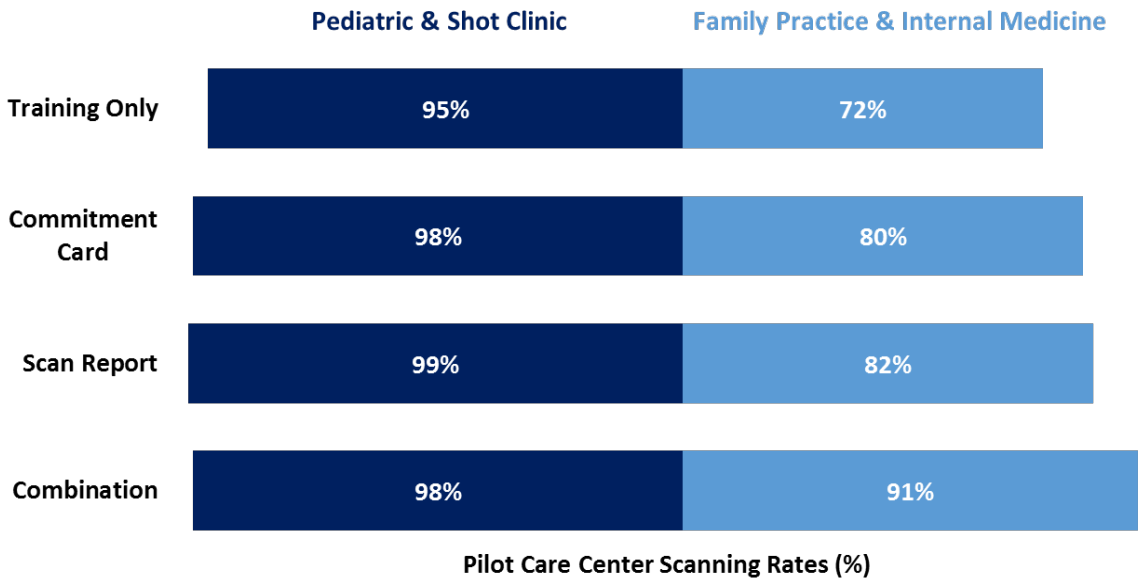
LOWEST ---------- **Level of Resources to Implement Strategy** ---------- **HIGHEST**

*Statistically significant at the p<.0001 level

Adherence Strategies Most Effective at Family & Internal Medicine Sites

Strategies performed similarly for **Pediatric and Shot Clinic** sites

Significant variation at **Family Practice and Internal Medicine** sites*



*Differences statistically significant at the p<.001 level

Next Steps

Next Steps

Share Pilot Findings – Reports/ Articles/ Presentations

Promote and Refine - Implementation Guide __ for Decision-Makers

Maintain National Drug Codes (NDC) Crosswalk Tables

Unit of Sale (UoS) & Unit of Use (UoU)

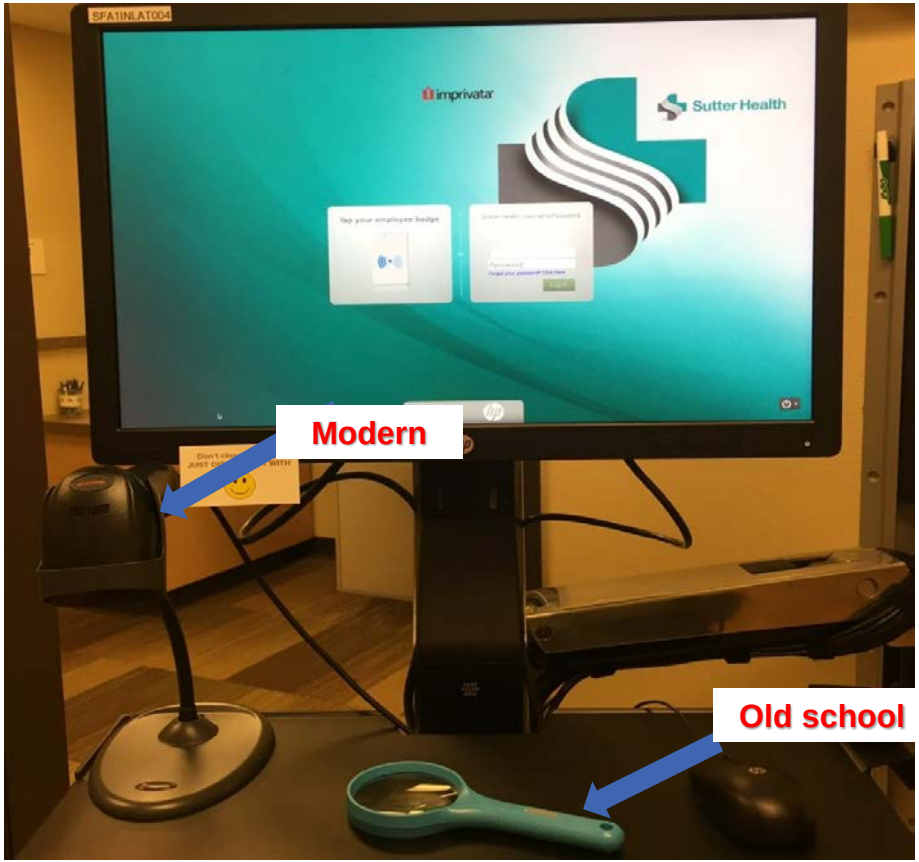
Maintain Functional Capabilities Report – for software developers

Engagement with Immunization Community Partners

Vaccine Manufacturers – EMR Vendors – Scanner Vendors - Providers

Monitor - Drug Supply Chain Security Act (DSCSA)

Where to find more information



Visit the CDC 2D barcode page for 2D vaccine barcode resources: http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/

Search Key Words: “CDC 2D Barcode”

What’s on the site?

- Current list of 2D barcoded vaccine presentations (vials/syringes)
- 2D Pilot artifacts, including:
  - **2018 Findings Report**
  - **2D Implementation Guide**
  - AAP Guidance
  - GS1 Guidance
  - 2D Functional Capabilities Report (for Developers)

“Thank You-Happy Scanning”

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

ADVANCES IN COLD CHAIN HANDLING: GLOBAL TEMPERATURE CONTROL

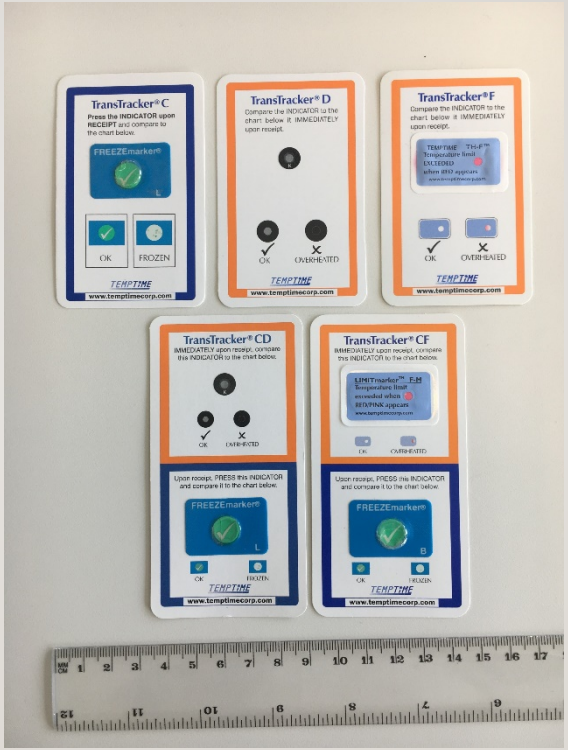
September 13, 2018

National Vaccine Advisory Committee

GEOFFREY GLAUSER LLC.

ADVANCES IN COLD CHAIN HANDLING

- Logistics
- Distribution / Last Mile deliveries
- Quality Management Systems
- Stability Budgeting
- **Temperature Data Loggers**
- **Insulated Containers**
- **Technical Advances**



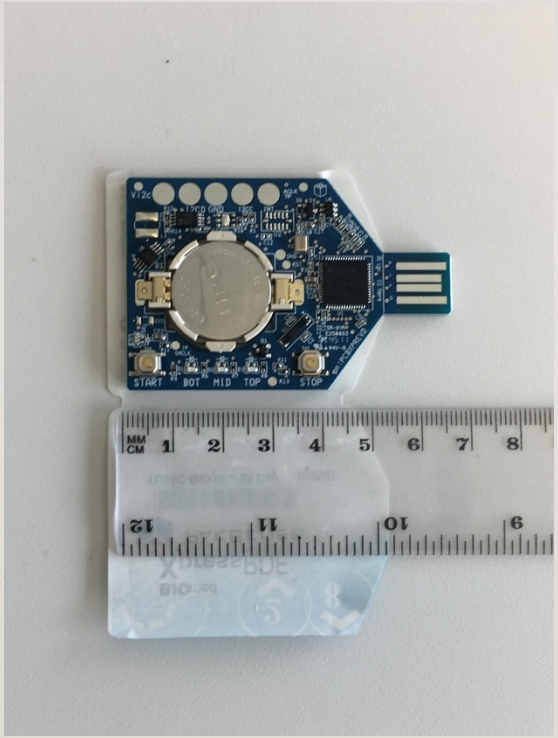
Previous Temperature Data Solutions

- One-time use
- Limited programming
- Limited data downloading capabilities
- Validation limitations
- Comparatively expensive

Electronic Data Recorders

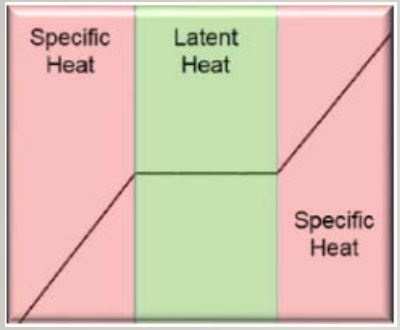
- Miniaturization is progressing
- Programmable
- Varied functionality
- Up to five year battery life
- Specific to the cold chain function
  - Long term storage recording
  - Short-time single use
- Adaptable to unique stability budgeting
- Uploading capabilities
- Robust
- Validated

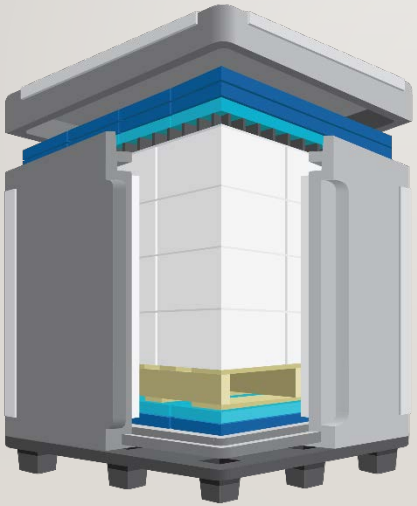
Competitive Market



Miniaturization

- 4-Year monitoring life
- Small enough for individual packages
- Cost competitive
- Upload capability
- Programmable to individual stability budgets
- Complete TOR record
- Multi-level alarms LED
- Automatic PDF reporting
- Validated
- NIST traceable
- Bluetooth enabled to Cell Phone with app
- Data can be loaded to a central database





Insulated Designs w/ Phase Change Materials

- Significant assembly enhancements
- Lower time out of refrigeration
- Reusable
- Replaceable components
- Phase change materials
- Ability to use for 2-8^{o}C, -20^{o}C, Controlled Room Temperature

Vacuum Insulated Panel Shippers

- More frequent use
- Cost competitive
- Reusability / recyclability
- Lifecycle considerations
- Replaceable components
- Returns' effectiveness

PharmaPort® 360 permits forklift access from four sides.

- **Pallet Quantity Shipping**

- Critical temperature control accuracy for 2-8ºC (E.g. Clinical, Heat labile materials)
- Refrigeration and heater mode are disabled during air transport.
- Regenerative cooling and heating in recharge mode **and** transport mode
- Tight configuration allowing for use in multiple aircraft

- **Arktek**

- Developed by Intellectual Ventures to transport 2-8ºC for up to 30 days in sub-Saharan temperature
- Utilized in Sierra Leone Ebola vaccine trial at ≤-60ºC with -80ºC phase change materials
- Limited vial capacity
- Solution for inaccessible or remote vaccination locations

Thank you!

Geoffrey Glauser
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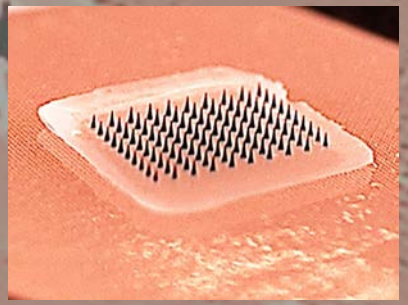
215-435-3390

Advances in Vaccination Technologies: The Microneedle Patch



September 13, 2018
National Vaccine Advisory Committee

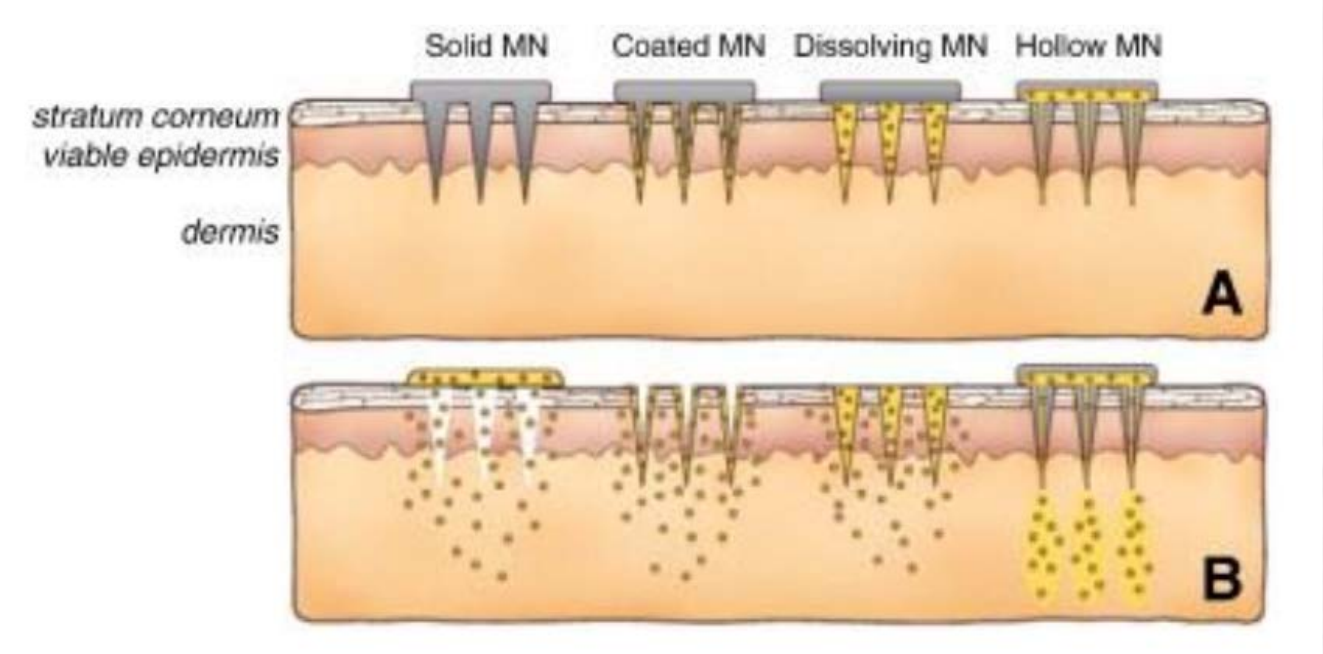
Šeila Selimović, PhD

National Institutes of Health
Turning Discovery Into Health

National Institute of Biomedical Imaging and Bioengineering

I declare that I do not have a financial interest, arrangement or affiliation with any commercial or other organization that may have a material interest in the subject matter of my presentation.

Microneedle Patch Technology



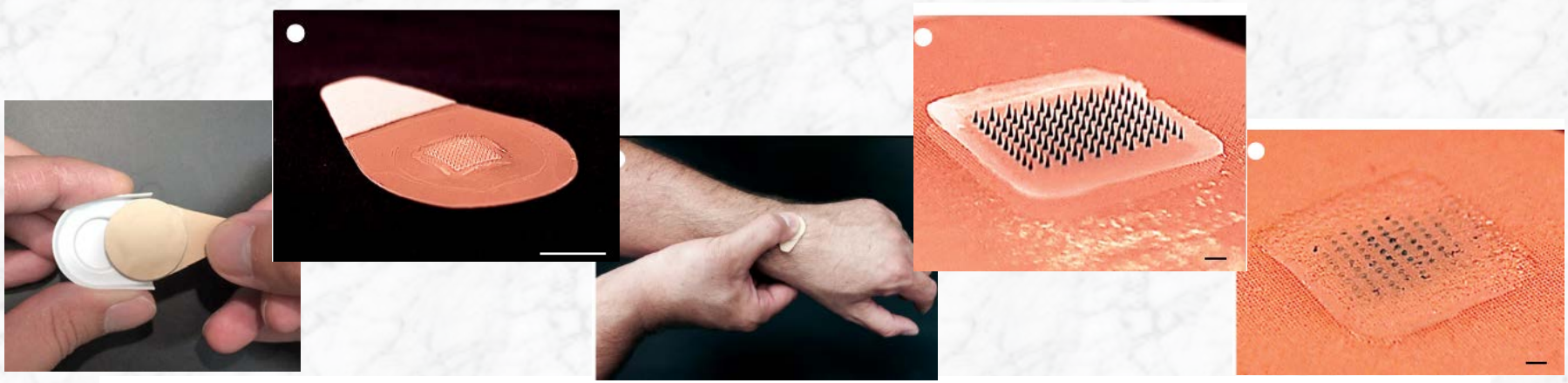
National Institute of Biomedical Imaging and Bioengineering

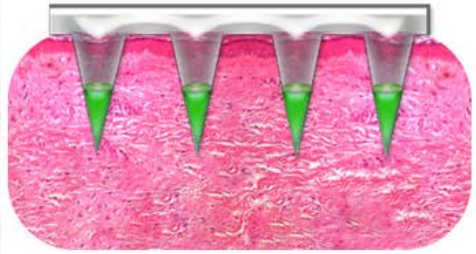
Jaya Arya, Dissertation 2016, Georgia Inst of Tech

Microneedle type		
Coated	Dissolving	Hollow
Adenovirus [39-42]	Adenovirus [39-42]	Anthrax [43-46]
BCG [47, 48]	Amyloid β peptide [49]	Botulism [45, 50]
Chikungunya virus [51]	Diphtheria [52-56]	Influenza [55, 57-83]
Hepatitis B [84-87]	HIV [88]	Japanese encephalitis [89]
Hepatitis C [90]	Influenza [55, 57-83]	Poliovirus [91]
Herpes simplex virus [92, 93]	Malaria [41, 52, 94]	Rabies virus [95]
HPV [96]	Measles [97]	Staphylococcus aureus [43, 45]
Influenza [55, 57-83]	Poliovirus [98]	Yersinia pestis [45, 99]
Measles [100]	Tetanus [52]	
Modified Vaccinia Ankara [39, 94]		
Rotavirus [101]		
Small Pox [102]		
West Nile virus [51]		

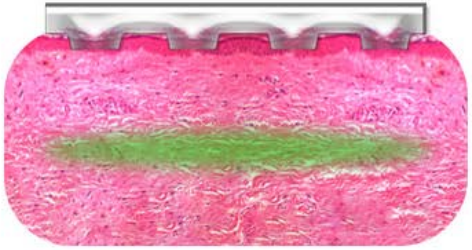
Jaya Arya,
Dissertation 2016,
Georgia Inst of Tech

Microneedle Patch Technology

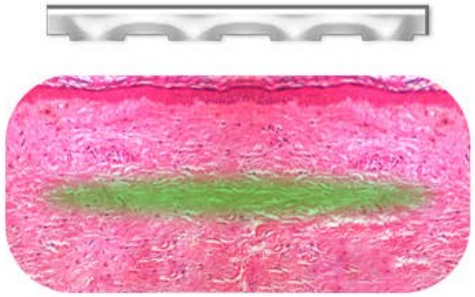




Patch is applied to skin



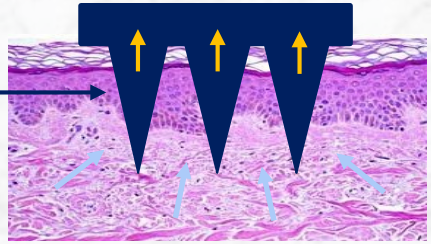
Microneedles disolve and release their active



Sharps-free backing is removed and discarded

Microneedle Patch Technology

Arrowhead microneedles



Skin Layer	Thickness
Stratum corneum	10-100 µm
Viable epidermis	50-160 µm
Dermis	1000-2000 µm

Enhanced immunogenicity due to skin route of vaccination (assessed by antibody and cell-mediated responses) – instead of novel antigens and adjuvants.

Dose sparing of influenza vaccine when administered via skin compared to intramuscular injection.

Water-soluble microneedles containing vaccine: minutes after patch shaft removal.

NIH National Institute of Biomedical Imaging and Bioengineering

Hypodermic Needles

- **COMPLEX**: administered by health professional
- **INVASIVE**: intramuscular / subcutaneous / intradermal
- **PAINFUL**: larger needle -> more painful
- **THERMALLY SENSITIVE**: vaccine in liquid form
- **VERSATILE**: applicable to multiple vaccines, not only influenza
- **REGULATED DISPOSAL**: sharps

Microneedle Patch Technology

- **SIMPLE**: can be self-administered
- **TARGETS SKIN**: minimally invasive
- **IMPROVED EFFICACY**: provokes immune reaction in skin
- **PAINLESS**: reducing needle size reduces pain; patient acceptance
- **STABLE**: single dose, thermostable, no reconstitution
- **VERSATILE**: applicable to multiple vaccines, not only influenza
- **EASY DISPOSAL**: no sharps
- **LOW COST**: microfabrication tech; $0.01 in mass production; no cold chain

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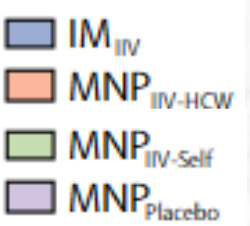
Phase I Clinical Trial

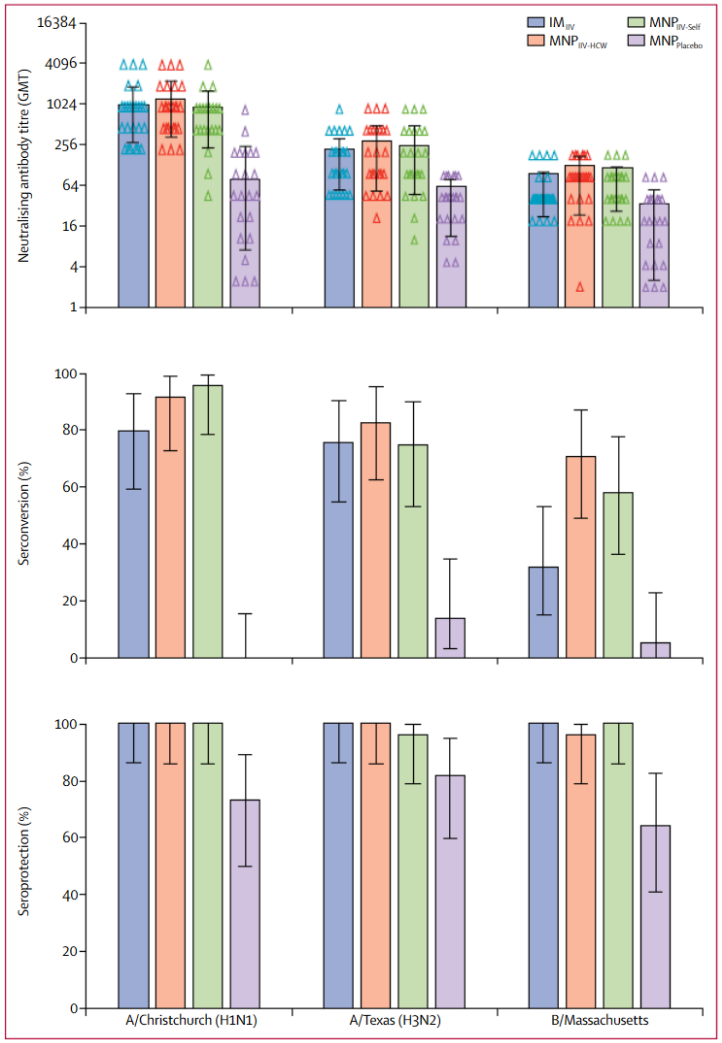
The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial

Nadine G Rouphael, Michele Paine, Regina Mosley, Sebastien Henry, Devin V McAllister, Haripriya Kalluri, Winston Pewin, Paula M Frew, Tianwei Yu, Natalie J Thornburg, Sarah Kabbani, Lilin Lai, Elena V Vassilieva, Ioanna Skountzou, Richard W Compans, Mark J Mulligan, Mark R Prausnitz*, for the TIV-MNP 2015 Study Group†*

www.thelancet.com **Vol 390 August 12, 2017**



Intramuscular (hypodermic needle)
Patch – administered by med professional
Patch – self-administered
Patch – placebo



Serological response to study drug administration

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Origins and Future

- Quantum Award to Prausnitz et al (Georgia Tech / Emory), 2013
- Now being commercialized by Micron Biomedical

CDC awards Micron research contract to develop a patch for co-administration of inactivated rotavirus vaccine (IRV) and inactivated polio vaccine (IPV)

Sep 1, 2016

Phase 1 clinical trial shows safety and immunogenicity of microneedle patch for flu vaccination for the first time

Jun 28, 2017

Micron to collaborate with Georgia Tech and CDC on measles-rubella project funded by UNICEF

Jun 19, 2017

Considerations

- Application to other vaccinations requires new vaccine formulations (stabilizing compounds may affect immunogenicity.).
- Slow-release materials instead of multi-dose delivery.
- Quick dissolving materials (1 minute or less).
- Mechanical strength of microneedles when exposed to short periods of humidity outside of storage packaging?
- Microneedle patch technology applicable to other uses, e.g. interstitial fluid extraction (diagnostics) / other drug delivery.
- Self-administration -> minimally trained personnel sufficient
- Assess policy issues associated with self-administered influenza vaccination using a microneedle patch.

Thank you!

Šeila Selimović, PhD
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National Institutes of Health
Turning Discovery Into Health

National Institute of Biomedical Imaging and Bioengineering