
Estimating the Economic and Public Health Impact of Microarray Patch (MAP)-Administered Vaccines in Pandemics

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Executive Summary

The rollout of COVID-19 vaccines highlights the need for continued innovation in how vaccines are delivered. Recognizing this, the US government and global stakeholders established objectives for simplifying vaccine distribution and administration, including through the development of new technologies and approaches to enable broader, faster rollout of vaccines in a pandemic. If successful, these innovations have the potential to end pandemics more quickly, save lives, and reduce economic harms.

Microarray patches (MAPs) are being developed as a new tool to enable intra- and trans-dermal vaccine administration. If MAP vaccines meet their development objectives, using them to deploy vaccines in a pandemic could accelerate availability across expanded populations and hard-to-reach places. Through dose-sparing capabilities, streamlined storage and distribution, and simplified administration, MAP vaccines could mitigate the public health and economic consequences of future pandemics.

Avalere modeled the potential impact of MAP vaccines under 2 pandemic scenarios measuring how MAP vaccines could affect cases, deaths, and pandemic duration, as well as mitigate economic losses resulting from pandemic-related business closures and lockdowns. Results demonstrated that, in both scenarios, MAP vaccines would contribute to shorter pandemics, at least 35% fewer cases, and at least 30% fewer deaths. Additionally, MAP vaccines would reduce US economic losses by at least \$200 billion and global economic losses by at least \$921 billion.

These results demonstrate MAP vaccines could enable more rapid vaccination of the global population, thereby bringing pandemics to a close more quickly, reducing potential for variants of concern, and moderating the negative economic effects of lockdowns and other mitigation measures. Findings from early-stage MAP vaccine clinical studies have been positive, demonstrating comparable or superior immunogenicity to traditional needle-and-syringe vaccines and improved acceptability among recipients. Some studies have demonstrated dose-sparing, meaning MAP vaccines could potentially achieve the same efficacy using a lower dose. Additionally, MAPs may not require cold chain distribution and could be well equipped to reach rural and remote communities. Targeted investment is needed to fully realize this technology's potential for accelerating vaccination and improving US and global pandemic response capabilities.

Introduction

The rollout of COVID-19 vaccines, both in the US and globally, has drawn attention not only to rapid vaccine development, but also to the need to improve the tools and approaches available for delivering vaccines. Recognizing this, the US government and global stakeholders established objectives for simplifying vaccine distribution and administration, including through the development of new technologies and approaches to enable broader, faster rollout of vaccines in a pandemic. Several life sciences companies are developing microarray patches (MAPs) for intra- or trans-dermal vaccine administration which, if successful, could offer advantages over traditional needle-and-syringe vaccine delivery.¹ Such advantages may include accelerating the availability of vaccine doses through dose-sparing, streamlining storage and distribution, simplifying administration, and reaching expanded populations. These advantages could have significant implications for the public health and economic effects associated with a pandemic.

This paper provides an overview of progress towards development of MAPs for vaccination and highlights technical and policy considerations for delivering them at the scale needed to achieve widespread economic and public health impact. It then examines the potential economic and public health effects of deploying MAP vaccines during a pandemic, drawing on the results of modeling conducted by Avalere Health. This modeling explored how, in 2 pandemic scenarios, deployment of MAP vaccines in combination with traditional needle-and-syringe vaccines could affect cases, deaths, and pandemic duration, as well as how MAP vaccines could influence the economic effects of pandemic-related shutdowns and other restrictions. While the primary focus of this analysis is on US domestic impact, Avalere also extrapolated high-level global data to demonstrate the broader potential impact of MAP technology.

Model results demonstrated that MAP vaccine use during either scenario would shorten pandemic duration and reduce economic losses. As MAP development continues, additional research into the effect of MAP vaccines on pandemics and other infectious disease scenarios may inform product development.

Progress in MAP Development

Several companies are advancing MAP technologies for vaccine delivery through preclinical and clinical development. Over the past 2 decades, researchers have conducted preclinical studies of MAP vaccines against a wide array of pathogens in animal models, including mice, monkeys, pigs, and other small mammals. These studies have demonstrated that intra- and trans-dermal MAP vaccine delivery can produce a strong, durable immune response and protective efficacy across all vaccine types and target pathogens.² In particular, preclinical MAP vaccine studies targeting viruses with pandemic potential induced suitable protection in mice, and studies of influenza vaccination in mice found long-term protective immunity.³

Despite promising preclinical findings, MAP vaccines have undergone limited human clinical testing. As of January 2022, 4 Phase I studies of MAP-delivered influenza vaccines have been completed, and 1 Phase I/II study of a MAP-delivered measles-rubella vaccine is currently underway.^{4,5} Additionally, 1 Phase I study of a MAP-delivered Japanese encephalitis vaccine has been completed.⁶ These early clinical trials demonstrated that MAPs have an acceptable safety profile and are capable of eliciting an immune response comparable or superior to that produced by traditional needle-and-syringe vaccines. For example, a Phase I trial of a MAP-delivered influenza vaccine demonstrated the vaccine was similarly immunogenic to traditional needle-and-syringe counterparts, was associated with no adverse events directly attributable to the MAP, and caused little to no pain for the majority of participants.^{7,8} Additionally, some studies are exploring the potential dose-sparing capability of MAPs, including one study that found MAPs were similarly immunogenic to traditional vaccines using 1/6th of the dose.⁹

Potential Advantages

MAPs have the potential to improve vaccination access by supporting dose-sparing, simplifying vaccine distribution and administration, and reducing barriers to vaccination.

Dose-Sparing

MAPs may support vaccination of more people using the same volume of vaccine material, as the higher density of antigen-presenting cells in the dermal skin layer may allow a vaccine delivered intra- or trans-dermally to achieve similar efficacy to intramuscular administration using a smaller dose.^{10,11} In preclinical studies, MAPs have demonstrated potential for this type of dose-sparing, which could increase the number of doses available from a fixed volume and decrease the cost per dose delivered.¹²

Simplifying Distribution & Administration

MAPs also may support streamlined, and less expensive, distribution processes. Early evidence shows that MAP vaccines may be able to withstand higher temperatures than traditional needle-and-syringe vaccines, which would require less stringent cold chain storage and distribution.¹³ Additionally, MAPs are generally smaller than needle-and-syringe counterparts, which would support more efficient use of storage and delivery space. These features could lower the cost of storage and distribution, allow MAPs to be distributed on an accelerated timeline, and leverage novel delivery methods, including direct-to-consumer.¹⁴

Vaccine administration also could be simplified with MAP technology. One study found that MAP vaccines required minimal training for administration, which could alleviate strain on the healthcare workforce by allowing providers without specialized training to administer vaccines and potentially support patient self-administration.¹⁵ Early usability testing also indicates that self-administration of MAP vaccines is feasible and could increase vaccine uptake, though additional study and regulatory guidance is needed.¹⁶

Reducing Barriers to Vaccination

MAP vaccines could increase vaccine uptake and combat hesitancy. Due to the small size of the microneedles on the device, MAP vaccines may have lower pain potential and could be preferable for some recipients who may fear needles.¹⁷ MAP vaccines may also be better able to reach homebound and other hard-to-reach individuals given size and thermostability profile.

Opportunities for Advancement

Considerations spanning technical, regulatory and policy, and acceptability and administration will need to be addressed for MAP vaccines to achieve widespread economic and public health value.

Technical

Additional clinical studies are needed to better understand MAP vaccine safety and efficacy, including studies that look at MAP delivery of different vaccine types in broader populations and those that further establish the potential for dose-sparing.¹⁸ Studies also should ensure that variation in skin characteristics and differences in application pressure do not affect delivery of accurate dosing.^{19,20} Further assessment of thermostability requirements for MAP-delivered vaccines also needs to be explored to support storage and distribution outside traditional vaccine cold-chain requirements.²¹

Greater investment in manufacturing standardization, including equipment and processes, would be required to achieve full-scale commercialization.²² Like traditional needle-and-syringe vaccines, MAP vaccines must meet strict aseptic manufacturing standards that require complex processes and can pose additional resource, training, and cost considerations.^{23,24} Lack of regulatory guidance on chemistry, manufacturing, and controls also creates uncertainty for manufacturers about critical quality attributes, testing methods, and sterility requirements.²⁵

Regulatory & Policy

The US Food and Drug Administration (FDA) has yet to publish guidance on review of MAPs for vaccine or drug delivery. MAP vaccines will follow a combination regulatory pathway, meaning multiple FDA centers will play a role in establishing standards to ensure that vaccines reformulated for MAP delivery are as safe and effective as their needle-and-syringe counterparts. New technologies and approaches for quality control inspections may be needed to assure integrity and standardization of the small components and complex machinery used to manufacture MAPs. To achieve the potential for self-administration of MAP vaccines, FDA also will need to provide guidance on required testing and evidence.

To ensure policy recommendations for use, optimal public and private coverage, and procurement contracts, manufacturers will need to demonstrate the added value that MAPs provide compared with existing vaccination methods.^{26,27} For example, value demonstration supports a positive recommendation from the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices, which drives coverage and

reimbursement for routine vaccines in the public and private markets. In the pandemic context, value demonstration may be critical for securing contracts with US government agencies, including the Departments of Defense and Health and Human Services.²⁸

Acceptability & Administration

More research is needed to understand potential MAP product uptake under different approval and use scenarios.²⁹ Intra- or trans-dermal vaccine administration introduces new user experience variables, such as skin reactions, that may affect user acceptability.³⁰ Additionally, potential self-administration of MAP-delivered vaccines will require new approaches to verify successful administration of the vaccine to the right person when outside the supervision of a trained healthcare worker.³¹

Economic & Public Health Model

Methods

Avalere assessed the public health and economic impact of MAP vaccines in 2 viral pandemic scenarios that would likely cause lockdowns, large-scale job loss, reduced economic activity, and diminished productivity. Characteristics of each scenario are summarized in Figure 1. Scenario 1 resembles SARS-CoV-2 and scenario 2 resembles pandemic influenza. Under both scenarios, Avalere determined the extent to which MAP-delivered vaccine availability reduced infections, deaths, and duration of each pandemic, in addition to the proportionate impact on net economic effects.

Figure 1. Characteristics of Model Pandemic Scenarios

	Scenario 1	Scenario 2
Virus Characteristics		
Infection Fatality Rate	0.6%	2.5%
Latent Period (Days)	5	2
Incubation Period (Days)	8	5
Transmissibility (R0)	2.5	2.0
Mutation Rate	.0036	.000002
Vaccine Dynamics		
MAP Dose Sparing Effect	50%	50%
Volume of Total Bulk Vaccine Supply to MAPs	10%	10%
Marginal Impact of MAPs on Vaccine Uptake	10%	10%
Vaccine Timing	Delayed	Available
Vaccine Supply	Constrained	Unconstrained
Vaccine Effectiveness	High (90%)	Moderate (60%)

The virus in scenario 1, which is similar to SARS-CoV-2, has a lower infection fatality rate but spreads rapidly and has a higher mutation rate. Vaccines under this scenario are highly effective but face a 12-month delay in availability and supply constraints. In this scenario, the model does not account for case, hospitalization, and mortality data beyond the Delta variant of COVID-19. The virus in scenario 2, which is similar to pandemic influenza, has a higher infection fatality rate than scenario 1 but spreads and mutates less rapidly. Vaccines in this scenario have moderate efficacy and are immediately and widely available.

In both scenarios, MAPs had a 2-to-1 dose-sparing effect, and 10% of the volume of bulk vaccine product was dedicated to MAP application. Additionally, both scenarios incorporated a 10% marginal impact on vaccine uptake. These assumptions are examined further in the limitations section of this paper.

The model used estimates of US gross domestic product (GDP) from January 2020 and July 2021 Congressional Budget Office (CBO) forecasts to capture the net economic effects of the COVID-19 pandemic. These estimates were modified proportionately for the virus in scenario 2, similar to pandemic influenza, and were used to model US economic effects, which Avalere then extrapolated to the global economy.

Results

Model results (shown in Figure 2) demonstrate that, compared to baseline, MAP vaccine availability would reduce pandemic duration, total cases, and total deaths in both scenarios. In addition, MAP vaccine availability would reduce US and global economic losses over a 2-year period and increase forecasted US economic gains over the next 10 years. A visual breakdown of model results is shown in the appendix.

Under scenario 1, MAP vaccine availability would result in 16.3 million fewer cases, 200,000 fewer deaths, and would reduce the duration of the pandemic by 150 days. Economic losses would be reduced by \$516 billion in the US and \$2.3 trillion globally over a 2-year period, and economic gains would be increased by \$793 billion in the US over a 10-year period.

Under scenario 2, MAP vaccine availability would result in 22.4 million fewer cases, 600,000 fewer deaths, and would reduce the duration of the pandemic by 30 days. Economic losses would be reduced by \$205 billion in the US and \$921 billion globally over a 2-year period, and economic gains would be increased by \$390 billion in the US over a 10-year period.

Figure 2. Model Results

Scenario 1

	US Public Health Impact			US Economic Impact (GDP \$B)		Global Economic Impact (GDP \$B)
	Duration (Days)	Cases	Deaths	2-year	10-year*	2-year
Baseline	655	46.7M	700K	(\$1,740)	\$1,889	(\$7,807)
With MAPs	505	30.4M	500K	(\$1,224)	\$2,682	(\$5,492)
Difference	(150)	(16.3M)	(200K)	\$516	\$793	\$2,315

Scenario 2

	US Public Health Impact			US Economic Impact (GDP \$B)		Global Economic Impact (GDP \$B)
	Duration (Days)	Cases	Deaths	2-year	10-year*	2-year
Baseline	180	43.5M	1.1M	(\$478)	\$518	(\$2,146)
With MAPs	150	21.1M	500K	(\$273)	\$908	(\$1,225)
Difference	(30)	(22.4M)	(600K)	\$205	\$390	\$921

Discussion

Model results demonstrate that MAP vaccines could enable more rapid vaccination of the population, bringing pandemics to a close more quickly, reducing potential for variants of concern, and moderating the negative economic effects of lockdowns and other mitigation measures. While this impact was seen in both scenarios, its magnitude was greater in scenario 1 where vaccine supply was constrained at the outset. In this scenario, MAP vaccines would enable more rapid scale-up of vaccination. While MAP vaccine availability would also result in increased vaccine uptake in scenario 2, this impact would be smaller given unconstrained supply.

The model results show that the pandemic in both scenarios would end more quickly with MAP vaccine availability. Shorter pandemics could reduce a pathogen’s potential to mutate and, in turn, reduce potential development of variants of concern. While this model did not incorporate a global goal of a 100-day timeline for pandemic vaccine availability, an expedited timeline could further reduce cases, deaths, economic losses, and mutation potential.

The economic impact results were driven by faster vaccination and increased uptake when MAP vaccines were available. The model assumed that, in a supply-constrained environment, dose-sparing allowed for more rapid scale-up of vaccination programs, further reducing pandemic duration. Faster vaccination of a population could result in fewer cases and deaths and reduce duration of lockdowns and other pandemic restrictions that negatively affect the economy. The

model also assumed, based on published literature, additional vaccine uptake with the availability of MAP vaccines due to their potential ability to reach individuals in rural or remote locations where traditional needle-and-syringe vaccines may be difficult to access, as well as individual acceptability by those who may be hesitant due to needle fear or who may otherwise avoid vaccination.

Attributes that support simpler distribution, including the potential to forego cold chain delivery and storage, may also allow MAPs to be delivered to homes, further improving vaccine uptake. For example, vaccine delivery by home health aides could improve vaccine access for homebound individuals. Additionally, MAPs may be well-suited for mail delivery to rural outposts. Avalere accounted for this potential in the model by assuming that the availability of MAP vaccines would increase uptake by 10%. Finally, while this model did not incorporate self-administration availability, this method could further improve model results if broadly accepted by medical professionals and vaccine recipients.

Limitations

In both scenarios, Avalere made assumptions about MAP attributes and availability, including:

- **Volume of bulk vaccine product dedicated to MAP application.** The amount of vaccine product dedicated to MAPs could vary depending on volume and availability of MAPs, vaccine product, and traditional vaccine supplies. While it is possible for a greater volume of vaccine product to be dedicated to MAPs, this will depend on acceptability among medical professionals, patients, competitive interests, and regulatory authorities.
- **Impact of MAP availability on vaccine uptake.** Actual vaccine uptake will depend on several factors, including vaccine supply availability, potential supply chain vulnerabilities, and individual- and community-level vaccine hesitancy.
- **MAP availability.** MAP vaccines were available in the needed volume at the same time as traditional needle-and-syringe vaccines and neither faced supply chain vulnerabilities. Distribution of MAP vaccines will depend on contractual relationships between MAP and vaccine manufacturers, which could affect the amount of vaccine each party would receive.
- **Dose-sparing effect.** Actual dose-sparing needs to be demonstrated in further clinical trials and likely will depend on MAP platform and vaccine formulation. As dose-sparing is a driver of accelerated vaccination, this directly alters the effect of MAPs.

CBO forecasts found that economic deterioration caused by the COVID-19 pandemic was offset by federal stimulus for households, businesses, and state and local governments, reducing 2-year economic losses and increasing 10-year economic gains in the model. Future results will depend on making similar government investments during future pandemics. For extrapolation

purposes, the model also assumed that all countries would experience similar economic effects and adopt similar policies, though this will vary by country in reality.

Finally, this model was based on 2 pandemic scenarios. Actual impact of MAP vaccines in a pandemic context depends on factors including virus dynamics, vaccine supply availability, and response from governments.

Conclusion

Avalere's analysis demonstrates that MAP technology has potential to improve the timeline for vaccination during a pandemic, positively affecting public health and economic factors. While MAP vaccines are not currently available, a review of MAP technology demonstrates the potential benefits these products could have, including increasing available doses, reducing supply constraints, and contributing to faster vaccine availability. The extent to which MAP vaccines can augment current vaccination efforts could have implications for future pandemic response efforts.

Uncertainties remain around MAP vaccines' safety and efficacy profile, method of administration, and commercial scale manufacturing, requiring additional clinical studies, feasibility and uptake assessments, and technology innovations. Further, guidance from FDA regarding regulatory review and approval of MAPs can provide more clarity for manufacturers.

The ability of MAP vaccines to speed up vaccine distribution and administration may reduce the circulation of viral variants and shorten a pandemic's duration. Additionally, MAP vaccine characteristics may influence patient acceptability. However, the potential for MAP vaccines to alter timelines, access, and acceptability thresholds depends on targeted investment in MAP products.

References

1. Bill & Melinda Gates Foundation, GAVI, PATH, Unicef, and WHO. "Vaccine microarray patches (MAPs): public summary of the VIPS Alliance Action Plan." 2020. https://www.gavi.org/sites/default/files/about/market-shaping/VIPS-Alliance-Action-Plan-for-MAPS_Public-Summary.pdf.
2. Nguyen, Thuy Trang, Yujeong Oh, Yunseo Kim, Yura Shin, Seung-Ki Baek, and Jung-Hwan Park. "Progress in microneedle array patch (MAP) for vaccine delivery." *Human Vaccines & Immunotherapeutics* 17, no. 1 (2020): 316-327. doi.org/10.1080/21645515.2020.1767997.
3. Ibid.
4. Bill & Melinda Gates Foundation, GAVI, PATH, Unicef, and WHO. "Vaccine microarray patches (MAPs): public summary of the VIPS Alliance Action Plan." 2020. https://www.gavi.org/sites/default/files/about/market-shaping/VIPS-Alliance-Action-Plan-for-MAPS_Public-Summary.pdf.
5. ClinicalTrials.gov. U.S. National Library of Medicine. <https://clinicaltrials.gov/>. (accessed January 24, 2022).
6. Iwata, Hiroaki, Kosuke Kakita, Keisuke Imafuku, Shota Takashima, Naoya Haga, Yasuyuki Yamaguchi, Kenji Taguchi, and Takayoshi Oyamada. "Safety and dose-sparing effect of Japanese encephalitis vaccine administered by microneedle patch in uninfected, healthy adults (MNA-J): a randomised, partly blinded, active-controlled, phase 1 trial." *The Lancet* 3, no. 2 (2022): E96-E104. doi.org/10.1016/S2666-5247(21)00269-X.
7. Nguyen, Thuy Trang, Yujeong Oh, Yunseo Kim, Yura Shin, Seung-Ki Baek, and Jung-Hwan Park. "Progress in microneedle array patch (MAP) for vaccine delivery." *Human Vaccines & Immunotherapeutics* 17, no. 1 (2020): 316-327. doi.org/10.1080/21645515.2020.1767997.
8. Roupheal, Nadine, Michele Paine, Regina Mosley, Sebastien Henry, Devin McAllister, HariPriya Kalluri, Winston Pewin, et al. "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." *Lancet* 390, no. 10095 (2017): 649-658. doi.org/10.1016/S0140-6736(17)30575-5.
9. Forster, Angus, Katey Witham, Alexandra Depelsenaire, Margaret Veitch, James Wells, Adam Wheatley, Melinda Pryor, et al. "Safety, tolerability, and immunogenicity of influenza vaccination with a high-density microarray patch: Results from a randomized, controlled phase I clinical trial." *PLoS Medicine* 17, no. 3 (2020): e1003024. doi.org/10.1371/journal.pmed.1003024.
10. Machingaifa, Francesca, Mel Addison, and Georgina Lewis. "Intradermal Vaccination." Melbourne Vaccine Education Centre. April 2020. <https://mvec.mcri.edu.au/references/intradermal-vaccination/>.
11. Migliore, Alberto, Gianfranco Gigliucci, Raffaele Di Marzo, Domenico Russo, and Massimo Mammucari. "Intradermal Vaccination: A Potential Tool in the Battle Against the COVID-19 Pandemic?" *Risk Management and Healthcare Policy* 14 (2021): 2079-2087. doi.org/10.2147/RMHP.S309707.
12. O'Shea, Jesse, Mark Prausnitz, and Nadine Roupheal. "Dissolvable Microneedle Patches to Enable Increased Access to Vaccines against SARS-CoV-2 and Future Pandemic Outbreaks." *Vaccines* 9, no. 4 (2021): 320. doi.org/10.3390/vaccines9040320.
13. Poirier, Danielle, Frederic Renaud, Vincent Dewar, Laurent Strodiot, Florence Wauters, Jim Janimak, Toshio Shimada, et al. "Hepatitis B surface antigen incorporated in dissolvable microneedle array patch is antigenic and thermostable." *Biomaterials* 145 (2017): 256-265. doi.org/10.1016/j.biomaterials.2017.08.038.
14. Bill & Melinda Gates Foundation, GAVI, PATH, Unicef, and WHO. "Vaccine microarray patches (MAPs): public summary of the VIPS Alliance Action Plan." 2020. https://www.gavi.org/sites/default/files/about/market-shaping/VIPS-Alliance-Action-Plan-for-MAPS_Public-Summary.pdf.
15. O'Shea, Jesse, Mark Prausnitz, and Nadine Roupheal. "Dissolvable Microneedle Patches to Enable Increased Access to Vaccines against SARS-CoV-2 and Future Pandemic Outbreaks." *Vaccines* 9, no. 4 (2021): 320. doi.org/10.3390/vaccines9040320.
16. Norman, James, Jaya Arya, Maxine McClain, Paula Frew, Martin Meltzer, and Mark Prausnitz. "Microneedle patches: usability and acceptability for self-vaccination against influenza." *Vaccine* 32, no. 16 (2014): 1856-1862. doi.org/10.1016/j.vaccine.2014.01.076.
17. O'Shea, Jesse, Mark Prausnitz, and Nadine Roupheal. "Dissolvable Microneedle Patches to Enable Increased Access to Vaccines against SARS-CoV-2 and Future Pandemic Outbreaks." *Vaccines* 9, no. 4 (2021): 320. doi.org/10.3390/vaccines9040320.
18. Marshall, Sarah, Laura Sahn, and Anne Moore. "The success of microneedle-mediated vaccine delivery into skin." *Human Vaccines & Immunotherapeutics* 12, no. 11 (2016): 2975-2983. doi.org/10.1080/21645515.2016.1171440.
19. O'Shea, Jesse, Mark Prausnitz, and Nadine Roupheal. "Dissolvable Microneedle Patches to Enable Increased Access to Vaccines against SARS-CoV-2 and Future Pandemic Outbreaks." *Vaccines* 9, no. 4 (2021): 320. doi.org/10.3390/vaccines9040320.
20. Roupheal, Nadine, Michele Paine, Regina Mosley, Sebastien Henry, Devin McAllister, HariPriya Kalluri, Winston Pewin, et al. "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." *Lancet* 390, no. 10095 (2017): 649-658. doi.org/10.1016/S0140-6736(17)30575-5.

21. Menon, Ipshita, Priyal Bagwe, Keegan Braz Gomes, Lotika Bajaj, Rikhav Gala, Mohammad Uddin, Martin D'Souza, and Susu Zughaier. "Microneedles: A New Generation Vaccine Delivery System." *Micromachines* 12, no. 4 (2021): 435. doi.org/10.3390/mi12040435.
22. Creelman, Ben, Collrane Frivold, Sierra Jessup, Gene Saxon, and Courtney Jarrahian. "Manufacturing readiness assessment for evaluation of the microneedle array patch industry: an exploration of barriers to fullscale manufacturing." *Drug Delivery and Translational Research* 12 (2021): 368-375. doi.org/10.1007/s13346-021-01076-4.
23. Nguyen, Thuy Trang, Yujeong Oh, Yunseo Kim, Yura Shin, Seung-Ki Baek, and Jung-Hwan Park. "Progress in microneedle array patch (MAP) for vaccine delivery." *Human Vaccines & Immunotherapeutics* 17, no. 1 (2020): 316-327. doi.org/10.1080/216455515.2020.1767997.
24. Menon, Ipshita, Priyal Bagwe, Keegan Braz Gomes, Lotika Bajaj, Rikhav Gala, Mohammad Uddin, Martin D'Souza, and Susu Zughaier. "Microneedles: A New Generation Vaccine Delivery System." *Micromachines* 12, no. 4 (2021): 435. doi.org/10.3390/mi12040435.
25. Creelman, Ben, Collrane Frivold, Sierra Jessup, Gene Saxon, and Courtney Jarrahian. "Manufacturing readiness assessment for evaluation of the microneedle array patch industry: an exploration of barriers to fullscale manufacturing." *Drug Delivery and Translational Research* 12 (2021): 368-375. doi.org/10.1007/s13346-021-01076-4.
26. Jacoby, Erica, Courtney Jarrahian, Harry Hull, and Darin Zehrung. "Opportunities and challenges in delivering influenza vaccine by microneedle patch." *Vaccine* 33, no. 37 (2015): 4699-4704. doi.org/10.1016/j.vaccine.2015.03.062.
27. O'Shea, Jesse, Mark Prausnitz, and Nadine Rouphael. "Dissolvable Microneedle Patches to Enable Increased Access to Vaccines against SARS-CoV-2 and Future Pandemic Outbreaks." *Vaccines* 9, no. 4 (2021): 320. doi.org/10.3390/vaccines9040320.
28. Congressional Research Service. "Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials." Updated March 1, 2021. <https://crsreports.congress.gov/product/pdf/IN/IN11560>.
29. Rouphael, Nadine, Michele Paine, Regina Mosley, Sebastien Henry, Devin McAllister, Haripriya Kalluri, Winston Pewin, et al. "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." *Lancet* 390, no. 10095 (2017): 649-658. doi.org/10.1016/S0140-6736(17)30575-5.
30. Medgadget. "No Pain, No Gain: R&D Challenges for Success of Microneedle Systems." January 21, 2019. <https://www.medgadget.com/2019/01/no-pain-no-gain-rd-challenges-for-success-of-microneedle-systems.html>.
31. Bill & Melinda Gates Foundation, GAVI, PATH, Unicef, and WHO. "Vaccine microarray patches (MAPs): public summary of the VIPS Alliance Action Plan." 2020. https://www.gavi.org/sites/default/files/about/market-shaping/VIPS-Alliance-Action-Plan-for-MAPS_Public-Summary.pdf.

Appendix

Figure 1. Scenario 1 Vaccination Rates, Baseline and With MAPs

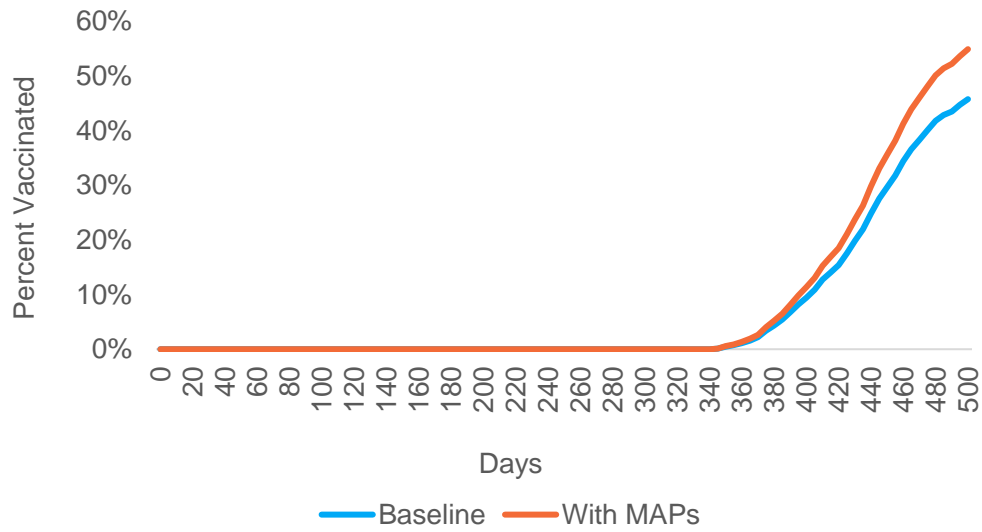


Figure 2. Scenario 2 Vaccination Rates, Baseline and With MAPs

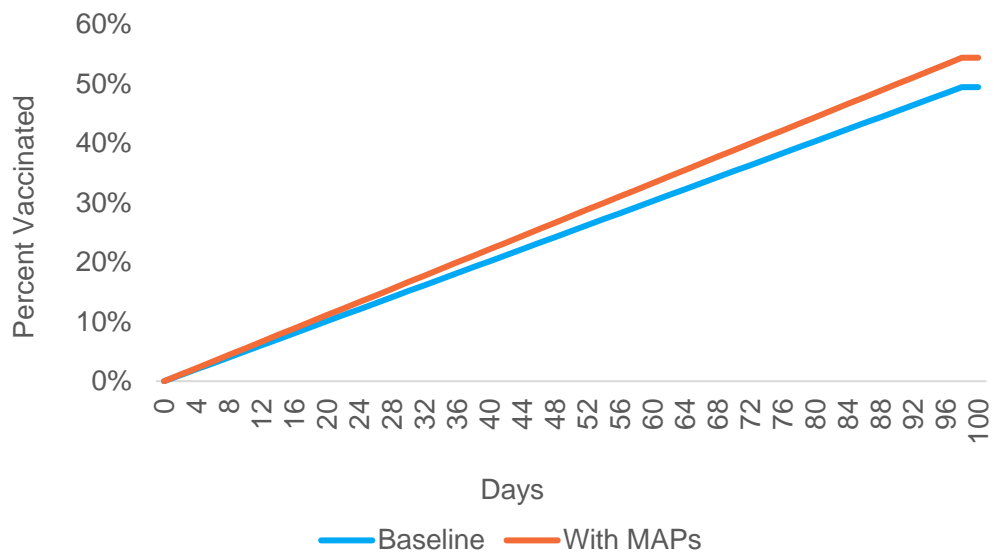


Figure 3. Baseline Scenario 1 Infections, New and Cumulative

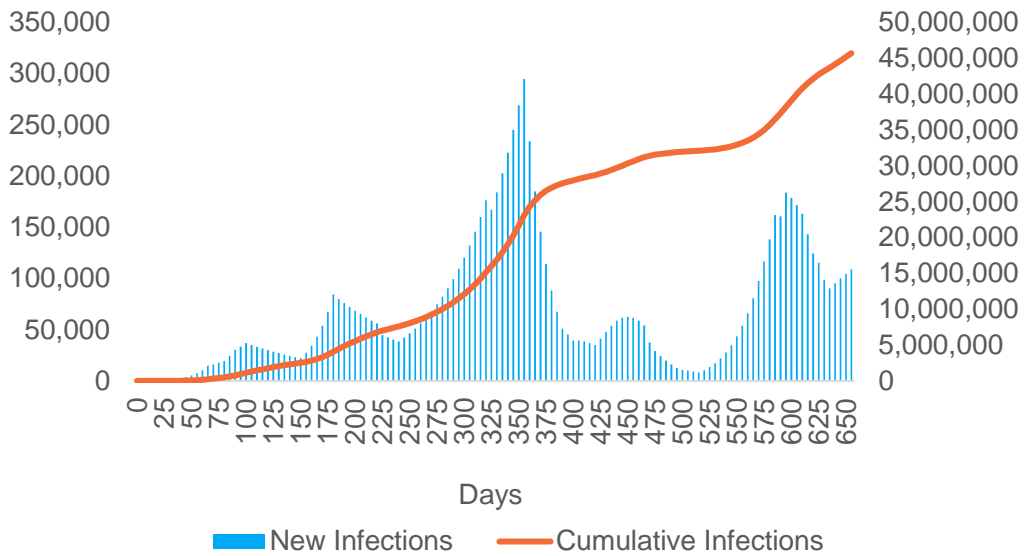


Figure 4. Scenario 1 Infections with MAPs, New and Cumulative

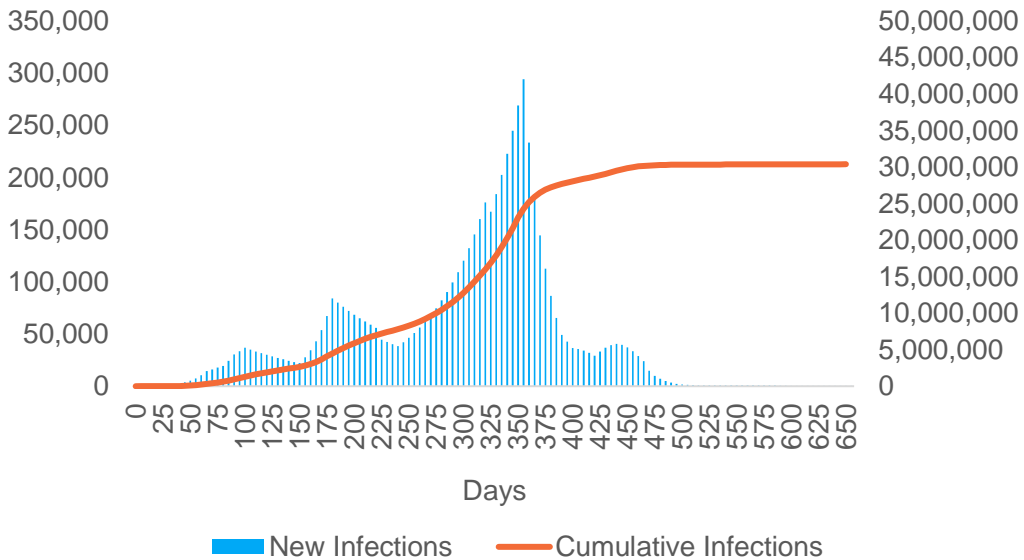


Figure 5. Baseline Scenario 2 Infections, New and Cumulative

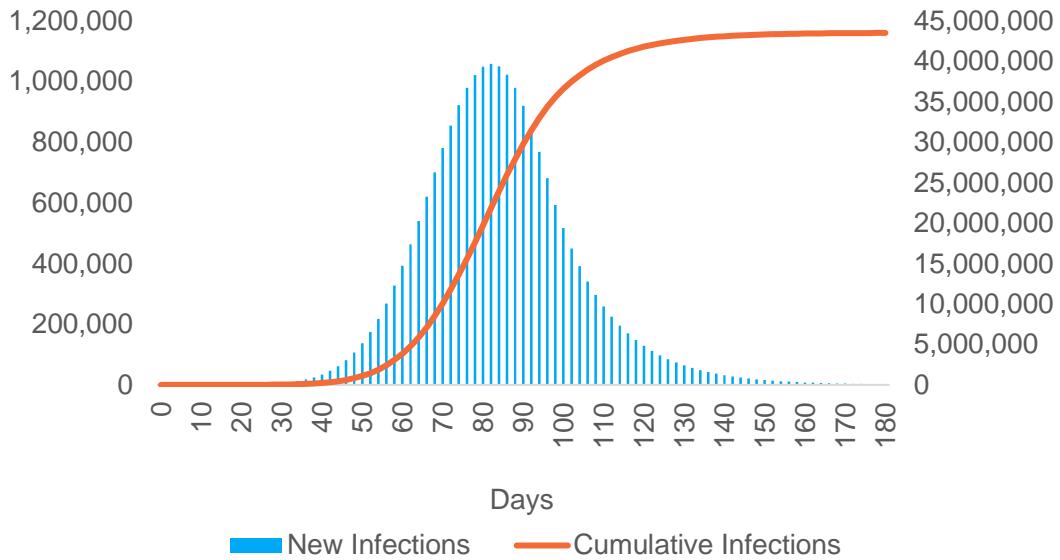
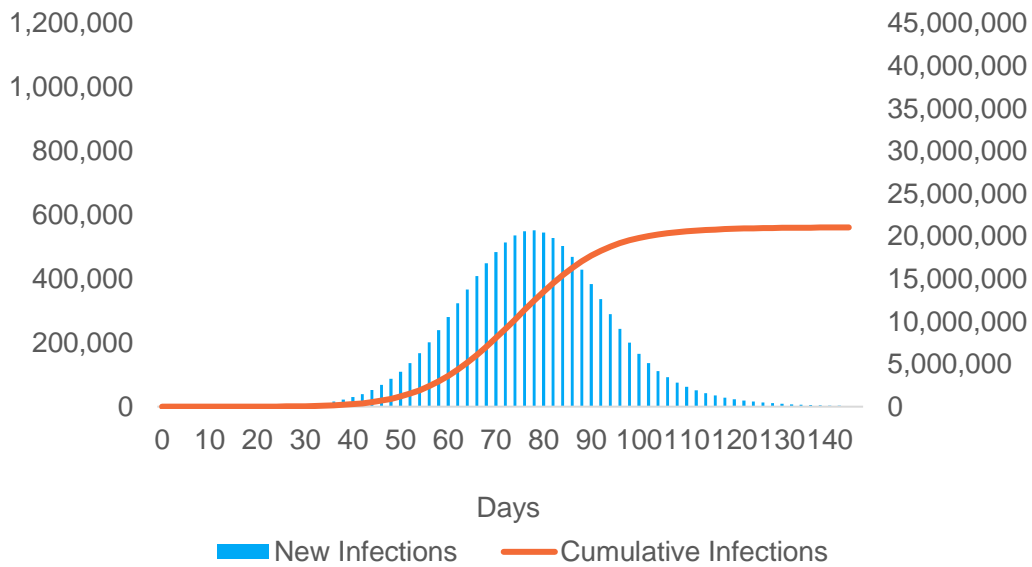


Figure 6. Scenario 2 Infections with MAPs, New and Cumulative



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A healthcare consulting firm for more than 20 years, Avalere Health partners with leading life sciences companies, health plans, providers, and investors to bring innovative, data-driven solutions to today's most complex healthcare challenges. For more information, please contact info@avalere.com. You can also visit us at [avalere.com](https://www.avalere.com).

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