



REFRAMING THE ROLE OF NASAL SPRAYS IN AN INCREASINGLY PATIENT-CENTRIC DRUG DELIVERY LANDSCAPE



Eric Kaneps of **LTS** looks at the reality of nasal drug delivery for liquid formulations and considers how advances not only open new opportunities but can also be seen in the context of a groundswell of momentum around non-invasive, patient-centric delivery. Mr Kaneps reflects on how this shift in dynamics, coupled with a shift in mindset, is opening the door for pharmaceutical companies to expand their drug delivery options and fully optimise the development pathway for their molecule.

In science, progress is predicated on the evaluation of hard evidence. As humans, however, we are hardwired to occasionally fall back on defaults, assumptions and heuristics to make sense of a complex world.

Because of this evolutionary trait, rather than reassessing and recalculating every situation, we rely on labels as shortcuts to meaning. They act as signals, triggering associations in our brain to help accelerate understanding and streamline decision making, easing our cognitive burden in the process. However, problems arise when those associations are inaccurate, incomplete or become outdated. Where fresh eyes would expand and update our perspective,

labels can keep our understanding within the parameters of legacy thinking. Or, to borrow from Oscar Wilde, “to define is to limit”.

In drug delivery, it can be argued that the term “nasal” is burdened with this fate. Driven by its capabilities in a wide range of therapeutic areas and despite rapid

“DESPITE RAPID EVOLUTION IN RECENT YEARS, NASAL CONTINUES TO BE STRONGLY ASSOCIATED WITH LOCALLY ACTING TREATMENTS FOR ALLERGIC RHINITIS AND DECONGESTION.”

evolution in recent years, nasal continues to be strongly associated with locally acting treatments for allergic rhinitis and decongestion.

With decades of experience in this space, the LTS Nasal and Sterile Drug Products division has engaged first-hand in the development of nasal drug delivery, consistently advocating nasal spray systems as a patient-friendly and effective delivery pathway for addressing important unmet patient needs.

THE DEFINING EARLY YEARS OF NASAL DEVICES

Looking at the history of liquid nasal sprays, perhaps it is easy to understand why we have arrived at this point. When they transitioned out of laboratories and into the commercial landscape in the 1950s and 1960s, drugs delivered via the nose were almost exclusively targeted for rhinitis and decongestion. Early market-approved products formalised the notion of the nasal route in the context of vaporised or atomised medicine, something that had previously been explored for medicinal purposes for hundreds if not thousands of years. In doing so, these devices defined the strong associations of nasal delivery with particular therapeutic areas.

Fougera Pharmaceuticals' (Melville, NY, US) Tyzine (tetrahydrozoline hydrochloride) and Bayer's Afrin® (oxymetazoline) were early examples of liquid-based nasal sprays designed to relieve nasal congestion by narrowing blood vessels in the nasal passages. Other major brands and generic alternatives followed, continuing to expand the market for nasally administered decongestants. Then, in later decades, corticosteroids were formulated as nasal sprays to alleviate the symptoms of allergic rhinitis and sinusitis, thus providing a preferable, topical alternative to systemic delivery.

Today, these segments are major contributors to a global nasal spray market worth an estimated US\$32.43 billion (£24.33 billion) in 2025.¹ While this scale, allied to the longevity of these products, makes it understandable that nasal delivery has become strongly associated with the symptomatic treatment of decongestion and rhinitis, the reality

"MOMENTUM TO DEVELOP NASALLY DELIVERED VACCINES HAS CONTINUED TO BUILD IN THE FOLLOWING DECADES, WITH CLINICAL TRIALS FOR A RANGE OF RESPIRATORY AND NON-RESPIRATORY DISEASES."

is far more diversified. In recent decades, advances in nasal devices and formulation technologies have improved the nasal delivery landscape, driven by enhanced knowledge of nasal physiology and its benefits as a platform for addressing many of the shortcomings of parenteral and oral delivery.

Evidence of this can be seen in a variety of places: intranasal opioids and triptans for rapid relief of migraine, headache and breakthrough cancer pain; benzodiazepines for treatment of epileptic seizures; intranasal metoclopramide liquids as an alternative to oral dosing for nausea and vomiting; nicotine nasal sprays for rapid systemic absorption in smoking cessation; sprays for heart-related indications; and even intranasal treatments for dry eye disease.

A NON-INVASIVE VEHICLE FOR VACCINES

Further advances in nasal delivery have been seen in the field of vaccines. In 2003, the first nasal spray vaccine was approved in the form of FluMist (MedImmune, Gaithersburg, MD, US), extending the boundaries of such devices beyond short-term symptom relief and into the territory of systemic immunity. This demonstrated the ability to provide equal protection via a safer, more practical and less painful method than injections, enhancing receptivity among needle-averse and more sensitive target groups, such as children.

Momentum to develop nasally delivered vaccines has continued to build in the following decades, with clinical trials for a range of respiratory and non-respiratory diseases, including HIV, tuberculosis and hepatitis B.² In the wake of the covid-19 pandemic, research into nasal vaccines and anti-viral treatments accelerated and expanded in scope, with researchers seeking to exploit the benefits of mucosal immunity at the primary site of entry for many pathogens. Injectable products

such as Sputnik V (Gam-COVID-Vac; Gamaleya Research Center, Moscow, Russia) have since received approval for application with a nasal applicator, while iNCOVACC (BBV154; Bharat Biotech, Hyderabad, India) and Pneucolin (dNS1-RBD; Beijing Wantai Biological Pharmacy Enterprise, Beijing, China) are examples of vaccines developed specifically for nasal delivery.³

Extensive work continues in this area. One such example is a Phase II randomised clinical trial of an azelastine nasal spray, which revealed that this commonly available over-the-counter (OTC) antihistamine provides pre-exposure prophylaxis against SARS-CoV-2 and other respiratory pathogens.⁴

And, most recently, a major breakthrough was reported by Stanford Medicine (Stanford, CA, US) researchers and collaborators, who shared promising findings from a study in mice regarding a nasally delivered vaccine formula that protects against a wide range of bacteria, allergens and respiratory viruses, including SARS-CoV-2, thus opening the door to the possibility of a nasally delivered "universal vaccine".⁵

SYSTEMIC DRUG DELIVERY AND PATHWAYS TO THE BRAIN

Furthermore, the non-invasive, rapid onset benefits of nasal delivery have also established this drug pathway in the field of emergency treatments. Narcan® (naloxone hydrochloride; Emergent BioSolutions, Gaithersburg, MD, US), a nasal spray for overcoming opioid overdoses, was first fast-tracked onto the market as a prescription drug in 2015 and was subsequently approved in the US in 2023 for OTC non-prescription use, underlining its importance in tackling illicit overdose use.⁶ Its success paved the way for other emergency nasal treatments. This includes the delivery of benzodiazepines such as

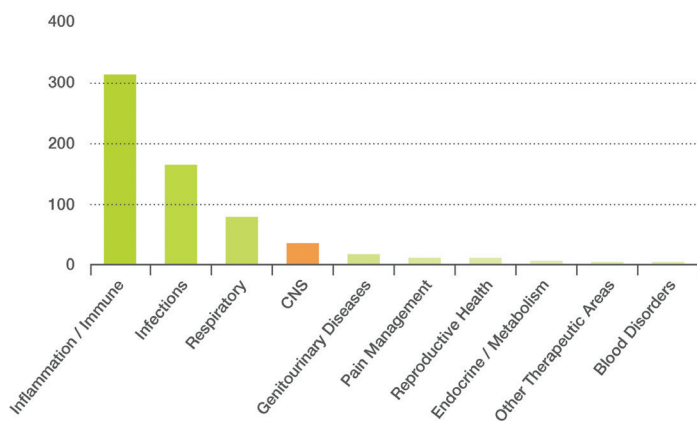
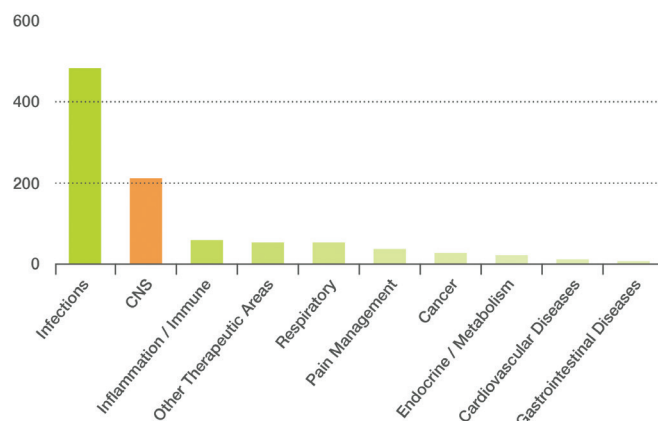
**MARKETED NASAL SPRAYS:
PROGRAMME COUNT VERSUS INDICATION****NASAL SPRAYS IN PIPELINE:
PROGRAMME COUNT VERSUS INDICATION**

Figure 1: Distribution of marketed nasal spray products and pipeline programmes by therapeutic indication. Currently marketed products are largely focused on inflammation/immune and infectious diseases, with relatively few CNS therapies. In contrast, CNS indications represent the second largest category in the development pipeline, suggesting a rapidly increasing interest in intranasal drug delivery for CNS disorders.

Nayzilam (midazolam; UCB, Brussels, Belgium) for epileptic seizures, and Neffy (adrenaline (epinephrine); ARS Pharma, San Diego, CA, US), which was approved in August 2024 as a nasal spray treatment for anaphylaxis, by both the US FDA and the EMA (where it is marketed as EURneffy).⁷

Designed to be absorbed via the nasal mucosa for systemic effect, these emergency cases underline the strengths of nasal delivery in providing rapid relief via simple administration methods to patients who are potentially unable to co-operate. This contrasts injections, where the barriers to administration are far higher for caregivers who might still be hesitant in emergency situations, even after training on the handling of syringes.

In the case of Narcan, nasal administration leads to systemic absorption of the API, enabling it to reach the brain, where it displaces opioids that have bound to the same receptors. Spravato® (esketamine; Janssen Pharmaceuticals), a blockbuster drug for treatment-resistant depression, is another case of a nasally delivered systemic

therapy acting on receptors in the brain. Various other examples, including insulin to alleviate symptoms of Alzheimer's disease as well as treatments for Parkinson's disease and multiple sclerosis, all serve as evidence of the growing interest in nasal delivery across a range of central nervous system (CNS) indications.⁸⁻¹⁰

More widely, the ability of nasal sprays to bypass the blood-brain barrier entirely via the olfactory/trigeminal nerve holds significant potential for treatments targeted at CNS conditions. Here, a broad range of active substances and various molecule types are under investigation, notably preclinical/clinical testing to explore nasal delivery of nucleic acid-based therapeutics (such as small interfering RNA and messenger RNA) using nanotechnology (Figure 1).¹¹

ANSWERING UNMET NEEDS AND ADDRESSING SHORTCOMINGS

Innovations such as these are made possible by ever-deepening knowledge of the nasal physiology, but they are also the product

of clear focus on meeting patient needs, both in terms of medical outcomes and the preference for convenient, non-invasive administration. Indeed, one study has shown that 88% of participants prefer EURneffy nasal sprays over traditional adrenaline autoinjectors.¹² In this context, nasal delivery can be seen as the endpoint of a development process that begins with a set of ideal requirements for how an API can be delivered, rather than making decisions on delivery based on preconceived ideas or typical formats of oral and parenteral delivery (Figure 2).

Unlike oral dosage forms, nasal delivery does not directly result in reduced efficacy through first-pass metabolism in the liver or gut wall and there are no complications associated with swallowing. Unlike injectable dosage forms, there is no problem with needle-related pain or fear of needlestick injuries. In addition, the burden associated with cold-chain storage requirements is either greatly reduced or removed entirely.

Of course, many factors must be considered when it comes to decision making around optimising delivery, but advances in non-invasive technologies, such as nasal sprays, mean that patient-centricity can increasingly be accommodated as a priority rather than something to be considered or optimised at a later stage of development. LTS's nasal expertise spans the entire product development cycle, with

“THE ABILITY OF NASAL SPRAYS TO BYPASS THE BLOOD-BRAIN BARRIER ENTIRELY VIA THE OLFACTORY/TRIGEMINAL NERVE HOLDS SIGNIFICANT POTENTIAL FOR TREATMENTS TARGETED AT CNS CONDITIONS.”

SUCCESSFUL NOSE-TO-BRAIN DELIVERY DEPENDS ON...

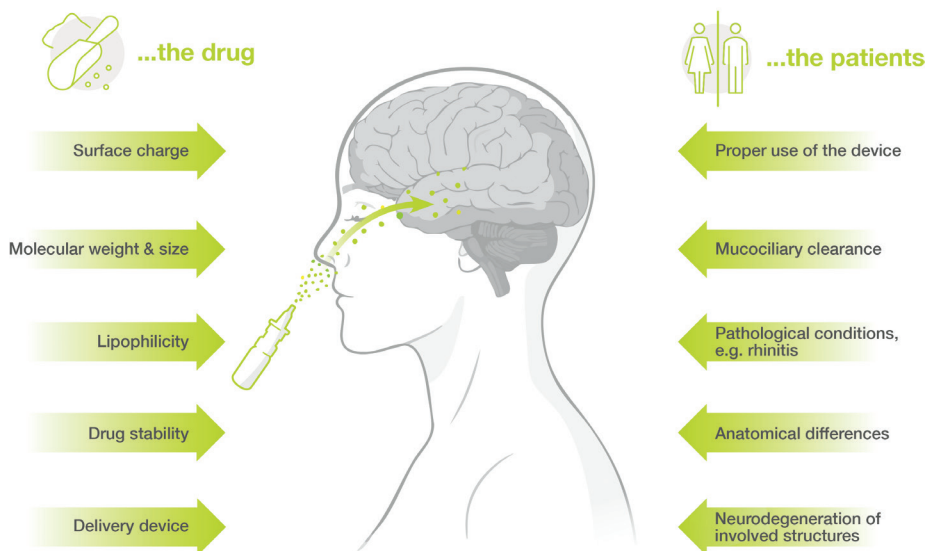


Figure 2: Factors influencing nose-to-brain delivery.

services in formulation science and spray testing complemented by device design/development and scale-up manufacturing capabilities for unit-dose, bi-dose and multidose devices.

These capabilities in nasal drug delivery are one important strand of a wider portfolio of non-invasive drug delivery technologies, which also incorporates transdermal therapeutic systems, oral thin films, micro-array patches and on-body delivery systems. While each route offers distinct benefits, these delivery platforms are all united by the fact that they all mitigate pain and are readily accepted by patients. In most cases they can also be self-administered or administered easily by caregivers in non-clinical settings, including the home. This fits with the healthcare sector's wider ongoing ambitions to reduce resource burden and costs while introducing far greater levels of patient convenience.

A DIVERSE DELIVERY LANDSCAPE OFFERS NON-INVASIVE OPPORTUNITIES

Such benefits show how the maturation of non-invasive technologies has significantly expanded the range of options for transporting an API to its target site in the body. Pharma partners today have far more choice in the delivery pathway

"SUCH BENEFITS SHOW HOW THE MATURATION OF NON-INVASIVE TECHNOLOGIES HAS SIGNIFICANTLY EXPANDED THE RANGE OF OPTIONS FOR TRANSPORTING AN API TO ITS TARGET SITE IN THE BODY."

available to their molecule. And with the full breadth of capabilities offered by LTS, they can access the necessary expertise to specify the optimal route and then to guide development through complex clinical and regulatory phases. This ensures that when a drug reaches the market, it does so in a form that truly supports sustained compliance with the dosing regimen.

In summary, there is a strong body of evidence to suggest that the landscape of drug delivery has been redrawn in the decades since intranasal devices first appeared on the market as approved products. To some, the label "nasal spray" continues to conjure mental images of

decongestants and rhinitis treatments, or that nasal is categorised singularly as an alternative to oral dosage forms or injections. But these limited definitions could stifle the future potential of promising molecules during critical early development stages.

At a time when the needs and wishes of patients are so central to effective, sustained and convenient models of treatment, it is arguably the time for mindsets to shift and for legacy thinking to be re-evaluated. By starting with a refreshed, broad-based view of the current drug delivery horizon, development pathways can be optimised, outcomes can be improved and unmet patient needs can be answered. Whether for locally acting or systemic drugs, whether delivered to the respiratory tract or the brain, and whether for chronic conditions or emergency treatments, nasal drug delivery must be appreciated in its full scope and in the broader direction of non-invasive, patient-centric delivery to ensure its huge potential is realised for patients of the future.

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Eric Kaneps

Eric Kaneps serves as the Vice-President of Sales & Marketing at LTS Nasal and Sterile Drug Products and has been in this role since 2018. Mr Kaneps has over 25 years of experience in sales, business development and account management in the pharmaceutical industry. Mr Kaneps worked at DPT Laboratories as the Director of Business Development from 2001 to 2016. In this role, he transitioned the OTC/Consumer Health-based business towards pharmaceutical-based nasal and sterile products, which became the foundation for Renaissance Lakewood (now LTS Nasal and Sterile Drug Products). In between his roles at the Lakewood site, he was Senior Vice-President of Business Development for Pharma-Tech Industries, a CMO that specialises in prescription and OTC ingestible and topical powder products. Mr Kaneps holds a BSBA in International Business & Economics from The Ohio State University, US.

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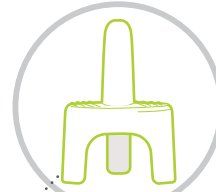


ENABLING BETTER THERAPIES THROUGH TAILORED DRUG DELIVERY

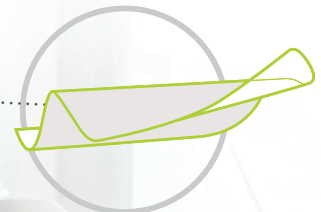
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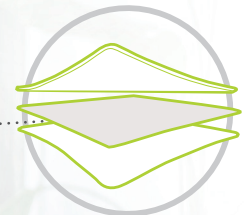
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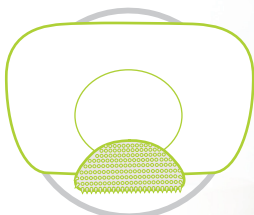
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