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‘Liquid Masks’ Could Be A Vital New Resource Against COVID-19

In many countries the COVID-19 pandemic has reached a new phase, with vaccination programs rolled out to large sections of the population. On a global scale, though, the picture can look very different.

According to recent data[1], 45.5% of the world population has now received at least one dose of a COVID-19 vaccine. The proportions are much higher in the US (63.8%), the UAE (93.4%) or in Western European countries like Italy (75.0%), Spain (80.7%) or the UK (71.0%). But less developed countries in Africa and elsewhere with limited access to vaccines have lagged behind alarmingly, to the extent that only 2.3% of the population in low-income countries have been at least partly vaccinated.

Moreover, despite the encouraging rates of vaccination in many countries better equipped to provide broad population coverage, there remains a strong need for vigilance and effective preventive measures to guard against viral variants and likely surges in winter infections. At the same time, public tolerance of lockdown restrictions, mask-wearing and standard hygiene measures such as handwashing, surface cleaning and ventilation is on the wane.

This raises the question of how product developers can maintain the momentum of COVID-19 prevention or, failing that, of early intervention to stop SARS-CoV-2 from replicating and transmitting in asymptomatic individuals. There is a potentially large gap in the market for scientifically supported yet user-friendly products, designed, positioned and priced for broad distribution and routine daily usage.

Hydrogen Peroxide-Hyaluronic Acid Combinations

One such opportunity is using approved combinations of hydrogen peroxide and hyaluronic acid, in nasal spray and mouth-rinse formats, to create a protective barrier adhering to the nasal or oral mucosa – effectively, a "liquid mask" for the nose and throat, explains Marco Mastrodonato, CEO and co-founder of Italy's BMG Pharma. These products perform a dual function, not only preventing SARS-CoV-2 from getting into the nose and mouth, but also killing any virus lodged in the nasal or oral mucosa in the few hours before the virus penetrates further into the body.

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While ingredients such as alcohol and chlorine are already available in hand sanitizers or surface disinfectants, hydrogen peroxide is also approved and marketed as an oral or nasal disinfectant, and for other health applications such as skincare or ear-wax removal. "The only one available to be used inside the body is hydrogen peroxide," Mastrodonato notes.

Researchers at the University of Naples have suggested that higher concentrations of hydrogen peroxide (e.g., 3%) could significantly reduce hospitalization and respiratory complications in asymptomatic patients with SARS-CoV-2, by intervening to inactivate the virus in the nasal or oral mucosa before it spreads to the lower respiratory tract.[2] As Mastrodonato points out, the typical route to COVID-19 infection is that "you get it on your hands, then you put your hands to your face."

"The antiseptic efficacy of hydrogen peroxide 3% against SARSCoV-2 on oral and nasal mucosa can be reasonably hypothesized," wrote Drs Arturo Caruso, Antonio Del Prete *et al.* in the 22 April 2020 edition of *Infection Control & Hospital Epidemiology*. This activity is due "not only to the known oxidizing and mechanical removal properties of hydrogen peroxide but also to the induction of the innate antiviral inflammatory response by overexpression of Toll-like receptor 3 (TLR3)", they added. "Thus, the overall progression of the infection from the upper to the lower respiratory tract can be reduced."

The researchers proposed off-label use of hydrogen peroxide 3% and 1.5 %, by means of oral and nasal washing respectively, immediately after the onset of the initial symptoms and a presumptive diagnosis of COVID-19, as well as "during the illness in home quarantine or by hospitalized patients not requiring intensive care." This might be achieved through a regimen of gargling three times per day for disinfection of the oral cavity, and of nasal washing with a nebulizer twice daily, reflecting the higher sensitivity of the nasal mucosa, Caruso *et al.* said.

Other researchers have highlighted more specifically the importance of the throat and salivary glands as sites for virus replication and transmission in early COVID-19 disease. They have further explored the potential for different mouthwash components, including hydrogen peroxide, to disrupt the lipid envelope enclosing the SARS-CoV virus and prevent transmission.

Currently Available Options

Some nasal sprays incorporating ingredients like hypochlorous acid, nitric oxide or hypromellose are already in development or marketed to reduce viral load in early SARS-CoV-2 infection. However, pricing has not been optimal to date. "The patients are already spending money on masks or hand gels," Mastrodonato observes. "If they spend $10-20 per product, that's fine. If they're going to $60, not so fine. Prevention is very difficult, because people are more inclined to look for a cure when they have a disease."

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Moreover, none of these products has been line-extended to mouthwashes. A dual formulation would address two of the primary sites for viral ingress and disease progression in COVID-19. As such, the products would have a better chance of reaching a broader population and encouraging regular usage.

BMG Pharma already developed, some 10 years ago, various product formulations, in particular a mouthwash and a gel for skin infection, combining hydrogen peroxide with hyaluronic acid. The combination provides a "smoother approach" than more aggressive antibacterials, while at the same time increasing the hydrogen-peroxide component to a level (5%) at which it is capable of eliminating viruses, Mastrodonato explains.

BMG now has approvals for a nasal spray and a mouthwash incorporating hydrogen peroxide and hyaluronic acid in combination. These products are registered as Class IIA medical devices offering a protective barrier against viral or bacterial infections including SARS-CoV-2. The company is talking to potential distributors in different parts of the world, while an Italian launch for BMG0705 Nasal Spray and BMG0703A Mouth Rinse is planned for January 2022.

Medical-Consumer Positioning

Product positioning would be as a part of the user's daily hygiene routine. "We need people to use these products habitually," Mastrodonato comments. "We cannot take the approach of saying, use this to prevent COVID-19, because that will be a one-shot proposition. It's going to be a product that disinfects, to really help you out day-by-day, while also preventing infections from going any further."

BMG wants to maintain a balance between pricing and presentation that encourage broad-based uptake as consumer products on the one hand, and a solid medical aura on the other, reflecting statistically significant evidence of efficacy from clinical research. It is therefore looking for pharmaceutical partners to undertake pharmacy-recommended distribution of the nasal spray and mouth rinse and possibly build some relationships with general practitioners.

The company already markets its core oral care, osteoarthritis and aesthetic-dermatology products in more than 80 countries worldwide. The geographical reach of its COVID-19 products will depend on distributor agreements, while the market for prevention or early treatment of asymptomatic COVID-19 is difficult to pin down. Nonetheless, a broad indication of commercial potential is that the global

nasal-spray market is worth an estimated US$16.5 billion in 2021, growing at 6.5% per year, BMG Pharma notes.

Scientific Validity

The scientific validity of the company's hydrogen peroxide/hyaluronic acid products for COVID-19 was recently boosted by the results of a randomized placebo-controlled clinical trial. Conducted in association with the University of Naples, the trial enrolled 106 asymptomatic COVID-19 patients, who completed the protocol in the second quarter of 2021.

In the study's placebo arm, 57.6% of patients had a positive PCR swab test following the index positive test. In the active arm, 31.9% of patients taking BMG0705 Nasal Spray and BMG0703A Mouth Rinse showed a positive PCR test after three full days of therapy. The P value for the difference between arms was 0.008, and there were no reported side-effects.

BMG plans to conduct further research to confirm the outcomes in population subgroups. In the meantime, it is gearing up to launch BMG0705 Nasal Spray and BMG0703A Mouth Rinse in a range of markets worldwide. Once available, these products could be a vital new resource in stemming any further spread of COVID-19, at a time when not only are there huge discrepancies in vaccination rates worldwide, but even countries with high rates of coverage are a long way from consigning the virus to history.

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References

1. "Statistics and Research: Coronavirus (COVID-19) Vaccinations" Coronavirus (COVID-19) Vaccinations – Statistics and Research, Our World in Data, updated 2021.

2. Arturo A. Caruso, Antonio Del Prete et al. "Might hydrogen peroxide reduce the hospitalization rate and complications of SARS-CoV-2 infection?" Infect Control Hosp Epidemiol. 2020 Apr 22: 1–2.

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Founded in 2011, BMG Pharma is a B2B biopharmaceutical company strongly dedicated to innovation in developing and registering, cutting-edge medical products. BMG Pharma responds to people's needs by focusing on 3 main therapeutic areas: oral care, osteoarthritis and aesthetic dermatology.

Headquartered in Milan, Italy, BMG Pharma has a production site in Troviscosa (UD), one of Europe's leading technology hubs focused on the development of new state-of-the-art biopolymers.

BMG Pharma operates in more than 80 countries around the world, marketing its products in Europe, Middle East, Asia, and Latin America and has a dense network of collaborators, to take advantage of the marketing and distribution of its products. It has signed 26 distribution agreements and boasts partnerships with five contract manufacturing organizations (CMO) world leaders for the manufacturing of its products. In June 2018, it acquired Sigea Srl, a private Italian biotech company, with an important pipeline in the field of patented polysaccharide derivatives that has allowed it to expand the product portfolio and accelerate the development of new products and dermo-cosmetics, allowing to bring to market the patented Hyaluromimethic® Technology.