

# The virologist's conundrum

## Abstract

I am neither a virologist nor immunologist. I'm a retired nephrologist who has been introduced to a new means of treating viral infections that falls into my area of interest. It is a broad spectrum, polyvalent device that removes N-linked glycosylated viruses from circulating blood by dialysis, lectin affinity plasmapheresis (LAP), for which at present the only hardware available in large numbers is that employed in hemodialysis.

But hemodialysis facilities deal primarily with End Stage Renal Disease patients and should not be shared with mortally ill, infected, and communicable individuals. Were the experts to create a polyvalent viral vaccine, one that would prevent the threat of epidemics due to glycosylated viruses, those vaccinated would be spared concern from pandemic events. For those not vaccinated or immune suppressed naturally or medically, treatment with the new device would be necessary in case of exposure to a viral pathogen. In this article, I shall deal with current and desirable future vaccines and the new mode of antiviral treatment, a device proven to be safe and effective and presently the subject of an FDA Expedited Access Pathway.

**Keywords:** viral pandemic, biowarfare, vaccine, plasmapheresis

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**Abbreviations:** ACIP, advisory committee on immunization practices; HPF, hemopurifier; GNA, galanthus nivalis agglutinin

## Introduction

We are warned that we must prepare for epidemics and/or pandemics due to the arrival of new, old, or modified pathogens, be they from natural causes or agents of biowarfare.<sup>1,2</sup>

There are 124 viral species known to infect humans; of these, only a small number have FDA-approved specific preventive or therapeutic interventions. Furthermore, 219 additional species are capable of infecting humans.<sup>2</sup> But this requires a cautionary note: For one thing, it is estimated that in addition to the thousands of viruses known, there are three to four new ones appearing each year be they hitherto previously unknown or known varieties that have evolved. And we must not overlook the possibility of meeting genetically engineered pathogenic forms developed for use in biowarfare.<sup>3</sup> An excellent article on biowarfare and bioterrorism can be found on Wikipedia.<sup>4</sup>

The risk has been neatly summarized as follows: "Unfamiliar viruses, such as the SARS and MERS-coronaviruses are hopping into humans from other mammals at an increasing rate. Each new emergence forces researchers into a reactive race, as they try to identify, study, and corral the new viral threats before they can trigger a pandemic."<sup>5</sup>

## Vaccines

Any discussion of viral (or other) pathogens must include prevention by vaccines and vaccination. When a new pathogen emerges and is identified, isolation and treatment of the first infected individual is the ideal but unfortunately rare occurrence. Generally there has been transmission of the causal agent to contacts who are immunologically naive, resulting in widespread dissemination of the pathogen.

In the case of infection with a previously unknown viral species or strain, developing a vaccine becomes urgent once the causal pathogen is identified. This is a time-consuming process, and often an epidemic or pandemic has run its natural course at great expenses in lives and

money before a vaccine is at hand. Moreover, since common viral infections such as those endemic in swine and fowl (e.g., H1N1 virus in pigs and H5N1 virus in domestic and wild birds) recur annually in genetically modified form, work is not over once the acute situation has resolved even if a univalent vaccine has been achieved.<sup>6</sup>

Were we to have and employ vaccines to prevent even the most common viral infections, the war would not be won, just the immediate battle, since in all probability we can look forward to the continuing arrival of new pathogens as well as old ones sporting new genetic alterations. So, vaccines that are univalent, derived for and effective against specific, single pathogens, while now appropriate and necessary, cannot be the end-all in our confrontations. Ideally, we should be able to create vaccines that are broad spectrum, polyvalent in concept and effect rather than being aimed at a single organism, that is those responsive to and effective against structures common to all those in a given species or genus. So, the major problem with existing and developing vaccines is that the methodologies result in products that are univalent, effective against one specific viral strain with only slight effectiveness against closely related strains<sup>7</sup> as we are currently experiencing with the 2017-18 vaccine that was prepared and promoted but is at best only 30% effective against the H3N2.

Vaccine viruses included in the 2017-18 U.S. trivalent influenza vaccines will be an A/Michigan/45/2015 (H1N1)pdm09-like virus, an A/Hong Kong/4801/2014 (H3N2)-like virus, and a B/Brisbane/60/2008-like virus (Victoria lineage). (From 2016-17 recommendations of the Advisory Committee on Immunization Practices (ACIP) regarding the use of seasonal influenza vaccines (MMWR Recomm Rep 2016;65 No. RR-5).

Here we have the conundrum: The conventional processes that generate a univalent vaccine when a new or modified viral pathogen appears are time consuming, laborious, and expensive and most frequently fail to achieve the objective. Would we be better off foregoing that approach and concentrating on developing a broad spectrum vaccine? Should funding be increased for research and development aimed at production and distribution of polyvalent vaccines, a task that might be facilitated through techniques like CRISPR.<sup>8</sup>

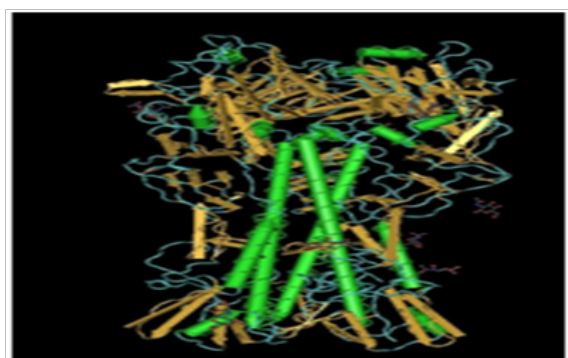
## A broad spectrum method of treating viral infections

All but two of the viruses infecting humans that have been studied carry N-linked glycosylation sites (glycans), structural components that play an important role in viral virulence and immune evasion.<sup>9</sup> If it were possible to generate a vaccine against structure(s) common to all infectious viruses, reducing the ability of the pathogen to enter the host cells and enabling the immune system to recognize the virus as non-self, treatment would not be necessary save for those immunosuppressed naturally or medically, such as those who had received organ transplants\*\*.

However, at this point of our sciences, there is need for treatment. To that end there is a new therapeutic device that will remove from circulating blood all viruses that carry N-linked glycosylation on the external surface, the Hemopurifier® (HPF) created by Aethlon Medical, Inc., San Diego, California. The HPF is a small dialysis capsule (Figure 1) that contains on the recipient side of the membrane a specific plant-derived lectin, known as galanthus nivalis agglutinin (GNA) (Figure 2), which has an affinity to bind a broad-spectrum of infectious viruses by irreversibly attaching to the viruses' glycans, thus preventing the pathogens from returning to the circulating blood without requiring a continuously flowing dialyzate stream.<sup>10</sup> Hemopurification with this device, has reduced the circulating viral loads in HIV-infected individuals and during conventional hemodialysis of ESRD patients with HVC infections.<sup>11</sup>



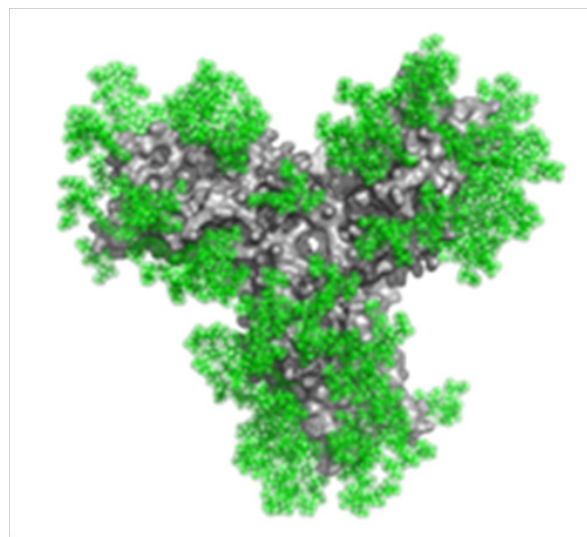
**Figure 1** The Hemopurifier®.\*



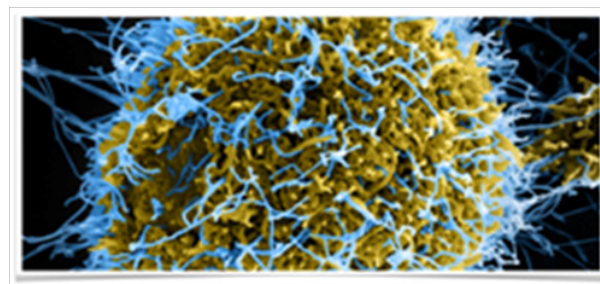
**Figure 2** GNA lectin.\*

In a single case, when applied to a mortally ill Ebola patient with multi-organ failure, HPF reduced the circulating loads of the virus and its toxins thus allowing the patient's previously overwhelmed immune system to clear the remaining virus. The patient has returned

to family and to the practice of his medical profession.<sup>12</sup> The treatment of the patient by lectin affinity plasmapheresis employing the HPF has been described in detail.<sup>13,14</sup> Note the multitude of replicants generated following the invasion by a single virus (Figure 4).



**Figure 3** Glycan shield (green) on HIV virus.\*



**Figure 4** Ebola viruses (blue) exiting infected cell.\*

The polyvalent activity of the HPF has been confirmed by its effectiveness against additional viruses for which there are no effective protective or therapeutic agents, some during *in vivo* clinical studies and all with *in vitro* testing: Zika virus, Lassa virus, MERS-CoV, Cytomegalovirus, Epstein-Barr virus, Herpes Simplex virus, Chikungunya virus, Dengue virus, West Nile virus, Smallpox-related viruses, H1N1 Swine Flu virus, H5N1 Bird Flu virus, and the reconstructed Spanish flu virus of 1918 as well as the previously mentioned Ebola virus, HIV virus, and HVC virus. In 2014, Time Magazine called the Aethlon HPF one the year's 25 best inventions.<sup>12,15</sup>

## Conclusion

In considering the defense of our country, we must think well beyond our current biological and medical capabilities and military hardware to possible biological terrorism and warfare. Historically, organ failure associated with sepsis has been the primary causes of death on the battlefield.<sup>16,17</sup>

Considering the current states of biological sciences and medical practices against viral and other pathogens and their toxins, the following are requirements for our best possible defenses today: Broad spectrum vaccines for both bacterial and viral agents and their toxins; >Mass production, distribution, and stockpiling of the HPF; Continuing the development of a light-weight, sturdy, and portable

dialyzer to be employed by Federal corpsmen and civilian emergency medical technicians.

1. The development of the ultimate vaccines, those that are not aimed at specific pathogens but at structural surface components that are common to all pathogens of a group, is under way through a program of Dr. Tony Fauci at NHI NIAID.
2. Mass production of the HPF is progressing while its distribution and commercialization are under discussion with the FDA.
3. The dialyzer is under development as part of DARPA's Dialysis-Like Treatment Program. It will use Aethlon's HPF and not require a high volume and flow sterile recipient stream.<sup>18,19</sup> It will be located not only in the traditional, high-end medical settings but also available and utilized on battlefields and in civilian mass-casualty situations where sanitary conditions and high volumes of sterile water are not present.

### Author's personal note

The goals are clearly obvious, and while talents and intentions are good, the major stumbling block is the source of financial support of the efforts.

I was active when President Kennedy proclaimed the goal of placing a man on the moon within a decade on May 25, 1961. Money flowed out of government coffers covering any and all research programs that could contribute to that effort, my own laboratory included. I participated as consultant and contractor to the Apollo program and clearly remember the Apollo 11 moon landing on July 20, 1969, just eight years after the goal had been set. Although that program had developments and off shoots that were beneficial to the public at that time and led to many others down the line, few were nearly as important to public health and welfare as what I have called for in this article.

### Disclaimer

Doctor Nash is not employed by or related to an employee of Aethlon Medical, Inc. and is not compensated for this article, and the Center for Scientific Analysis of Policy, LLC, has no interest, large or small, in Aethlon Medical, Inc., and is not compensated for this article.

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Figures taken with permission from <https://www.aethlonmedical.com/news-media/presentations>

### Conflicts of Interest

None.

### Funding

None.

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