



YFS EXPLORE

A QUARTERLY PUBLICATION

YFS Pharma Status update

You First Services announces the improvement of its Active Pharmaceutical Ingredient (API) plant in Buffalo, NY. These upgrades are a continuation of a long-term capital improvement initiative that results from an increased demand for the contract manufacturing of commercial APIs and cosmetics.

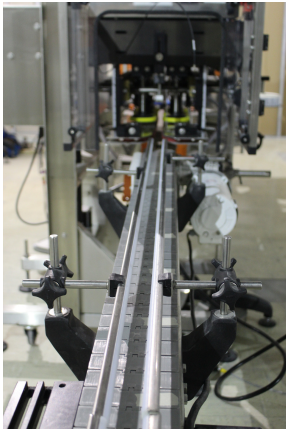
Our customer's demand for YFS Pharma commercial APIs services continues to grow; upgrading our facilities are a must as we grow with our customers. We will continue to upgrade and expand our facilities, ensuring supply and offering new services and capabilities for our customers. When completed, the upgraded facilities are expected to facilitate in a 50% increase in API production. Improvements to the plant include the addition of an indexed filler, new larger processing mixing tank, USP Water System and an industrial vacuum pump among other systems and capabilities.

Recently, a filling line capable of filling 18mL to 355mL bottles was commissioned with integrated capping, coding and labeling. The filling line will have the indexed filler added to it. The recent upgrades to our manufacturing facility are all about operational efficiency. With these improvements we can increase our functional capacity by approximately 20%, allowing us to produce more material in a shorter amount of time for our clients.



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YFS Pharma is an experienced, contract development and manufacturing organization (CDMO), specializing in active pharmaceutical ingredients (API) and pharmaceutical intermediates. YFS leverages a talented group of scientists and supporting staff, as well as a centralized approach to project management, to ensure on-time and on-budget completion of projects involving the development, scale-up, and manufacturing of complex API facility located in Buffalo, NY. The team of technicians at YFS Pharma manufactures, tests, and packages specialty over-the-counter, cosmetic products and, custom manufacturing solutions. Our team has pushed through incredible challenges to bring this factory online. We are now ready to put it to work, bringing our technologies to market. Our cGMP manufacturing and analytical facilities are ready to support the development of early clinical and commercial products with formulation capabilities, stability evaluations and more. In the coming months the YFS will be continuing to expand our production capacity. With further developments, we are now preparing to fulfill material deliveries to numerous end markets that we are targeting for growth in 2020.



Xerostomia: A Problem in an Aging Population



Dr. Sebastian G. Ciancio

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The widely held belief that saliva production significantly decreases with age is not well supported in the literature dealing with this subject. Aging does not appear to play a major role as a single contributing factor in causing xerostomia.¹

However, as our population ages, they receive medication that produces the side effect xerostomia. The aged also develop medical problems that can diminish saliva production. For these reasons, most of the studies of xerostomia have focused on older patients. One study reported a direct positive association between the intake of anticholinergic drugs, sedatives, and hypnotics.¹ Over 500 drugs have been identified as potential reducers of salivary flow by acting on the cholinergic (parasympathetic) system either directly or indirectly.² Another study found that use of drugs producing xerostomia increases with age, and, as expected, is highest in institutionalized patients. There are over 30 classifications of prescription and nonprescription medications that can reduce salivary flow. The major categories of medications are listed in Table 1.

Table 1 Common Drug Categories Associated with Xerostomia

Analgesics (narcotics)	Antianxiety agents
Antiarthritics	Antibiotics (quinolones)
Anticholinergics	Antidepressants
Antihypertensives	Antiparkinsonian agents
Antipsychotics	Antispasmodics
Anti-ulcer medications	Asthma inhalers
Cardiac medications	Muscle relaxants
Sedatives	

Other factors that can cause xerostomia are systemic disorders (see Table 2) and radiation.³ These factors must be considered in the differential diagnosis of xerostomia.

Clinical Testing

If xerostomia is suspected but not confirmed, whole salivary flow can be measured. The measurement should be done at least 2 hours after food or liquid intake, oral hygiene procedures, or smoking.

Clinical Problems and Xerostomia

Clinical problems that are associated with reduced salivary flow include difficulty chewing foods, reduced denture retention, recurrent caries, root surface caries, and oral candidiasis (low grade). When any of these conditions are found in a patient, regardless of age, reduced salivary flow should be considered in a differential diagnosis of the problem.

Cardiac failure	Decreased masticatory function
Diabetes insipidus	Pernicious anemia
Rheumatoid arthritis	Sjögren's syndrome
Stress	

Treatment

Treatment of patients with reduced salivary flow should include: (1) drug and dosage changes by the patient's physician in consultation with the patient's dentist; (2) use of artificial saliva in a spray form; (3) use of mouth moisturizers and lip balms; (4) use of sugarless hard candy; (5) frequent sipping of water; (6) use of decaffeinated products; (7) use of pilocarpine (Salagen) 3- 5 times daily; and (8) inclusion of citrus and pineapple flavors in the diet.

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Why is my mouth so dry? An insight to Dry mouth or Xerostomia

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The term xerostomia comes from the Greek word *xeros*(dry) and *stoma* (mouth), which means dry mouth. Dry mouth is one of the most common and unpleasant symptoms for which patients often seek help from a dentist. ^{1,2}

It is a feeling that there is not enough saliva in the mouth. Everyone has a dry mouth once in a while that is if they are nervous, upset or under stress. But if the dry mouth is present most of the time, it can be uncomfortable and can lead to serious health problems or it could be a sign of underlying systemic disease.

SALIVA IS.....

Saliva is the fluid in the mouth, which is not just water but, a complex fluid, mostly composed of water (99%) and remaining, variety of non-organic and organic substances such as enzymes, hormones, antibodies, antimicrobial constituents and growth factors. Essential for maintaining good oral and general health^{2,3}

There are multiple causes for dry mouth which includes side effects of⁴

- Medications like antihypertensives, antihistamines, antidepressants, hypoglycemic, levothyroxine
- Therapeutic radiation to head and neck,
- Systemic diseases like Diabetes Mellitus, HIV, Emotional stress & mental depression
- Disease involving the salivary glands such as Sjogren's syndrome

PATIENTS WITH XEROSTOMIA EXPERIENCE ^{3,5}...

- A dry, sticky feeling in the mouth and throat
- Increased frequency of thirst
- Difficulty in swallowing, speaking, chewing
- Difficulty in wearing dentures
- Change in taste sensation
- Burning or tingling sensation in the mouth
- Sores on the oral mucosa
- Fissured tongue or dry, red, raw tongue
- Cracked corners of the mouth and lips.
- Tissue sticking to teeth
- Bad breath



Xerostomia associated problems ^{6,7}

Dental Caries
Oral Candidiasis (fungal infection)
Demineralization of teeth
Mucosal Changes

MANAGEMENT^{8,9,10}

Cause and degree of damage to salivary glands, systemic and immune status of patient and/or medications will influence the management of xerostomia, so it may be a single therapy or a combined therapy.

Stimulation of salivary glands may help increase the salivary output, and this includes:

- Local stimulation: by using chewing gums, acidic fruits, low level laser therapy and acupuncture
- Systemic stimulation: agents which has the ability to increase salivary production (Prescription sialogogues: pilocarpine (5 milligrams three times per day and at bedtime)
- Symptomatic approach: use of agents in the form of liquid, spray or gel which have moistening and lubricating properties to provide prolonged wetness of oral mucosa.

Home remedies for dry mouth* irrespective of the cause of xerostomia^{11,12,13}

1. Discontinue or substitute all medications that cause dry mouth.
2. Eat smaller more frequent meals to stimulate saliva flow.
3. Increase intake of liquids during the day
4. Minimize time in air conditioned environments such as offices, supermarkets.
5. Use a humidifier at bed time to increase nighttime moisture and decrease discomfort
6. Avoid smoking
7. Chew sugar-free gum or suck on hard diabetic or sugar-free candies to activate reflexes that will increase saliva.
8. Use artificial saliva (2-3 squirts in the mouth every hour while awake and at night time as needed)
9. Avoid alcohol containing mouthwashes, fluoride rinses or products that can aggravate oral dryness or burning
10. Apply vitamin E oil (liquid or punch a hole in the capsule) or moisturizing gels to dry or sore parts of the mouth or tongue. Use 2-3 times per day after meals when talking or any other times when your mouth need long lasting relief.

*These are not to be considered as treatment and does not preclude the need for proper diagnosis and investigations

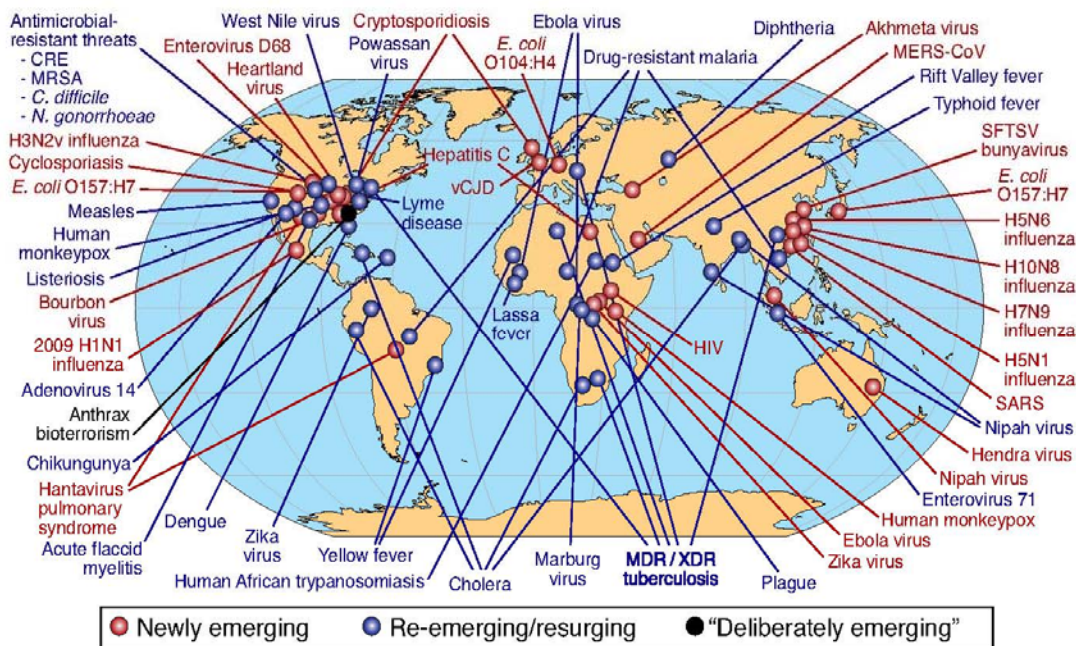
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Are we ready for the next global pandemic?

Bindukumar Nair

The world is unprepared for a global pandemic that could wipe out 80 million people in less than 36 hours along with 5 per cent of the global GDP. This is unless increasing funding for disease control and coordinate their efforts to develop strategies to contain the disease, the Global Preparedness Monitoring Board (GPMB), convened by the World Health Organization (WHO) and the World Bank, said in a report. The report after taking into account everything from emerging political trends to climate change, the team concluded that "there is a very real threat of a rapidly moving, highly lethal pandemic of a respiratory pathogen with increased mobility, unprepared health facilities and the possibility of weaponising disease, can travel through the world quickly, turning into an outbreak capable of killing up to 80 million people and wiping out 5% of the world's economy.



The WHO tracked 1,483 epidemics between 2011 and 2018 in 172 countries, including SARS, Ebola, zika and the nipah virus. It detected man-made and previously unknown viruses in the last 50 years and mapped them. Disease outbreaks disrupt the entire health system reducing access to health services for all diseases and conditions, which leads to even greater mortality and further economic depression. In addition to loss of life, epidemics and pandemics devastate economies. Estimated costs of past events include: a loss of over US\$ 40 billion in productivity from the 2003 SARS epidemic. The World Bank estimates that a global influenza pandemic akin to the scale and virulence of the one in 1918 would cost the modern economy US\$ 3 trillion, or up to 4.8% of gross domestic product (GDP); the cost would be 2.2% of GDP for even a moderately virulent influenza

pandemic . Models predict the annual cost of a global influenza pandemic would mean that South Asia's GDP would drop by 2% (US\$ 53 billion), and sub-Saharan Africa's GDP by 1.7% (US\$ 28 billion)

Required actions

The report further recommend to take the following actions. Heads of government in every country must commit to preparedness by implementing their binding obligations under the International Health Regulations (IHR ,2005). They must prioritize and dedicate domestic resources and recurrent spending for preparedness as an integral part of national and global security, universal health coverage and the Sustainable Development Goals (SDG).

Heads of government must appoint a national high-level coordinator with authority and political accountability to lead whole-of-government and whole-of-society approaches, and routinely conduct multisectoral simulation exercises to establish and maintain effective preparedness. They



Predicted country vulnerability to pandemic economic loss, 2018 (% GDP loss)

must prioritize community involvement in all preparedness efforts, building trust and engaging multiple stakeholders (e.g. legislators; representatives of human and animal health, security, and foreign affairs sectors; the private sector; local leaders; and women and youth). The Secretary-General of the United Nations, with WHO and United Nations Office for the Coordination of Humanitarian Affairs, must strengthen coordination in different country, health and humanitarian emergency contexts, by ensuring clear United Nations system wide roles and responsibilities; timely triggers to rapidly reset preparedness and response strategies during health emergencies; and enhancing United Nations system leadership for preparedness, including through routine simulation exercises. WHO should introduce an approach to mobilize the wider national, regional and international community at earlier stages of an outbreak prior to a declaration of an IHR (2005) Public Health Emergency of International Concern.

Product Updates

We have been working hard to reach the goals set forth. Many remarkable achievements have been made during that period

SteriSpace™

Sterispace is undergoing the final tune up modifications before the Scheduled launch . It performed as expected during an in house performance test by connecting to the actual tent



provided by the partner HDT Global.

GloTran™

In our most recent collaborations with the University of Tennessee at Chattanooga Clinical Infectious Disease Control Research Group, we are focusing on prevention strategies to mitigate Healthcare-associated infections resulting from

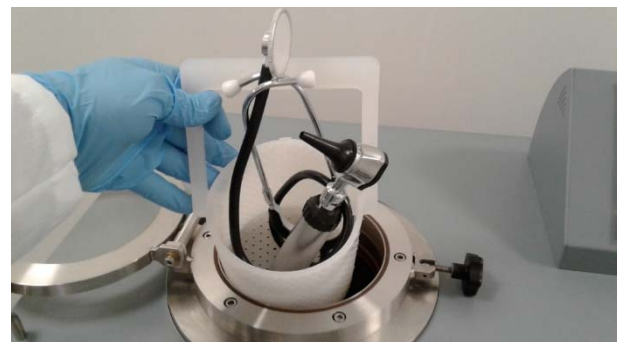


contaminated medical devices in a Pulmonary Outpatient Clinic.

The GloTran™ Disinfection Device was recently shipped to a Pulmonary Outpatient Clinic to undergo a 1 ½ month clinical Investigation. The purpose of the study is to test the effectiveness of GloTran at killing notable pathogens on reusable medical equipment in the



pulmonary unit. Stethoscopes, Otosopes, Ophthalmoscope, Computer mouse, Blood pressure cuffs, Pulse Oximeters, and pulmonary breathing tubes will be treated in the automatic disinfection

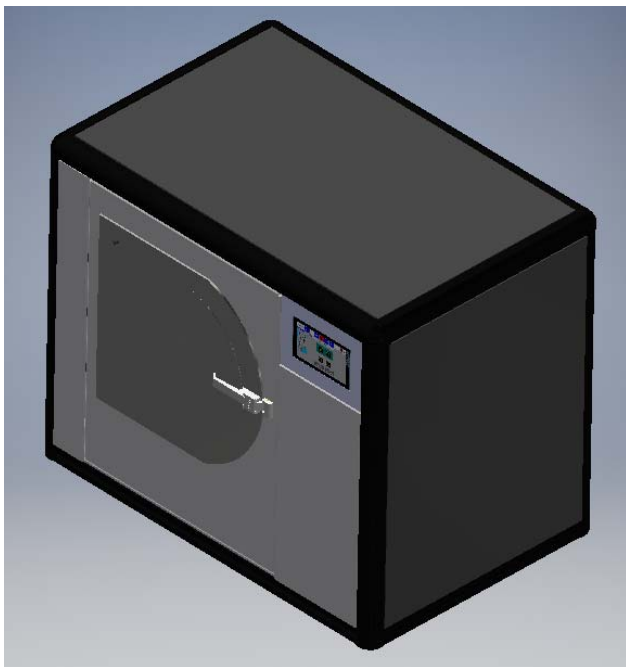


cycle. The principal objectives of the study will be to determine the effectiveness of the GloTran device to reduce bacterial contamination on the medical devices studied. Another objective of the study will be to determine the cost effectiveness of the use of the GloTran device in the disinfection of the medical

equipment used, vs. the use of regular chemical disinfectants. The ease of use of the automated machine will also be evaluated compared to the manual a demonstration of the equipment. This will facilitate the product evaluation by the Infection Control Officer. They will be providing feedback regarding things that are important for hospitals in using the disinfection equipment, for safety and efficacy. The company received several new inquiries from domestic clients as well as international clients who are interested in new ways of mitigating the spread of hospital acquired infection from non-critical medical device.

GloTran 2

The engineers designed an iteration of the GloTran which is a table top model rather than a standalone



model. It has the chamber volume of 33.8 liters. It is almost 3 times of the size of previous model. Also the devices are loaded horizontally compared to the previous model.

Oral Health

The Oral Healthcare division has achieved some major developments this past quarter. The greatest achievement among them is the distribution of



Lubricity and MetaQil through Cardinal Health across US. Further In the past few months, we have added new distribution channels with key distributors, expanding the availability of Lubricity and MetaQil products.



Our continued focus on increasing product knowledge and brand awareness has helped us penetrate and build relationships within the dental and oncology markets across the USA. The sales leadership has also begun exploring marketing opportunities and strategic partnerships in other key target markets both domestically and internationally. We were successful in reaching an agreement with a distributor in Thailand. We have

also strengthened our sales team to help maximize sales and increase customer satisfaction. The oral health team participated in the Buffalo Dental show in September and the Orlando Oncology Conference in October. In early December, our product line will be showcased at the Greater New York State Dental Conference in NYC.



You First Services Inc. (YFS) has signed an agreement with HDT Global to produce and market Patient Isolation Shelter Systems for the containment of highly infectious patients. The system uses YFS' patented SteriSpace™ air sterilizer technology, which has been shown in independent testing to destroy greater than 99.9999% of airborne biological contaminants.

The isolation of patients with infectious diseases and treatment of contaminated air has become increasingly important in the containment and prevention of epidemics. The SteriSpace™ air sterilizer maintains negative air pressure in a rapidly-deployable HDT shelter and effectively destroys airborne biological pathogens, exhausting uncontaminated air from the shelter. The SteriSpace™ system operates without filters, eliminating the risk of exposure from contaminated filters or filter disposal.

The recently developed SteriSpace™ unit was tested with HDT's Patient Isolation Shelter System and it effectively created and maintained the conditions required to achieve the level of biological destruction required by the CDC for infectious disease isolation. When connected to an HDT expeditionary shelter, the system achieved the CDC's target flow rate and required negative pressure inside the shelter. You First Services and HDT plan to launch the Patient Isolation Shelter System in January 2020. "This partnership with HDT Global marks a major milestone for You First Services, enabling greater access to the worldwide isolation shelter market," said Dr. John Lordi PhD, Executive Vice President of Engineering at YFS. HDT Global Inc. is widely recognized for its industry-leading development and production of state-of-the-art, fully-integrated deployable solutions, including shelters, generators, heaters, air-filtration devices, robotics and other engineered technologies currently used by U.S. and allied military units worldwide as well as civilian government and commercial customers.

"The patented SteriSpace™ technology will substantially reduce hospital acquired airborne infections. YFS, with its unique and innovative technologies, will contribute to protecting people of all ages from contracting serious infectious diseases while helping to reduce the economic burden on the healthcare system significantly," said Dr. Satish Sharma MD FACS, Executive Chairman and Chief Executive Officer of YFS.

Clinical Studies

Oral Rinse for Plaque control and mouth freshness

The new oral care product for plaque control and mouth refreshing will be tested in a clinical study in the School of Dental Medicine, University at Buffalo. This double blind, placebo controlled study will be estimating the effectiveness of the oral rinse in reducing plaque, gingivitis and effectiveness of the oral rinse in improving a patient's breath. Duration of the study is a month.

Vaginal Dryness Relief

Clinical study to evaluate the ability of an HA formulation to provide relief to vaginal dryness is progressing. This randomized study at the Department of Gynecology at the University at Buffalo and will investigate the tolerability of a lubricating solution in patients with symptomatic vaginal dryness and its efficacy in minimizing the symptoms associated with dyspareunia. Please call (716)-323-0725 for more information or enrollment.

Clinical Investigation of GloTran Low Temp Plasma/H₂O₂ Disinfection Device in a Pulmonary Outpatient Clinic

This 8 week study will be conducted by members of University of Tennessee, Chattanooga's (UTC's) Clinical Infectious Disease Control (CIDC) research group in collaboration with co-investigators at Erlanger Hospital. The first objective of this study will be to determine if small reusable medical devices currently serve as potential vectors of bacterial contamination from patient to patient. The second objective of this study will focus on determination of the ability of the GloTran to reduce bacterial contamination of small, reusable medical devices in the KOC Pulmonary unit. Using data generated in the first phase of this study we will determine the most contaminated small pieces of reusable equipment and perform a follow up study on those devices.

Welcome New Employees



Domenic Gigliotti
Director of Sales and Marketing



Brian Warren
SALES SUPERVISOR



Thomas Meyers
PROJECT MANAGER



Takenya Allison
ONCOLOGY MANAGER



Daniel Chmura
GRAPHICS & WEB DESIGN
MANAGER



Kevin Hughes
DIGITAL MARKETING
MANAGER



Visiting young scientists and TV News crew from India were hosted by YFS foundation and were given a tour of You First Services manufacturing facility explaining different technologies.