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Digitized Innovative Solutions to Screen and Diagnose Ocular Health and Thyroid Disorders for the Underserved

Varsha Singh

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Dr. Varsha Singh
Assistant professor[1]/Founder & Director[2]
Center for Life Sciences, Chitkara School of Health Sciences, Chitkara University, Punjab, India
[2]Medzak Healthcare *Pvt. Ltd.*

varsha.singh@chitkara.edu.in, varsha_sh@hotmail.com

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Introduction:

There is an alarming rise in communicable and non-communicable diseases globally. The major concern is that few of the burdening diseases can be treated and prevented, however there are no screening, diagnosis and treatment options available especially for underserved populations. The dominant model and method of laboratory testing is changing as healthcare faces limit in the growth of budgets or reduced health care spending's especially in developing nations. As a result of economic pressure, it should be a mandate that healthcare recognition should be more patient centered. To achieve the goals, the aim should be to reduce relatively expensive care in tertiary and secondary hospitals, and more patients should be encouraged to have treatments at primary care health centers. Many of the healthcare options available either are not affordable or proper awareness does not exist among the unmet population.

To curb the process, alternative models of using point-of care (POC) diagnostic tests and equipment's are being increasingly considered especially for the people living in rural or semi urban areas. These remote areas are now a target in order to provide less expensive screening and diagnosis of health diseases. The need of an hour is to make patients accessible to more healthcare facilitates with minimal setups and affordable healthcare facility. The major objective of the policy makers should be to consider non-communicable diseases. The growth is in setting up POC facilities for primary screening and devices for a more effective care.

Small devices for POC exist from small dipstick to auto analyzers which have recently been launched possessing unique innovations and bringing them to the market for social impact. The true portable devices serve to monitor or screen the patients at low costs and require no sophisticated lab facilities especially in rural and semi-rural areas. Digital health facilities incorporated with POC will allow dissemination of specialized knowledge among the medical community. Advanced networks, medical information among peers, distance reporting, faster screening and reporting can be achieved with ease.

Digital healthcare is the most coveted field in India for startups. Medzak Healthcare *Pvt. Ltd.* focuses on digital POC screening devices for ocular health and detecting thyroid disorders. Ocular health and thyroid disorders are preventable diseases. However, millions are suffering from the diseases as the occurrence of the diseases remain asymptomatic for longer periods of time. However, the consequences can be fatal. Medzak, as a new start-up, will build *noninvasive device* to detect secondary eye problems and *minimally invasive* cost-effective digital device to detect thyroid problems especially for rural and semi-urban clinical settings. Therefore, the present paper describes the start-up's focus on building the two devices.

Multi-use Automated Point-of-Care (POC) Device for Imaging Ocular Health

With increasing burden of communicable and non-communicable diseases, causes of ocular health is a rising concern as a secondary complication. With advanced age, smoking, extreme heat or cold weather conditions, low relative humidity, use of visual display terminals, refractive surgery, contact lens wear, alcohol, LASIK and certain medications; dry eye diseases (DED), cataracts, keratoconus, vitreous hemorrhages progressive eye diseases whose numbers are evidently rising. Chronic eye infections, vision blurring, cataracts due to dry eye diseases (DED) are seen not only in patients with medical conditions such as HIV, diabetes, thyroid disorders and Vitamin A deficiency, but spending as minimal as 2-4 hours using visual display terminals (VDT) (laptops and mobiles) causes tears to get evaporated from the surface of the eyes leading to meibomian gland dysfunction (MGD).

This is largely causing red eye, eye irritation, blurred vision and chronic infections, and all have taken a steep rise as degenerative eye disease. Further leading to above mentioned complications. MGD is one of the most common causes of abnormality of the tear film, characterized by partial or absence of the MG in upper and/or lower lids of the eye. Overall, ocular health is largely ignored due to lack of awareness, regular check-up of vision and appropriate vision solutions accessible to everyone.

Current devices employ solutions to the existing problems, however, are not accessible to everyone and are expensive. Many hospitals do not provide full facilities to the instrumentations because the facilities are bulky and expensive, require special lab facilities to run and store the equipment and trained professionals. The devices do not provide a cost-effective integrated solution to multiple diseases associated with ocular health. The limitations of the other meibography and keratography system are of being expensive, bulky, non-portable, trained technician oriented for only hospital/clinical settings, and no measures have been taken to bring the facilities to rural/semi-urban areas. Therefore, it becomes important to consider eye check-up as a routine to prevent chronic vision problems and infection in all ages. The device will be useful at primary healthcare centers, schools, hospitals, private clinics to routinely screen patients with DED having MGD and provide better eye care. This way the young population can be prevented from eye weakness and aged population can have better preventive care for their eyes.

POC (point-of-care) testing is attractive because it rapidly delivers results and enables faster consultation with multiple devices/tests in a single system. Medzak has integrated the innovative solution to measure extent of damage of meibomian glands and tear film, quantify the tear break up time and image eyes for ocular health for diseases like dry eyes, cataract, glaucoma, keratoconus screening, opaque corneas, and vitreous hemorrhages. The automated digitized multi-use device integrates 4 different types of systems and imaging analysis, else found separately, for diagnostic purposes. The present existing to detect ocular health do not integrate more than two detection methods and are not portable. This POC technology has a potential to improve the management of ocular health for both communicable and non-communicable diseases. The diagnosis by the present invention will offer preliminary screening, rapid results, allowing timely initiation of appropriate therapy and facilitate linkages to care and referral of patients. This device will prevent various types of end-stage vision problems and preliminary screen patients for ocular health.

5-year commercial plan

The five-year execution plan for the ocular device is to target 50% market in India. MeiboX being a POC device which offers multiple eye tests at a cost-effective price. There are over 60,000 potential B2B customers in India who are registered ophthalmologists and optometrists. In India about 30-40% known patients have DED and only 6-10% are being treated for other eye diseases, since other chronic diseases such as HIV, diabetes, allergies, keratitis blepharitis and conjunctivas causes and poses risk of having DED and MGD, patients can be targeted through 250+ NGOs, hospitals across India. For commercialization we will target 50% rural hospitals (7699/15398), Urban hospitals (2209/2219), dispensaries (13000/26107), Sub-centers (75842/151685), primary health care centers (12,224/24,448), community health centers (2593/5187), 75% of Universities offering Optometry courses (443/591) and further ophthalmologist clinics and centers.

The unique competitive advantage of the present invention over other systems and equipment is that *it is cost-effective, portable, non-contact and non-invasive screening device* which requires no sophisticated lab facility and can be used with minimum training. Checking eye problems should become a mandatory protocol along with other clinical tests in the coming times to prevent chronic eye diseases among children, patients, workers and other population. For this, the present invention is specifically designed for rural/semi-rural populations as a handheld device with immediate results and available technology in their neighborhood.

The present prototype we have developed at Medzak Healthcare *Pvt. Ltd.* is different from other products and services in the following manner: 1) It is a portable device suitable for any small or big clinic as well as rural/semi-rural settings; 2) Other keratographs cost between $2,000 - $36,951, not affordable by all private practicing ophthalmologists, eye center clinics and definitely not installed in rural/semi-rural settings; 3) Our unique in-built software with the device gives both qualitative as well as quantitative analysis of the eyes. It does not require PCs or heavy screens to be installed; 4) The analysis is easy and requires

minimal training for professionals and certified users. It does not require presence of ophthalmologist and optometrist at the site and provides cloud storage of the images to be accessible; 5) After conducting camps and check-ups, a repository system can be shared online from the test location with the clinicians.

Thyro-D: Digitized Device to Detect Thyroid Disorders

In India, 42 million people are suffering from thyroid disorders, of which 13 million are in rural India. The rural segment in India is largely ignored and health complications due to thyroid are on the rise. Since India is becoming a thyroid burden country after diabetes, thyroid cases are increasing alarmingly. The problem is persistent mostly in females and results in infertility problems, pregnancy complications, premature abortions, and children are born with health complications such as congenital hypothyroidism, disturbed metabolic disorders, mental retardation, stunted growth etc. Due to lack of awareness in these areas, they face infertility or reproductive problems, due to which the newborns are born with birth defects and congenital hypothyroidism. Worse, there are no new born screening programs. Even worse, it can be easily manageable, but the rural population is not provided with well-equipped facilities to get them tested. Hypo- and Hyperthyroid disorders are increasing alarmingly especially in the non-urban population. Present conventional methods do not offer cost-effective therapeutic diagnosis against rapid detection/screening of thyroid disorders. The diagnosis relies on serological tests, but the exceedingly established ELISA test uses expensive antibodies generated from animals making it expensive and compromising on sensitivity and specificity. Monoclonal antibodies continue to be predominantly used for these purposes. However, production of large quantities of antibodies itself is expensive, time-consuming and majorly requires animal sacrifice. Therefore, there is a need to detect thyroid biomarkers for screening the undiagnosed cases of thyroid disorders especially among the rural population.

The invention underway by Medzak is a cost-effective, sensitive and specific approach to develop a digital device, Thyro-D, to detect thyroid biomarker for screening thyroid disorders which is superior than using present conventional diagnosing system. The device will utilize minimal invasive technique and use 10 ul of blood at finger prick just like a glucometer. The Advantages offered by this technology for societal challenges: 1) The technology defines a new and cost-effective method of detecting thyroid biomarkers for thyroid disorders, 2) Affordable technology can be used for rural setup with no sophisticated and expensive lab setups.

To approach the development of the project and to bring the Thyroid biomarker in participation for clinical use, the following approaches participation/development will be used: 1) Induced involvement: The strategy, design and work plan of the project would be determined and the intended beneficiaries such as testing labs (or clinicians) will be encouraged to use the therapeutic design of using a novel detection method as an alternative, stable, specific technique to ELISA to detect thyroid disorder; 2) Device formation: Medzak is developing a cost-effective technology to screen thyroid disorders. The device and/or technology modified will be used especially in the rural areas where

estimated of 7.7 million undiagnosed cases of thyroid at reproductive age exist; 3) The technology would further be added as an advantage to the urban community. The project has a specific objective to create new or strengthen existing forms of technologies based on immunoaffinity through which patients will have access to cost-effective, specific services at labs across. The clinicians will be participating and learning through refresher program.

The digital healthcare system is rapidly evolving. The Indian healthcare sector needs to untap the potential for building and strengthen the healthcare start-ups with societal impacts especially with POC technologies. Medzak Healthcare *Pvt. Ltd.* Focuses on providing cost-effective technologies for societal benefits and aims to provide digital healthcare to redefine healthcare delivery system.

About the Author

Dr Varsha Singh is an Assistant Professor at Center for Life Sciences, Chitkara School of Health Sciences, Chitkara University, Punjab. She is the Founder & Director of Medzak Healthcare Pvt. Ltd. She is an alumnus of the Hangzhou Conclave in 2017, representing India in the biotechnology forum.

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