Skin cancer screening and prevention in primary health care setting: a pilot program in Delhi, India

Master of Public Health Integrating Experience Project

Program Implementation Framework

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List of Abbreviations

ASR	Age Standardized Rate
AIIMS	All India Institute of Medical Sciences
AUA	American University of Armenia
BCC	Basal Cell Carcinoma
BSCT	Basic Skin Cancer Triage
CME	Continuing Medical Education
DALY	Disability Adjusted Life Years
GLOBOCAN	Global Cancer Incidence, Mortality and Prevalence
HDI	Human Development Index
ICS	Indian Cancer Society
IHME	Institute of Health Metrics and Evaluation
IRB	Institutional Review Board
LMIC	Low- and Middle-Income Countries
MSC	Melanoma Skin Cancers
NGO	Non-Governmental Organization
NMSC	Non-Melanoma Skin Cancers
PBCR	Population-Based Cancer Registry System
PHC	Primary Health Care
QALY	Quality Adjusted Life Years

SCC	Squamous Cell Carcinoma
SEER	Surveillance, Epidemiology, and End Results
SSE	Self Skin Examination
SDI	Socio Demographic Index
TBSE	Total-Body Skin Examination
TNM	Tumor, Node, Metastasis
US	United States
UV	Ultra-Violet A and B radiations
VBHC	Value Based Healthcare
WHO	The World Health Organization
YLD	Years Lived with Disability
YLL	Years of Life Lost

Executive Summary

Situational analysis
Skin cancer is classified as the most common type of cancer worldwide and is also one of the most preventable cancers. As per Global Cancer Statistics, melanoma skin cancer and non-melanoma skin cancer were the 19th and the 5th most frequently occurring cancers respectively worldwide in 2018. It is evidenced that most countries do not have a population-based cancer registry and those nations which do, usually do not account for skin cancers which implies probable underestimation of skin cancer burden. Skin cancer treatment availability, accessibility and cost vary throughout the world and substantially contribute to increased clinical and economic burden quantifiable in terms of lack of timely diagnosis, under-diagnosis, misdiagnosis, advanced medical care requirement and life-years lost. In India, skin cancer statistics are undocumented, however, it is estimated that skin malignancy represents about 1-2% of all cancer diagnoses; accurate statistical data associated with skin cancer is scarce due to lack of regulations to report any disease-specific death or diagnosis.

Strategy appraisal
Considering the need to mitigate the economic and public health burden of skin cancer, population based secondary preventative strategies are recommended. Annual Total Body Skin Examination (TBSE) administered by primary health care physicians is a cost-effective and time-efficient skin cancer screening method. The proposed pilot program is aimed at incorporating TBSE in an annual routine check-up provided by primary health care physicians in a public hospital in Delhi, India.

Program
The proposed pilot program will be designed as a randomized controlled trial in All India Institute of Medical Sciences (AIIMS), Delhi in collaboration with Indian Cancer Society. The project will be executed in three phases, namely, planning; implementation; and evaluation. In total, 190 study participants will be sampled and assigned equally into intervention and control groups. The study participants of the intervention group will undertake an active learning: a web-based medical education training course, Basic Skin Cancer Triage (BSCT), designed by a multidisciplinary team of medical and public health experts. The objectives of the program will be to assess the change in the behavior, intention and skills of primary health care physicians, and estimate the change in the total number of identified skin cancer cases and assess the proportion of cases identified at an early stage. The contingency plans of the proposed project are based on a biphasic algorithm consisting of physician-centered algorithm and patient-centered algorithm. The strategy for allocation of resources will include optimizing the use of existing resources and budgeting for the required new resources. The timeline of the project is anticipated to be 18 months, commencing from January 01, 2021 and the estimated budget is 3,670 USD approximately.

Conclusion
The proposed program will be undertaken as a pilot project, and if the evaluation of the project is conclusive in demonstrating the effectiveness of the program, the project will be recommended to be implemented throughout the primary healthcare system in India as a population-based nationwide skin cancer screening.

1 Situational analysis / Priority setting

1.1 Skin cancer

"Skin cancer is defined as the abnormal and uncontrolled growth of skin tissue." (NCI, 2007). Skin cancers are broadly classified as melanoma skin cancers (MSCs) and non-melanoma skin cancers (NMSCs) (NCI, 2007; Sideris and Thomas, 2019). MSCs originate from the pigment producing cells or melanocytes and the NMSCs originate from keratin producing cells or keratinocytes (Lacy and Alwan, 2013). NMSCs include squamous cell carcinoma (SCC) which arises in flat squamous cells and basal cell carcinoma (BCC) which arises in basal cells of epidermis (Madan et al., 2010; Sideris and Thomas, 2019).

NMSCs are not as life threatening as MSCs and are rarely lethal (Madan et al., 2010; Lacy and Alwan, 2013; "Skin cancers", 2020). NMSCs can be curable if diagnosed at an early stage, whereas MSCs can metastasize to different organ systems easily and are difficult to manage (Madan et al., 2010; Marcil and Stern, 2000).

Within skin cancer family, MSCs are responsible for less than 5% of all skin cancers and NMSCs accounts for about 95% of all skin cancers (Madan et al., 2010; Lacy and Alwan, 2013). Within NMSCs, 80% are BCCs and 20% are SCCs (Dacosta et al., 2013; Khazaei et al., 2019; Rees et al., 2014). Mortality exclusive to skin cancers is extremely low but given the high prevalence and increasing incidence of skin cancers, mortality associated with weak immunity and co-morbidity is estimated to increase globally by 2030 (Barton et al., 2017; ECCO, 2017; Garcovich et al., 2017).

1.2 Global burden

Skin cancer is classified as the most common type of cancer worldwide and is also one of the most preventable cancers (Khazaei et al., 2019; Leonardi et al., 2018; Siegel et al., 2020). As per Global Cancer Statistics 2018, the Global Cancer Incidence, Mortality and Prevalence

(GLOBOCAN) estimates MSCs as the 19th and NMSCs as the 5th most frequently occurring cancers worldwide (Ferlay et al, 2018; Ferlay et al, 2019; "Global Cancer Observatory", 2020; Wild et al., 2020). According to the Institute of Health Metrics and Evaluation (IHME), in 2017, global mortality rates associated with NMSCs and MSCs were ranked 23rd and 24th, respectively, in relation to the mortality associated with other types of cancers (Fitzmaurice et al., 2019; Roser and Ritchie, 2015). In 2018, as per the cancer records by Khazaei et al. (2019), NMSCs and MSCs had the highest incidence and mortality in the Oceania continent ("Global Cancer Observatory", 2020; Khazaei et al., 2019). The incidence and mortality for MSCs were reported to be 28.3 per 100,000 person-years and 3 per 100,000 person-years, respectively; and the incidence and mortality for NMSCs were reported to be 56.2 per 100,000 person-years and 1 per 100,000 person-years, respectively (Khazaei et al., 2019). In 2018, approximately 300,000 diagnosis of MSCs and over a million new cases of NMSCs were registered worldwide, albeit this is a probable underestimation (Bray et al., 2018; Ferlay et al, 2018; Ferlay et al, 2019; Razi et al., 2015; "Skin cancers", 2020; Wild et al., 2020). It is important to mention that most countries worldwide do not have cancer registries and those nations which do, usually do not account for skin cancers (Apalla et al, 2017; Bray et al., 2018; De Vries et al., 2016; Ferlay et al, 2019; Lomas et al., 2012; Razi et al., 2015; Verkouteren et al., 2017). The majority of statistical cancer rankings generally omit data on NMSCs (particularly BCCs) (Bray et al., 2018; Ferlay et al, 2019; Lomas et al., 2012; Zhu et al., 2012). This translates as dearth of actual data, underreported statistics and overall underestimation of global burden of skin cancer (Bray et al., 2018; Ferlay et al, 2019; Lomas et al., 2012; "Skin cancers", 2020).

1.2.1 Non-melanoma skin cancers (NMSCs)

According to IHME list of global prevalence of cancers by type, NMSCs rank raised from 10th to 7th within a decade from 2002 to 2012 (Fitzmaurice et al., 2019; Roser and Ritchie,

2015). It is noteworthy that the Global Burden of Disease Cancer Collaboration (GBDCC) estimated that almost 5,500 people died globally due to NMSCs every month in 2018 (Fitzmaurice et al., 2019). In 2017, approximately 8 million cases of NMSCs were diagnosed globally, of which 6 million were BCC and 2 million were SCC (Fitzmaurice et al., 2019; Siegel et al., 2020). Overall, this led to 65,155 (0.73 per 100,000) deaths and 1.3 million disability-adjusted life-years (DALYs) (Fitzmaurice et al., 2019; Khazaei et al., 2019). DALYs was expressed in 97% years of life lost (YLLs) and 3% years lived with disability (YLDs) (Fitzmaurice et al., 2019). According to GBDCC, the odds of developing NMSC throughout a lifespan for men and women worldwide were 1 in 7 and 1 in 10, respectively (Fitzmaurice et al., 2019). Similarly, GBDCC also collated the range of odds of developing NMSCs by Socio-demographic Index (SDI) of the countries (Fitzmaurice et al., 2019). The odds of developing NMSCs among men were 50% higher in high SDI countries as compared to low SDI countries; and the odds for developing NMSCs among women were 25% higher in high SDI countries as compared to low SDI countries (Fitzmaurice et al., 2019). However, the difference in the estimation of odds must be utilized carefully given the lack of adequate reporting of skin cancer statistics globally, specifically in the low-and middle-income countries (LMICs) ("Basal & Squamous Cell Skin Cancer Statistics", 2020; Khazaei et al., 2019; "Melanoma of the Skin Statistics", 2019; Siegel et al., 2020; Wild et al., 2020; Zhu et al., 2012). The World Health Organization (WHO) recently stated that, *"the temporal trends of the incidence of non-melanoma skin cancers are difficult to determine, because reliable registration of these cancers has not been achieved."* ("Skin cancers", 2020).

1.2.2 Melanoma skin cancers (MSCs)

The global annual incidence of MSCs is doubling up every 10–20 years (Lens and Dawes, 2004; Matthews et al., 2017). The incidence of MSCs has been increasing across the globe for over 40 years (Khazaei et al., 2019; Matthews et al., 2017; Siegel et al., 2020).

According to The US Academy of Dermatology, there is a notable disparity in the incidence between countries, MSCs are most prevalent in Australia and New Zealand, but are equally widespread among Asian, African and Latin American population (Ali et al., 2013; Khazaei et al., 2019). This variation in incidence can be attributable to the country's proximity to the equator, magnitude of ozone layer depletion, and the amount of melanin in their respective population ("Melanoma Skin Cancer Statistics", 2020).

In 2018, the incidence of MSCs was the highest in Australia, with 40 new diagnoses per 100,000 population-year, and the lowest in South-Central Asia, with 0.2 new diagnosis per 100,000 population-year (Khazaei et al., 2019). In 2018, MSCs were responsible for 60,712 deaths with an age-standardized rate (ASR) of 1.33 per 100,000 persons globally (Khazaei et al., 2019). In 2015, MSCs accounted for over 1.5 million DALYs with an ASR of 23 DALYs per 100,000 persons (Karimkhani et al., 2017). Each death attributable to MSCs results is 15 YLL, which contributes to nationwide social and financial burden related to MSCs (Guy et al., 2015b; Karimkhani et al., 2017). Although MSCs are mostly noticed among population with higher socioeconomic status, the mortality is higher among population with lower socioeconomic status (Khazaei et al., 2019; Reyes-Ortiz et al., 2006). Factors like access to screening programs, monetary resources and higher awareness explain the increase in the incidence of MSCs among the populations with higher socioeconomic status (Johnson-Obaseki et al., 2015). Whereas, populations with lower socioeconomic status have lower awareness, lack of resources and are usually diagnosed in an advanced stage which results in poor prognosis (Idorn and Wulf, 2014; Johnson-Obaseki et al., 2015). A study in US reported that populations with higher socioeconomic status had 12% lower risk of MSC-specific mortality after adjusting for socio-demographic variables, associated co-morbidity, and tumor lesion characteristics like stage at diagnosis, thickness, histological sub-type, and anatomic site (Reyes-Ortiz et al., 2006). Reyes-Ortiz et al. (2006) also reported that populations of

color (nonwhites) were likely to be diagnosed with thicker lesions (~40 mm) and in more developed stages of skin cancer (regional or distant) than white people when stratified by income (Reyes-Ortiz et al., 2006). Another study, Clarke et al., (2017) in California reported that the highest incidence for thick MSC lesion (>4 mm) was among low socioeconomic status groups, who were considered to be less aware and might have not had access to regular skin screening (Clarke et al., 2017). This contributes to the economic burden of LMICs and its citizens with low socioeconomic status. (Guy et al., 2015b; Khazaei et al., 2019; Siegel et al., 2020)

The 5-year relative survival rate for localized, regional and distant metastasis of MSCs are 99%, 65% and 25%, respectively, as reported by The American Cancer Society based on SEER (Surveillance, Epidemiology, and End Results) ("Cancer Facts & Figures", 2020; Garbe et al., 2016; Howlad et al., 2019; Siegel et al., 2020). MSCs have the second highest survival rate (92%), based on the combined stages of TNM (Tumor, Node, Metastasis) system (Siegel et al., 2020). However, this high survival rate is mostly attributable to the advancements in medical treatments, only if MSCs are diagnosed timely (Siegel et al., 2020).

The advancement in medical treatments slightly mitigate the global clinical burden attributable to skin cancers, however, the continuous increase in incidence and mortality due to MSCs inflated the cost of treatment and induced burden to the global economy (Pollack et al., 2011; Tripp et al., 2016).

1.2.3 Economic burden of skin cancers

The increasing global clinical burden of skin cancer worldwide is contributing to significantly higher costs and subsequently huge economic burden quantifiable in terms of both medical care and life-years lost (Apalla et al, 2017; Chen et al., 2016; Fransen et al., 2012; Guy et al., 2015a; Mofidi et al., 2018). Despite relatively lower mortality attributable

to skin cancers, the associated cost of treatment, functional and cosmetic morbidity add substantial economic burden to the national health care systems (Ciążyńska et al., 2018; Trakatelli et al., 2012). With increasing incidence and prevalence associated with skin cancer, the costs of skin cancer management (direct and indirect care cost) are estimated to increase concurrently (Pollack et al., 2011; Tripp et al., 2016).

Solely in the US, the annual average cost of skin cancer management increased by 288% within a decade (2004 - 2014) (Guy et al., 2015a; Tripp et al., 2016). Out of this, 130% of the increase has been noticed from 2006 to 2011, whereas, the annual average management cost for all other malignancy increased only by 25% during the same timespan (2006 - 2011) (Chen et al., 2016). The annual cost of skin cancer management was about 8 billion US dollars in 2012, out of which 3 billion US dollars were spent on treatment of MSCs and 5 billion US dollars were attributable to NMSCs (Chen et al., 2016; Guy et al., 2015a). The average treatment cost per skin cancer patient also increased from 1000 US dollars in 2006 to 1600 US dollars in 2011 (Chen et al., 2016). Gay, et al., estimated the annual indirect cost, such as lost productivity associated with MSCs to be approximately 39 million US dollars for morbidity and about 3 billion US dollars for mortality (Guy et al., 2015a; Tripp et al., 2016).

In Australia, the skin cancer health and welfare costs were the highest in comparison with all other cancers in 2009 (Fransen et al., 2012). The cost of treatment was over 400 million Australian dollars, out of which about 50 million Australian dollars were spent on treatment of MSCs and 370 million Australian dollars were attributable to NMSCs (Fransen et al., 2012; Vallejo-Torres et al., 2013). In Germany, Stang et al., (2007) reported the estimated annual costs attributable to NMSC and MSC hospitalization to be around €130 million and €60 million, respectively (Stang et al., 2007).

Another study in Canada reported the economic burden attributable to NMSCs including direct and indirect costs to be about 29 million Canadian dollars, of which 30% were related with indirect costs[1] and 70% with direct costs[2] (Mofidi et al., 2018). NMSC associated intangible costs[3] of 5.7 million Canadian dollars were also calculated based on 50,000 Canadian dollars per quality-adjusted-life-years (QALY) (Mofidi et al., 2018).

1.3 Causes and risk factors

The development of skin cancer is multifactorial with environmental, genetic and phenotypical factors playing key roles. Environmental risk factors include ozone depletion, prolonged outdoor activities in the sun, type of coverage, lifestyle choices like consumption of alcohol and food with high fat content, geographic factors like habitation at higher altitude, lower latitude or bordering on the equator (Khazaei et al., 2019; Lakhani et al., 2014).

WHO estimated that for every 10% decline in ozone levels, an increase of 300,000 cases of NMSCs and 4,500 cases MNCs are observed ("Skin cancers", 2020). It is well established that exposure to natural and artificial (sunbeds, tanning parlor) solar radiations, specifically exposure to UV-radiations (ultraviolet-A ¼ 315e400 nm and ultraviolet-B ¼ 280e315 nm) instigate mutations in the human skin cell genome and contributes to the development of various forms of skin cancers (Armstrong and Kricker, 2001; Cleaver and Crowley, 2002; Greinert and Boniol, 2011; Ikehata and Ono, 2011; Leiter and Garbe, 2008; Norval et al., 2007; Ramos et al., 2004).

[1] "Indirect costs: Productivity loss costs, including the monetary value of lost days of work due to mortality, morbidity, and care seeking; home production loss costs." (Mofidi et al., 2018)

[2] "Direct costs: Healthcare costs, including diagnosis, treatment, and follow-up; out of pocket costs, including travel, prescription drugs, homemaking services, vitamins and supplements, accommodations and meals, devices and equipment; informal caregiving costs." (Mofidi et al., 2018)

[3] "Intangible costs: Pain, suffering, and loss of enjoyment of life; values associated with engaging in social roles (e.g., family, community, leisure and work role engagement)." (Mofidi et al., 2018)

Availability of sunbeds, tanning trend among adolescents and occupation with requirements to work in sun are a few other risk factors responsible for steady increase in skin cancer (NMSCs, MSCs) incidence among the white population across the world (Greinert and Boniol, 2011; Greinert, 2009). It is noteworthy that although darker-skinned individuals produce more melanin and are better protected from UV radiation, they are not protected from the UV - induced melanomas (Chang et al., 2009; Gloster and Neal, 2006). Hence, skin cancer is also a concern for skin of color (Gupta et al., 2016).

In addition to sun exposure, family or personal history of skin cancer, aging global population, recent increase in freckles or uneven moles, co-morbidities influencing immune system or medication after organ transplants to suppress immunity are the potential risk factors leading to the development of skin cancer (Lakhani et al., 2014; Samarasinghe and Madan, 2012).

1.4 Signs and symptoms

MSCs can develop on any area of skin, exposed or not exposed to sunlight (Lacy and Alwan, 2013). Literature suggests that MSCs can affect skin of any area, type, tone and texture (Lacy and Alwan, 2013), whereas, NMSCs affects the area of skin which are persistently exposed to the sun rays (Lacy and Alwan, 2013).

Pigmentation of the skin is the main pre-malignant symptom (Lacy and Alwan, 2013). The pigmented malignant lesion in MSC have the following features – asymmetry, border irregularity, uneven color, lesion diameter more than 6 mm, and enlarging or changing lesion (Lacy and Alwan, 2013). In SCC, the lesion can be hyperkeratotic, nodular and ulcerous (Lacy and Alwan, 2013). The lesions in BCC are usually present on sun-exposed skin areas such as face, nose, ears, shoulders and back (Lacy and Alwan, 2013). In addition to these

specific symptoms, the malignant skin lesions can have general symptoms such as erythema, pain, itching and bleeding (Lacy and Alwan, 2013).

1.5 Skin cancer management

1.5.1 Prevention

Primary prevention of skin cancers (MSCs, NMSCs) includes strategies aimed at controlling and/or modifying the natural and artificial risk factors associated with skin cancer (Kornek and Augustin, 2013; Marcil and Stern, 2000). These strategies include limiting natural and artificial solar exposure, using textile protection such as hats and sunglasses, applying broad-spectrum sunscreen and sunblock for protecting against ultraviolet A and ultraviolet B radiations, frequently reapplying sunscreen and sunblock, avoiding exposure to tanning beds, educating about skin cancer and its prevention and raising awareness about regular skin examinations (Greinert and Boniol, 2011; Kornek and Augustin, 2013).

Secondary prevention of skin cancers (MSCs, NMSCs) include strategies aimed at managing and controlling the spread of skin cancer to decelerate or cease the progression of skin cancer (MSCs, NMSCs) post diagnosis. Secondary prevention is comprised of skin examination to diagnose disease at an early stage and prevent malignant transformation of the suspected skin lesions. For example, topical use of bio-chemical agents like nicotinamide (vitamin B3 - water soluble) and retinol (vitamin A) on the suspected lesion may prevent the development of skin cancer (Kornek and Augustin, 2013). Several studies have highlighted the effectiveness of incorporating self-skin examination (SSE) and total-body skin examination (TBSE) for early detection and diagnosis of skin cancer (Guy et al., 2015a; Khazaei et al., 2019; Tripp et al., 2016). To maximize the diagnostic sensitivity for skin cancers (MSC and NMSC), literature suggests that TBSE is essential (Greinert and Boniol, 2011; Kornek and Augustin, 2013). Since most lesions in skin cancer are de novo, TBSE is

highly sensitive in recognizing new lesions and changes in existing lesions, when performed by a trained physician (Greinert and Boniol, 2011; Kornek and Augustin, 2013).

Tertiary prevention of skin cancers is comprised of strategies to follow-up patients at risk of any type of epithelial cancer or patients with prior history of skin cancer aimed to avoid potential complications and recurrence of skin cancer (Kornek and Augustin, 2013). Several other strategies aimed at the prevention of metastasis (i.e. spread of the cancer to other organ systems though lymphogenic and hematogenic pathways) are excision of the skin cancer lesion through surgical intervention, radiotherapy and/ or chemotherapy to control metastasis and eschew possible recurrence of the skin cancer (Kornek and Augustin, 2013).

1.5.2 Diagnosis and treatment

Diagnosis of skin cancer can be done through several techniques. The choice of the diagnostic method depends on the history of the patient, presence of comorbidities and classification of the skin lesion. Skin cancer diagnosis typically starts with a total body visual examination. The American Cancer Society and Skin Cancer Foundation advocate for a monthly self-skin examination and an annual visual screening (TBSE) performed by a physician to detect and prevent potential skin cancer ("Annual Exams ", 2020; "Skin Examination", 2019). Self-skin examination includes visual inspection of the entire skin surface, while paying attention to new moles and itchy, flaky skin surface. However, self-skin examination is not convenient because of limited accessibility of human body, such as inadequate mobility and improper eye level (Sondermann et al., 2016). Annual physician visit is required for everyone, particularly the high-risk group (Bajaj et al., 2019; Johnson et al, 2017). TBSE is a comprehensive perceptible evaluation of the patient's entire epidermal layer of the skin (Helm et al, 2019; Johnson et al, 2017). It includes evaluation of scalp, face, eyes (iris and sclera), ears, oral mucosa, neck, chest, abdomen, back, hands, feet, upper and lower extremities, pelvic region (genitals and buttocks), hair and nails by physician (Johnson et al,

2017). The potential mole, spot or lesion is further examined and in case of speculation, imaging tests, dermoscopy or a biopsy is performed for confirming the diagnosis (Telfer, Colver, and Morton, 2008). The visual screening of the total body will assist physicians to early diagnose new lesions, before the beginning of clinical manifestation of skin cancer and prevent the metastasis of skin cancer just by analyzing the skin by its appearance (Helm et al, 2019). Additionally, it provides an exclusive benefit to the physicians of diagnosing other systematic diseases simultaneously (Rigopoulos et al, 2011; Uliasz et al, 2008).

As per the guidelines of the TBSE program, all the primary health care (PHC) physicians must incorporate basic A-B-C-D-E-F skin screening criteria and identify the potential warning signs of skin cancer cells development. This criterion assists physicians to distinguish between normal and pathological mole by analyzing key clinical features of a potential cancerous mole like Asymmetrical shape, Irregular border (notched or scalloped), uneven Color tone, Diameter greater than 6mm, Evolution or expansion in the structure of mole (shape, size, height or color) and Firm or funny appearance (Daniel, Jensen, and Elewski, 2015).

The optimal skin cancer management depends on the histological sub-type (Jameson, et al., 2018). The identified cancer tissue can be excised using several procedures such as, cryotherapy, excisional surgery, Mohs surgery, curettage or electrodessication (Jameson, et al., 2018). To prevent recurrence of the skin cancer, procedures like chemotherapy, photodynamic therapy, radiation, biological therapy and immunotherapy are prescribed after the excision of cancerous skin tissue (Jameson, et al., 2018).

Skin cancer treatment availability, accessibility and cost vary throughout the world (Krensel, Schäfer, and Augustin, 2019; Trakatelli et al., 2012). Advanced diagnostic techniques and treatment methods like optical biopsy and Mohs surgery are either expensive

or not available in all the countries (Krensel et al., 2019; Trakatelli et al., 2012). The development index of the country is the primary factor responsible for the health disparity in the accessibility of treatment, health care facilities, providers and the costs of treatment (Krensel et al., 2019; Trakatelli et al., 2012). A few other factors like awareness among population, presence or absence of screening programs, geographical location of the country, privatization of health care facilities, insurance system, patient's income, socioeconomic and insurance status are also responsible for the health inequity in skin cancer care (Gupta et al., 2016; Khazaei et al., 2019; Krensel et al., 2019; Trakatelli et al., 2012).

It is challenging to estimate the health inequities associated with skin cancer management across the world due to absence of literature on estimating the skin cancer management (treatment and diagnosis) specific cost (Krensel et al., 2019; Trakatelli et al., 2012). People belonging to lower socioeconomic group and those with below average wealth index are affected by the consequences of health inequity in skin cancer care since timely diagnosis and advanced care are especially inaccessible for poorer patients (Krensel et al., 2019; Trakatelli et al., 2012). Few studies have shown that implementation of TBSE in primary health care settings can provide equally accessible skin cancer care to all patients regardless of their socioeconomic or insurance status, reduce the proportion of misdiagnosed cases of MSC by one third, decrease false positive results, and encourage early diagnosis (Aldridge et al., 2013; Argenziano et al., 2012; Johnson et al, 2017).

Several studies reported that patients usually seek clinical care only in the advance (invasive) stage of skin cancer and that they are responsible for more than 70% of the delay in diagnosis (Gajda and Kaminska-Winciorek, 2014; Hwang et al., 2016; Kummet and DiBaise, 2015). Patients may not consult a medical professional initially due to asymptomatic lesions (painless), lack of adequate awareness, absence of family history, fear of diagnosis, treatment process and cost (Hwang et al., 2016; Kummet and DiBaise, 2015). Failure of

adequate diagnosis of skin cancer has critical ramification on prognosis of the disease and it is not often documented (Abikhair et al., 2014; Elmore et al., 2017; Hwang et al., 2016). The weak diagnostic precision of skin cancer is of clinical concern because if it goes undetected, it may metastasize and become fatal (Elmore et al., 2017). Similar discordance in diagnosis are identified in other disciplines of clinical medicine (for instance, a physician misinterpreting mammograms or misdiagnosing breast biopsies), however, they are not as pronounced as misdiagnosis of skin cancer (Elmore et al., 2017).

Most often initial skin irregularities due to NMSCs are misdiagnosed for other diseases (Hwang et al., 2016). It is reported that 75% of stage II, 60% of stage III and 55% of stage IV skin cancer cases are misinterpreted initially (BMJ, 2017). Approximately, 72% of BCCs, 50% of SCCs, and 35% of MSCs are misdiagnosed initially (Blach et al., 2009; Bristow et al., 2008; Fortin et al., 1995; Heal et al., 2008; Sondermann et al., 2016). MSCs of thick skin (feet or palm) are 10% more frequently misdiagnosed in comparison with MSCs of other anatomical sites (Baade et al., 2006; Krige et al., 1991; Metzger et al., 1998). Initial misdiagnosis of MSCs decreased the 5-year survival rate from 91% to 68% (Metzger et al., 1998). Almost 40% of initial pigmentations on skin surface are misdiagnosed in pediatric age group, which delays the treatment and results in poor prognosis (Ferrari, 2005). Byrd et al., (2004) reported that 32% of patients with deeper skin tone were diagnosed with skin cancer at more advanced stage, whereas, only 13% of lighter skin tone patients were diagnosed in advanced stage at the Washington Cancer Institute (Byrd et al., 2004).

1.6 Situation in India

According to GLOBOCAN (2018) cancer burden estimation, over a million new cancer cases were registered, and about 0.8 million people died from cancer in India, in 2018 (Dar and Sharma, 2020; "Global Cancer Observatory", 2020; Sahoo et al., 2018). Also, as per the GLOBOCAN (2018) modeled projection of cancer burden in India, increase in the number of

new annual cases up to 2 million and about 1.3 million deaths attributable to cancer are predicted by 2040 (Dar and Sharma, 2020; "Global Cancer Observatory", 2020). Preventable cancers (such as, cervical cancer, stomach cancer, skin cancer, uterine cancer) are accountable for about 70% of the cancers associated mortality in India (Dar and Sharma, 2020; Gandhi et al., 2017). Approximately 80% of the cancer cases are diagnosed in the advanced stage, which instigates the poor prognosis of cancer in India (Dar and Sharma, 2020; Sahoo et al., 2018).

Factors like the low socioeconomic status, poor access to health care facilities, absence of mandatory health insurance system, expensive cancer care facilities, high out-of-pocket expenditure, inadequate population-based cancer registry system (PBCR), lack of proper cancer awareness and stigma around cancer are potentially responsible for the higher burden of cancer in India (Behera and Patro, 2018; Chatterjee et al., 2016; Dar and Sharma, 2020; Sahoo et al., 2018; Sahoo et al., 2019; Smith and Mallath, 2019).

In most LMICs including India, physicians are not required to report new cases of cancer diagnosis to the cancer registry system (Dar and Sharma, 2020; Sahoo et al., 2018). The PBCR in India covers only 10% of the total population and is mostly limited to the urban areas (Behera and Patro, 2018; Gajalakshmi et al., 2001). According to The World Bank (2018), 65.97% of the Indian population resides in rural areas (TWB, 2019), and only 0.1% of the Indian rural population is covered by the PBCR, which attests that the data from almost two-third of the Indian population are not collated by the PBCR (Behera and Patro, 2018). Also, disease-specific mortality data are not available in India because of the inadequate medical certification of deaths (Behera and Patro, 2018; Chatterjee et al., 2016). Hence, the cancer statistics (incidence, prevalence, morbidity, and mortality data) are underestimated and do not illustrate the actual burden associated with cancer due to the narrow scope of

cancer registry system in India (Behera and Patro, 2018; Dar and Sharma, 2020; Sahoo et al., 2018).

In India, skin cancer statistics are not well documented, however, a few sources suggest that skin malignancy represents about 1-2% of all cancer diagnoses (Godbole et al., 1968; Khullar et al., 2014; Lal et al., 2016). Accurate statistical data (incidence, prevalence, mortality) associated with skin cancer (NMSC and MSC) are difficult to estimate as it is not mandatory to report any death or diagnosis associated with skin cancer to the Indian State Cancer Registry (Behera and Patro, 2018; Chatterjee et al., 2016; Dar and Sharma, 2020; Kumar et al., 2014; Lal et al., 2016; Sahoo et al., 2018; Smith and Mallath, 2019).

In India, the literature related to NMSCs is scarce and restricted to some case reports and reviews (Khullar et al., 2014). BCCs are the most common type of skin cancer across the world; however, in India, several studies have reported SCCs as the most prevalent form of skin cancer (Adinarayan and Krishnamurthy, 2011; Khullar et al., 2014; Kumar et al., 2014; Panda 2010; Raina et al., 2019). Irrespective of the missing statistics in India, the GLOBOCAN (2018) cancer comparative ranking report listed MSCs as the 33rd and 31st cancer in India with regards to the number of new diagnoses and associated mortality, respectively (Dar and Sharma, 2020; "Global Cancer Observatory", 2020). According to the GLOBOCAN (2018) report, 3048 new cases and 2053 deaths were attributable to MSCs in India in 2018 (Dar and Sharma, 2020; "Global Cancer Observatory", 2020). Furthermore, MSCs were ranked as the 32nd most prevalent type of cancer in India in 2018, with 5-year prevalence of 7331 cases per 100,000 population (Dar and Sharma, 2020; "Global Cancer Observatory", 2020).

Skin cancer (NMSCs and MSCs) associated 5-year prevalence (2.8 per 100,000 population), age-standardized incidence rate (1.1 per 100,000 population cases) and age-

standardized mortality rate (0.53 per 100,000 population) in India are the highest among countries with medium Human Development Index (HDI) and countries belonging to the south-central Asian region ("Global Cancer Observatory", 2020). Even though the incidence of skin associated malignancies in India is lower when compared to other western countries, the absolute number of cases is estimated to be substantial because of the large population (Deo et al., 2005; Lal et al., 2016; Leiter et al, 2014; Juzeniene et al, 2014; Kumar et al., 2014). Despite the presumably high global burden of the disease, the low numbers in India and many other countries can be explained by lack of timely diagnosis, under-diagnosis and misdiagnosis (Gupta et al., 2016; Tucker and Goldstein, 2003; Zell et al., 2008).

2 Strategy appraisal

Several studies emphasize the need for population-based secondary preventative strategies to mitigate the global clinical, economic, and public health burden of skin cancer (Ciążyńska et al., 2018; Guy et al., 2015b; Karimkhani et al., 2017; Trakatelli et al., 2012; Thrift & Gudenkauf, 2019; Loomans-Kropp & Umar, 2019). According to the literature, the most effective population-level secondary screening strategy for skin cancer is the annual PHC physician administered visual screening (TBSE) (Bajaj et al., 2019; Ciążyńska et al., 2018; El-Kenawy et al., 2017; Grossman et al., 2018; Guy et al., 2015b; Helm et al., 2019; Hoorens et al., 2016; Johnson et al., 2017; Karimkhani et al., 2017; Moran et al., 2011; Trakatelli et al., 2012; Thrift & Gudenkauf, 2019; Ward et al., 2017; Woo et al., 2017). A study conducted in US suggest that implementation of TBSE may not just combat rising incidence and mortality associated with skin cancers, but will also have the potential to substantially decrease the national economic burden attributable to skin cancers by approximately 0.25 to 2 billion US dollars per year (Guy et al., 2015b). Based on this and the literature discussed above, the proposed program is aimed at incorporating TBSE in an annual routine check-up provided by PHC physicians in Delhi, India.

In the US, more than 50% of PHC providers recognize the importance of an annual TBSE (Johnson et al, 2017). However, in India and many other LMIC settings, TBSE is not included in the annual routine examination provided by the physicians because of lack of awareness (Ebell et al, 2019; Valachis et al, 2009). Several studies have demonstrated the cost-effectiveness of TBSE, both from a societal and public health care payer perspective (Helm et al, 2019; Pil et al, 2017; Karimkhani et al., 2015; Losina et al., 2007; Robinson and Halpern, 2016). For instance, based on the results of a clinical trial, it was reported that a one-time TBSE leads to a significant gain in QALYs in Belgium (Europe), with an incremental cost-effectiveness ratio[4] of 35,475 USD per QALY among men and 20,045 USD per QALY among women (Pil et al, 2017). Furthermore, annual TBSE screening for adults aged 18 years and above has been predicted to gain about 2380 healthy population life-years. In other words, a one-time TBSE screening can reduce the mortality from skin cancer by 5.6% at a cost of 4.40 US dollars per adult (Pil et al, 2017).

TBSE is not only cost-effective, but also a time-efficient screening method as it takes only about 2 to 4 minutes to visually examine the total epidermal surface (including scalp, genital area, and all mucousal membranes) of a patient using dermoscope as needed (Hartman et al., 2020; Helm et al, 2019; Hoorens et al., 2016). And, biopsy of the suspected skin lesion takes about additional 10 minutes per skin cancer detected (Hartman et al., 2020; Ogbechie et al., 2016). TBSE is a feasible screening tool as any physician trained for TBSE-skills can perform effective skin screening, regardless of their clinical experience (Helm et al, 2019).

There is limited evidence regarding the sensitivity and specificity of TBSE. However, literature supports that the sensitivity and specificity are slightly higher, when TBSE is

[4] "Incremental cost-effectiveness ratio: It is used to summarize the cost-effectiveness of competitive health care interventions to represent the economic value and evaluation of the intervention. The ratio is estimated by dividing the difference in cost of competitive interventions with the difference in their effect." (ICER, 2016)

performed by a dermatologist (Wernli et al, 2016). In a study aimed at detecting melanoma, it was reported that the sensitivity and specificity of TBSE performed by PHC physicians, were 40.2% and 86.1%, respectively (Wernli et al, 2016). In comparison, when TBSE was performed by dermatologists, the sensitivity and specificity increased to 49.0% and 97.6%, respectively (Wernli et al, 2016). Thus, to strike a balance between the screening costs and the effectiveness of TBSE, the proper training of PHC physicians in identification of skin integrity and precancerous lesions is suggested.

The theoretical principles of the program are based on the value-based healthcare (VBHC) approach, developed by Porter and Teisberg in 2006, which focuses on integrated holistic care for patients with skin cancer by improving health outcomes through provision of better quality of care at minimal service costs (Redondo et al., 2019). The VBHC framework is depicted in Appendix 1.

3 Program goals and objectives

3.1 Program goal

The overarching aim of the proposed program is to introduce and pilot TBSE in a primary health care setting as a skin cancer screening and prevention approach in All India Institute of Medical Sciences (AIIMS), Delhi, India.

3.2 Program objectives

The specific objectives of the pilot program include:

1) By the end of one year after training, there will be 30% relative improvement in the skin cancer screening behavior among the trained PHC physicians (Hartnett and O'Keefe, 2016; Markova et al., 2013; Robinson et al., 2018).
2) By the end of one year after training, there will be 40% relative improvement in the skin cancer screening intentions among the trained PHC physicians (Markova et al., 2013).

3) By the end of one year after training, there will be 60% relative improvement in the skin cancer screening skills among the trained PHC physicians (Markova et al., 2013).
4) By the end of one year after training, the total number of skin cancer cases detected per annum by the trained PHC physicians will increase by 30% (Markova et al., 2013).
5) By the end of one year after training, the proportion of annual skin cancer cases identified at an early stage by the trained PHC physicians will increase by 20% (Markova et al., 2013).

4 Program description

4.1 Program design

The proposed program will be designed as a randomized controlled trial in a public hospital, AIIMS, Delhi, with a daily average of 4,128 outpatient visits per day and approximately 1,506,791 patients in the general outpatient department in 2018-19, i.e. from 1st of April 2018 to 31st of March 2019 (AIIMS Annual Report 2018-2019, 2019). The PHC physicians will be the unit of analysis. The outpatient department patients in this hospital are assigned to a specific PHC physician for walk-in and follow-up visit(s). Each PHC physician serves about 40 patients per day (AIIMS Annual Report 2018-2019, 2019). There are more than 800 PHC physicians, including residents and faculty members, at AIIMS, Delhi (AIIMS Annual Report 2018-2019, 2019), out of which 190 PHC physicians will be randomly selected and assigned to an intervention group or a control group (see below).

The intervention group will be trained in conducting TBSE in PHC settings, using a web-based Basic Skin Cancer Triage (BSCT) Curriculum which employs active learning methods to emphasize the importance of PHC provider administered TBSE. The control group will not receive this training. A collaboration with a regional non-governmental organization (NGO), namely, Indian Cancer Society (ICS) will be established for the execution of the program.

4.2 Sample size

The sample size is calculated using the formula for comparing proportions in two independent equal groups. The sample size is calculated with the level of significance of 0.05 and power of 80%.

$$n = (z_{\alpha/2} + z_{\beta})^2 \frac{\{p_1(1-p_1) + p_2(1-p_2)\}}{(p_1-p_2)^2}$$

Since the majority of the available literature refers to the research conducted in high income countries, such as Germany, Australia, US, or Canada, the possibility of estimating a reliable proportion of the skin cancer cases detected at an early stage per annum for a LMIC, such as India, is limited. Hence, using the most conservative approach for sample size calculation, it can be assumed that p_1 = 60%, p_2 = 40%, therefore,

$n = (1.96 + 0.84)^2 \frac{\{0.6(1-0.6) + 0.4(1-0.4)\}}{(0.2)^2}$ = 95 per group, which implies total n = 190.

The participants will be recruited until the required sample size of 190 is achieved.

4.3 Outline of the proposed program

The proposed program will have three phases, namely, planning; implementation, and evaluation.

The planning phase will include (1) participant recruitment, and (2) allocation of resources. The implementation phase will include biphasic algorithm consisting of (1) physician-centered algorithm, and (2) patient-centered algorithm. The focus of the implementation phase will be on physicians training using web-based BSCT curriculum, conducting skin screening using TBSE in a PHC facility, referring suspicious skin lesions for biopsy and making treatment referral for positive biopsies. The evaluation phase of the program will include collecting data on the indicators, such as (1) change in provider behavior, intention and skills (2) total number of identified skin cancer cases, and (3) proportion of cases identified at an early stage.

4.4 Program timeline

The program timeline is illustrated in Appendix 2. The duration of the program will be 18 months. The planning phase will commence on the 1st of January, 2021 and last until 31st March, 2021. The implementation phase will commence on the 1st of February, 2021 and last until the 28th of February, 2022. The post-intervention evaluation will begin on the 1st of March, 2022 and conclude on the 31st of April, 2022. The project will tentatively conclude around 30th of June, 2022.

5 Program planning

5.1 Participant recruitment

The study participants, that is, PHC physicians, will be recruited from the general out-patient department at AIIMS hospital, Delhi. Participants will be randomized into two groups (intervention and control), by an independent statistician using a computer-generated randomization sequence. Block randomization method will be used to randomly assign equal number of participants into each group using 'Windows Random Allocation' software. The sample size will be imputed in the software and the two groups will be labeled as 'Group-1' and 'Group-2'. To control for selection bias, allocation concealment technique will be used, whereby the allocation sequence is concealed until the moment of assignment.

5.2 Allocation of resources

The strategy for allocation of resources will include optimizing the use of existing resources and budgeting for the required new resources.

5.2.1 Operational and material resources

The proposed program will be executed in an educational public hospital, AIIMS, in Delhi. The training materials and financial support will be provided by ICS. The training will

be conducted actively using digital technology with audio-visual aids in addition to web-based tutorial and reference materials.

As AIIMS is a teaching hospital which regularly conducts educational classes, the space for training of PHC physicians will be provided by AIIMS. Other material resources include monetary costs such as salary, educational supply costs, internet and maintenance charges. The web-based BSCT training materials are available online and the program will only need resources to purchase them.

5.2.2 Web-based BSCT curriculum

BSCT curriculum is an online continuing medical education (CME) program designed by a multidisciplinary team of medical and public health experts in the field of dermatology, primary health care services, psychology, social and behavioral sciences and medical education (Eide et al., 2013; Goulart et al., 2011; Hartnett et al., 2016; Lygidakis, McLoughlin and Patel, 2016; Markova et al., 2013).

The aims of BSCT curriculum are to strengthen the knowledge of physicians regarding skin cancer, improve visual skin inspection practices for the early detection of skin cancers and enhance physicians' skills in performing TBSE (Cook, 2007; Eide et al., 2013; Fordis et al., 2005; Goulart et al., 2011; Hartnett et al., 2016; Lygidakis et al., 2016; Markova et al., 2013).

BSCT is a two-hour curriculum which includes a stepwise diagnostic algorithm for detection of skin lesions using TBSE and 108 frames of case-scenarios (Hartnett et al., 2016; Lygidakis et al., 2016; Markova et al., 2013). The components of BSCT curriculum are – "welcome screen and navigation tutorial, general skin cancer introduction and epidemiology, clinical characteristics of skin lesions, and the BSCT algorithm" (Hartnett et al., 2016; Lygidakis et al., 2016; Markova et al., 2013).

The stepwise BSCT diagnostic algorithm focuses on improvement of physician skills to perform TBSE and it includes – skin lesion pattern identification, differentiation of benign and malignant lesions, steps to perform TBSE, clinical counseling of patients on skin cancer, skin biopsy referral strategies, and patient education regarding thorough skin self-examination (Eide et al., 2013; Goulart et al., 2011; Hartnett et al., 2016; Lygidakis et al., 2016). PHC physicians will also be trained to systematically approach patients and seek permission from the patients prior to performing TBSE. The trainers will not require any prior training as the web-based training package includes introduction of the program, explanations of all the key functions and layout for trainers. Hence, the role of trainers during the training will be limited to communication, management and effective organization of the training sessions.

5.2.3 Human resources

The human resources required for the program, include a student investigator as an outcome assessor, trainers for conducting trainings of PHC physicians at AIIMS, official representative of ICS at AIIMS, financial manager at ICS and a statistician.

The trainers for the training of PHC physicians will be provided by ICS. The ICS has a diverse workforce, consisting of physicians, nurses, public health educators, administrative staff, hospital coordinators, organizational collaborators, interns and volunteers. The trainers will be recruited through ICS based on their educational qualifications, experience and current role and position at ICS. In addition to the trainers, an official representative of the ICS will be appointed at AIIMS. The responsibilities of the official representative include scheduling physician trainings, managing educational supplies and digitalizing the records of trainings. Also, a financial manager will be appointed at ICS. The responsibilities of the financial manager will be to control the flow of funding on a monthly basis such as salary, training material costs, internet, and maintenance. A statistician at AIIMS will be responsible

for collating and registering the following indicators – number of TBSE conducted at PHC visit, number of biopsy referrals, number of confirmed skin cancer cases and the stage of cancer identified for each case. The student investigator will be responsible for hiring team members, allocating resources, coordinating the evaluation process including distribution and collection of the questionnaires, synthesizing the data, conducting data analyses and reporting the findings.

6 Program implementation

The timeline and contingency plans of the proposed project are developed based on a biphasic algorithm consisting of physician-centered algorithm and patient-centered algorithm.

6.1 Physician-centered algorithm

The physician-centered algorithm will be used to implement the training of PHC physicians. A trainer, recruited from ICS, will be appointed at AIIMS. The PHC physicians in the intervention group will receive the BSCT training. The physicians will be trained about the identification of cancerous skin lesions using the ABCDEF criteria, differential diagnosis of lesions, biopsy referral process of suspicious lesions, and treatment referrals for the positive biopsies. The physicians will also be trained regarding the follow up care of the patients.

6.2 Patient-centered algorithm

The patients visiting the outpatient department at AIIMS are randomly assigned to a PHC physician in their first visit and continue with the same PHC physician during follow-up visits. If the patient is assigned to a PHC physician belonging to the intervention group, the physician will provide a general medical check for the patient, and TBSE. The physician will assess all skin lesions using the skills acquired during the training process. A two-stage referral process will be implemented. The first referral stage will involve biopsy referrals of

any suspected skin lesions detected after TBSE. The second referral stage will involve treatment referrals for positive biopsies.

7 Program evaluation

The program evaluation design will be *pretest-posttest control group experimental design*, and it is depicted using the Campbell-Stanley nomenclature as follows –

R	O_1	X	O_2
R	O_3		O_4

7.1 Evaluation objectives

The specific evaluation objectives of the pilot program include:

1) By the end of one year after training, the trained physicians will demonstrate 30% relative improvement in the skin cancer screening behavior as compared to the non-trained physicians (Markova et al., 2013; Robinson et al., 2018).
2) By the end of one year after training, the trained physicians will demonstrate 40% relative improvement in the skin cancer screening intentions as compared to the non-trained physicians (Markova et al., 2013).
3) By the end of one year after training, the trained physicians will demonstrate 60% relative improvement in the skin cancer screening skills as compared to the non-trained physicians (Markova et al., 2013).
4) By the end of one year after training, the total number of skin cancer cases detected per annum by the trained physicians will increase by 30% as compared to the total number of skin cancer cases detected per annum by the non-trained physicians (Hartnett and O'Keefe, 2016; Markova et al., 2013).
5) By the end of one year after training, the proportion of annual skin cancer cases identified at an early stage by the trained physicians will increase by 20% as compared to the

proportion of annual skin cancer cases identified at an early stage by the non-trained physicians (Markova et al., 2013).

7.2 Evaluation indicators

The evaluation phase of the program will include indicators such as (1) change in provider behavior, intention and skills, (2) total number of identified skin cancer cases, and the proportion of cases identified at an early stage.

7.2.1 Change in provider behavior, intention and skills

Prior to the commencement of the training, a survey instrument will be provided to all the selected PHC physicians for the baseline assessment of physician's behavior, intention and skills (Appendix 3). Immediately after the training, a short survey will be administered to assess the physician's satisfaction and experience regarding the training (Curran, Fleet and Kirby, 2010; Deliberato et al., 2017; Gregory and Demartini, 2017) (Appendix 4). The follow-up assessments of the physician's behavior, intention and skills will be conducted one year after the training session through the same survey instrument which was administered at baseline (Appendix 3) in order to avoid instrumentation bias. The evaluation will be conducted among all physicians, that is, all the selected participants will undergo the baseline and the follow-up assessment after one year, regardless of their assignment status. The student investigator will be blind to physician assignment status. The survey will be self-administered. The instrument comprises of close-ended items regarding the demographical information of the physician and three conceptual domains measured using five-point Likert scale. The survey instrument is adopted from similar studies and adapted to context (Curran et al., 2010; Deliberato et al., 2017; Gregory et al., 2017; Harris et al., 2001; Hartnett et al., 2016; Markova et al., 2013). The instrument to evaluate physician's behavior, intentions and skills is attached in Appendix 3 and the instrument to evaluate physician's experience is attached in Appendix 4.

7.2.2 Total number of identified skin cancer cases, and the proportion of cases identified at an early stage

The indicators such as number of TBSE conducted at PHC visit, number of biopsy referrals, number of confirmed skin cancer cases and the stage of cancer identified for each case will be registered using a standardized record review form for each patient. The record review form will be included with the medical charts of a patient to record and manage the data related to the skin cancer screening and referrals. It will be completed by the physicians and will also include a component to record physician's ID, which will assist the statistician to identify the intervention or control status of the participant during the analyses. The record review form is attached in Appendix 5.

8 Budget

The budgeting of the program will primarily include the salaries of the team members such as trainers, official representative, financial manager, statistician, cost of online purchasable training materials, stationaries and internet connection charges. The estimated budget for the entire pilot program is calculated as 3,670 USD. The budget is given in Appendix 6.

9 Risk analysis

The project will seek collaboration with AIIMS in Delhi, since it is a public hospital, a teaching institute, and a research center. However, in case of refusal or unsuccessful collaboration with AIIMS, one PHC facility will be chosen at random from the pool of all government PHC facilities in Delhi. Similarly, in case of refusal from ICS, one regional NGO will be selected at random from the list of all the NGOs in Delhi. The random selection will be done using the RANDBETWEEN function in Excel.

The cost-effectiveness ratio per QALY for TBSE estimated for the program is based on evidence from high income countries, which usually have higher HDI. The reason for this estimation is the lack of literature and dearth of evidence in LMIC such as India. Hence, the cost-effectiveness ratio per QALY after TBSE program implementation in India is at a risk of overestimation.

Since the proposed program randomizes the participants in the same facility, there might be a risk of potential contamination as the control group participants may acquire information about the intervention from their colleagues. The burden of the proposed study also extends to the patients examined by the study participants since they are at a risk of obtaining false positive results which may lead to unwarranted stress. There may also be potential cultural and gender barriers as patients might be unwilling or uncomfortable to undergo visual examination of the entire skin surface including genital region, especially when the exam is conducted by a physician of the opposite-gender.

10 Ethical considerations

An informed oral consent will be sought from the study participants. The study participants will be informed about the general theme of the project and their rights such as voluntary participation, confidentiality of information and the liberty to pause or terminate their participation in the program without any risks or harm. Physicians will be required to seek permission from the patients before conducting TBSE. The patients will be informed about the TBSE procedure, and their right to confidentiality and refusal to participate will be emphasized by the physicians prior to conducting TBSE. The oral consent is attached in Appendix 7. The protocols of the proposal comply with the requirements of the Institutional Review Board (IRB) at the American University of Armenia (AUA). After obtaining funding to implement the proposed project, the project will seek approval from the AUA IRB and local IRB in Delhi prior to starting the project.

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Appendices

Appendix 1 – Theoretical framework: Value-based healthcare (VBHC)

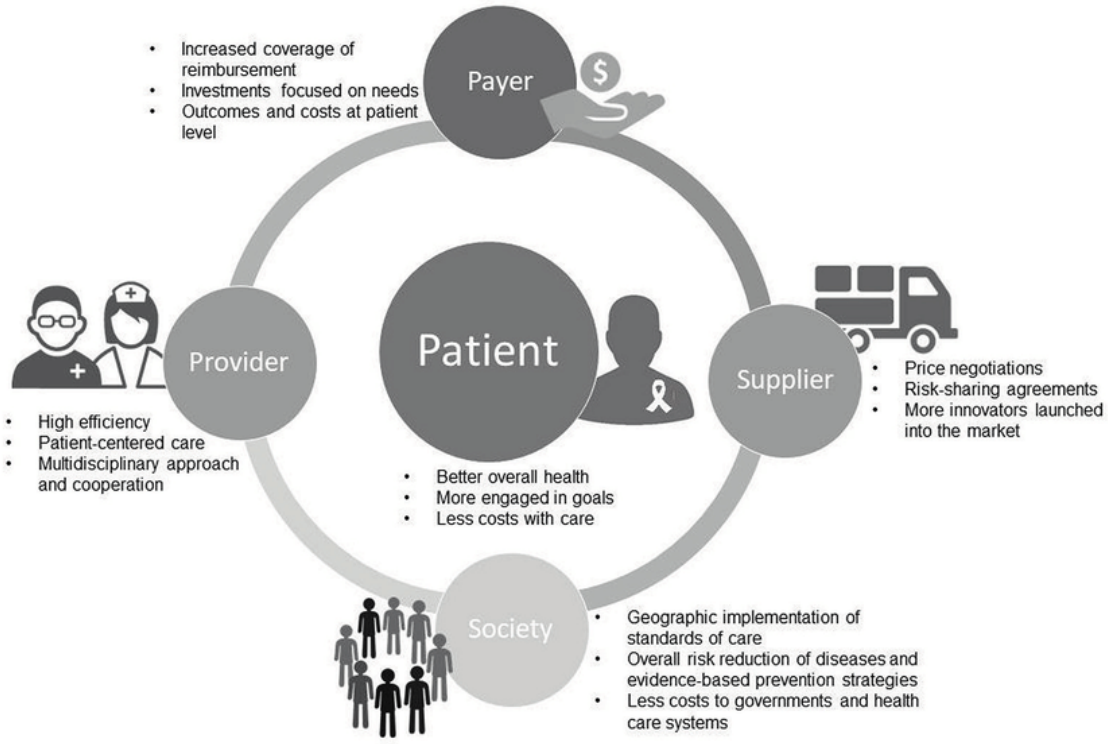

Figure 1: Benefits of value-based healthcare in the full-cycle system of integrated practice units to provide effective care and better survival outcomes. (Redondo et al., 2019)

Appendix 2 – GANTT contingency chart

Monthly Project Schedule

	Start Date	Jan 1, 2021

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
	Jan '21	Feb '21	Mar '21	Apr '21	May '21	Jun '21	Jul '21	Aug '21	Sep '21	Oct '21	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22	Apr '22	May '22	Jun '22
Phase One (Planning)	Participant Recruitment																	
	Allocation of Resources																	
Phase Two (Implementation)		BSCT for PHC physicians																
				Conducting TBSE at the pilot PHC facilitiy														
				Biopsy referrals of suspicious skin lesions														
Phase Three	Baseline Data Collection (physician-centered indicators)																	
	Baseline Data Collection (case-centered indicators)																	
				Follow-up Data Collection (physician's experience)														
(Evaluation)															Follow-up Data Collection			
															Data entry			
																	Data Analysis	
																	Report Writing	

Figure 2: Monthly project schedule using GANTT contingency chart

Appendix 3 – Survey instrument (Physician's Behavior, Intentions, and Skills)

Physician ID _____

Date ____/____/____ (dd/mm/yyyy)

A. General Demographic Information

1) Please indicate your date of birth.

   ____/____ (mm/yyyy)

2) Please indicate your gender.

   1. ☐ Male

   2. ☐ Female

3) Please indicate your qualification.

   1. ☐ MBBS

   2. ☐ MD, Internal Medicine

   3. ☐ MD, Family Medicine

   4. ☐ MD, Internal Medicine and Pediatrics

   5. ☐ Other Please specify _____

4) Please indicate your clinical experience in years.

   _____ years

5) Please indicate if you have participated in any dermatology training programs in the last one year.

1. ☐ Yes
2. ☐ No
3. ☐ Refuse to answer

B. Physician's Behavior

6) During an annual exam, how frequently do you perform a total body skin examination?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

7) During an annual exam, how frequently do you provide patients with counseling, resources, or materials to assist them to reduce their risk of skin cancer?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

8) During an annual exam, how frequently do you provide patients with counseling, resources, or materials to assist them to examine their skin and identify skin lesions that require further evaluation?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

9) During an annual exam, how frequently do you refer patients to a dermatologist for issues related to skin cancer?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always, (when indicated)

C. Physician's Intentions

10) How often have you considered discussing skin cancer detection techniques, such as self-skin examination with your patients during an initial history-taking in a walk-in patient visit?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

11) How often have you considered discussing skin cancer risk factors and prevention strategies, such as regulating daily sun exposure duration or using sun protection, with your patients during an initial history-taking in a walk-in patient visit?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

12) How often have you considered discussing skin cancer detection techniques such as self-skin examination, with your patients during an annual health checkup?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

13) How often have you considered discussing skin cancer risk factors and prevention strategies, such as regulating daily sun exposure duration or using sun protection, with your patients during an annual health checkup?

1. ☐ Never 2. ☐ Rarely 3. ☐Sometimes 4. ☐ Often 5. ☐ Always

D. Physician's Skills

14) How confident are you in your ability to counsel patients about reducing sun exposure?

1. ☐ Not confident at all
2. ☐ Slightly confident

3. ☐ Somewhat confident
4. ☐ Fairly confident
5. ☐ Very confident

15) How confident are you in your ability to perform a total body skin examination (TBSE) for skin cancer detection?

1. ☐ Not confident at all
2. ☐ Slightly confident
3. ☐ Somewhat confident
4. ☐ Fairly confident
5. ☐ Very confident

16) How confident are you to examine skin lesions using the ABCDEF criteria?

1. ☐ Not confident at all
2. ☐ Slightly confident
3. ☐ Somewhat confident
4. ☐ Fairly confident
5. ☐ Very confident

17) How confident are you in your ability to identify suspected skin lesions?

1. ☐ Not confident at all
2. ☐ Slightly confident
3. ☐ Somewhat confident
4. ☐ Fairly confident
5. ☐ Very confident

Appendix 4 – Survey instrument (Physician's Experience)

1) Have you completed the web-based BSCT training in March 2021?

   1. ☐ Yes

   2. ☐ No

   If Yes, please continue.

   If No, please end the survey here……..…Thank you for your participation!

2) How would you rate your overall training experience?

   1. ☐ Excellent

   2. ☐ Good

   3. ☐ Average

   4. ☐ Poor

   5. ☐ Very poor

3) How would you rate the quality of web-based BSCT training?

   1. ☐ Very Good

   2. ☐ Good

   3. ☐ Neither good nor poor

   4. ☐ Poor

   5. ☐ Very poor

4) How would you rate the difficulty level of the final online quiz at the end of the web-based BSCT training?

   1. ☐ Very difficult

2. ☐ Difficult

3. ☐ Average

4. ☐ Easy

5. ☐ Very easy

6. ☐ I did not take the quiz

5) How would you rate the perceived intensity of the workload during the training?

1. ☐ Extremely heavy

2. ☐ Heavy

3. ☐ Adequate

4. ☐ Light

5. ☐ Extremely light

For the following items, please indicate to what extent do you agree with the following statements.

6) The training was useful for my professional career.

1. ☐ Strongly agree

2. ☐ Agree

3. ☐ Neither agree nor disagree

4. ☐ Disagree

5. ☐ Strongly disagree

7) The content of the training addressed my learning needs.

1. ☐ Strongly agree

2. ☐ Agree

3. ☐ Neither agree nor disagree

4. ☐ Disagree

5. ☐ Strongly disagree

8) The training was directly applicable in my clinical practice.

1. ☐ Strongly agree

2. ☐ Agree

3. ☐ Neither agree nor disagree

4. ☐ Disagree

5. ☐ Strongly disagree

9) The content of the training was clear and easy to understand.

1. ☐ Strongly agree

2. ☐ Agree

3. ☐ Neither agree nor disagree

4. ☐ Disagree

5. ☐ Strongly disagree

10) I received adequate help with technical problems.

1. ☐ Strongly agree

2. ☐ Agree

3. ☐ Neither agree nor disagree

4. ☐ Disagree

5. ☐ Strongly disagree

11) I prefer the online mode of training.

1. ☐ Strongly agree
2. ☐ Agree
3. ☐ Neither agree nor disagree
4. ☐ Disagree
5. ☐ Strongly disagree

12) I would recommend the training to my peers.

1. ☐ Strongly agree
2. ☐ Agree
3. ☐ Neither agree nor disagree
4. ☐ Disagree
5. ☐ Strongly disagree

Thank you for your participation!

Appendix 5 – Record review form

Physician ID _____

Patient ID _____

Date ____/____/____ (dd/mm/yyyy)

1)	Was TBSE performed in this visit?	1.☐ Yes 2.☐ No
2)	Were skin cancer risk factors identified in this visit?	1.☐ Yes 2.☐ No
3)	Was skin cancer prevention counselling provided to patient in this visit?	1.☐ Yes 2.☐ No
4)	Were any suspicious skin lesions identified in this visit?	1.☐ Yes 2.☐ No If No, please stop
5)	Was skin lesion biopsy referral made in this visit?	1.☐ Yes 2.☐ No
6)	Which stage of skin cancer was detected by biopsy?	1.☐ Stage 1 2.☐ Stage 2

		3.☐ Stage 3 4.☐ Stage 4
7)	Was treatment referral made for the patient?	1.☐ Yes 2.☐ No

Appendix 6 – Budget

Personnel/Item	**Quantity**	**Cost/ Salary (per month)**	**Duration**	**Amount in Indian Rupees (Quantity*Cost*Duration)**	**Amount in US Dollars (1 USD = 75.50 INR)**
Web-based-BSCT	01	3,350 INR	02 months	6,700 INR	88.74 USD
Internet connection	01	1,500 INR	02 months	3,000 INR	39.73 USD
Stationary	50	1,200 INR	02 months	2,400 INR	31.79 USD
Trainers	10	10,000 INR	02 months	100,000 INR	1324.50 USD
Official representative	01	5,000 INR	02 months	10,000 INR	132.45 USD
Statistician	01	10,000 INR	12 months	120,000 INR	1589.40 USD
Financial manager	01	7,000 INR	05 months	35,000 INR	463.58 USD
Student investigator	01	In-kind	18 months	In-kind	In-kind
Total				**277,100 INR**	**3,670 USD (approx.)**

Appendix 7 – Consent form

American University of Armenia
Institutional Review Board # 1
Oral Consent Form

Hello, my name is Darshan Shingala, and I am a graduate student of the Master of Public Health program at the American University of Armenia (AUA) and of the General Medicine faculty at the Yerevan State Medical University (YSMU).

Turpanjian School of Public Health in collaboration with All India Institute of Medical Science, Delhi (AIIMS) and Indian Cancer Society (ICS) is conducting a study to investigate the effectiveness of a web-based educational training program among primary health care physicians. You were selected randomly from the pool of primary health care physicians at AIIMS, Delhi. I invite you to participate in this study as you currently serve as a primary health care physician at AIIMS, Delhi.

The study is a Randomized Controlled Trial, meaning that you will be randomly assigned into either an intervention group or a control group. Thus, your participation entails a randomization process, and I will orally convey the group assigned to you as soon as the decision is available. If you are selected in the intervention group, you will be requested to undertake a web-based medical education training course designed by a multidisciplinary team of medical and public health experts. It is a two-hour curriculum which includes clinical information such as stepwise diagnostic algorithm and 108 frames of case-scenarios. Undertaking the training will help you to gain evidence-based medical knowledge and enhance your clinical practice in community-based medical diagnoses and prevention. If you are selected in the control group, the same web-based training program will be made available to you after completion of the study, such that you will receive an equal opportunity to gain evidence-based medical knowledge and enhance your clinical skills in community-based medical diagnoses and prevention.

As part of your participation in the study, we will ask you to complete a short survey before commencement of the training and one year after the completion of the training. The survey will include close-ended questions to assess the changes in behavior, intention and skills regarding secondary clinical prevention strategies. The survey will take no longer than 5-7 minutes. During your everyday practice, you will also be asked to complete a short record review form for each patient along with their medical charts, which would take no longer than 1-2 minutes.

Your participation in this study is voluntary. There are no risks associated with your refusal to participate. You can withdraw from the study at any time point without penalty. The information provided by you will remain confidential and will be used only for academic research purposes. After completion of the study, the information obtained from all the study participants will be collated into a report and the data will be presented in aggregate. Only summarized information will be reported without any personally identifiable information.

Your participation in this study will substantially contribute to the development of future interventions which may be implemented at a population level to mitigate the public health burden and promote better community health. Your participation is highly valuable, and I sincerely acknowledge your time and effort.

If you have any queries or concerns regarding the study, you may contact my primary advisor, Dr. Ani Movsisyan, via email: ani.movsisyan@ibe.med.uni-muenchen.de or via phone: +374 60 612 592. In case during the study, you experience unfair or offensive treatment, you may contact the Human Protections Administrator at AUA Institutional Review Board (IRB), Varduhi Hayrumyan, via email: vhayrumyan@aua.am or via phone: +374 60 612 561.

Do you agree to participate?

Thank you.