TLI FOUNDATION

HEALTH INNOVATION & THOUGHT LEADERSHIP MONTH

WHITE PAPER

AT THE INTERSECTION OF THOUGHT LEADERSHIP & INNOVATION: WHERE MEANINGFUL HEALTHCARE CHANGES HAPPEN

PART 1

April 2021 has been officially designated as a national Healthcare Thought Leadership & Innovation Month in the Health Observances & Recognition Days calendar published by ***The Society for Health Care Strategy & Market Development*** *(SHSMD), part of the* ***American Hospital Association*** *(AHA).*

SHSMD releases this calendar every year to provide healthcare strategists with practical, timely ***resources****. The Thought Leadership and Innovation Foundation (TLI), a not-for-profit organization, serves as the proud sponsor of this month-long event.*

As thought leadership serves as a key foundation for high performance, successful innovators recognize that strategic use of data remains fundamental to sustainable progress in improving healthcare in the United States. Now more than ever, thought leadership holds an important key to effecting positive changes, with higher stakes resulting from COVID-19 and its impact on individuals, behavioral health and the economy.

Leaders throughout the healthcare and related business ecosystem need an organization to help them think through complex, highly challenging issues. For more than a decade, the Thought Leadership & Innovation Foundation (TLI) has developed an approach for tackling these tenacious problems at the community, regional and national levels. Over the years, we have taken on issues related to healthcare redesign, including limb loss, the opioid epidemic and regenerative medicine – to name a few. TLI's methodology and track record for deriving innovation from data in each project drives the thinking behind our mission and processes.

We work at the nexus of science, technology and healthcare, recognizing the promise of big data in measuring improvement in better patient outcomes, improved economic efficiency for healthcare delivery and enhanced resilience to the threats of pandemics. We research other societal crises that impact individual well-being and mental health, such as natural disasters or opioid misuse and addiction.

No longer an issue of solely dedicating financial resources, the COVID-19 pandemic and associated crises validate the need for an effective strategy built around a collective commitment to transform thinking into initiating coherent, mutually reinforced actions, policies and behaviors. With shared goals and solutions aimed at achieving alignment among diverse groups, the nations' communities, both urban and rural, can realize meaningful change.

WHO WE ARE:
THOUGHT LEADERSHIP & INNOVATION FOUNDATION

An important part of our mission aims to better support underserved patient populations most harshly impacted by these problems. We embed this value proposition across programs covering chronic disease and economic empowerment and continue to serve specific groups of people when the need for greater support becomes evident.

Tackling these and other critical health challenges exemplifies TLI: a not-for-profit organization that helps communities across the country to successfully address serious issues by deploying a coordinated, cohesive set of actions to effect change in healthcare. Today, growing demand exists for thoughtful, practical and sustainable solutions.

In the past 10 years, TLI has worked with federal and commercial organizations, as well as partners around the world. Guided by experienced leadership, our teams have learned tremendous lessons that can be applied to current challenges. Positioned as more than a think tank, TLI serves as a change agent that designs data analysis tools and implements collaborative programs with intent, process, diligence, broadmindedness, humility and a touch of humor.

Because few people can grasp what effective healthcare looks like, TLI focuses upon carefully thinking and innovating in a coordinated fashion, always aware that second and third order consequences can be devastating, despite good intentions. The opportunity lies in remaining persistent and building programs and performance measures that lead to genuine transformation.

TLI PROJECTS
REFLECT SPECIFIC ORGANIZATION MODELS

A pipeline of innovation projects and a product/service line development team responsible for identifying technology partners, stitching technologies and methodologies together for robust solutions and developing service lines and internal tools.

INNOVATION HUB

COLLABORATIVE MODEL

This hybrid model brings together relevant groups and stakeholders – especially those who have not traditionally been included – to overcome the deep societal challenges related to health and well-being that currently threaten to undermine our nation's communities.

A comprehensive toolset, implemented in planned phases, benefits the participating organizations and establishes a governance mechanism to provide ongoing oversight.

DATA ANALYTICS TOOLSET

CLINICAL RESEARCH

Superfunds dedicated to research and implementation of innovative technologies to advance understanding of diseases, as well as the relationship between chronic infection and chronic illness, increased diagnostic capabilities and healthcare redesign to achieve improved patient functionality and outcomes.

MAYO CLINIC AND TLI: EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE FOR CHILD HEALTH AND HUMAN DEVELOPMENT LIMB LOSS AND PREVENTION REGISTRY

As a subcontractor to the Mayo Clinic, TLI currently supports the National Institute of Health (NIH) and the National Institute of Child Health and Human Development (NICHD) in the development and launch of a Limb Loss and Preservation Registry (LLPR). For the past two years, TLI has worked with the Mayo Clinic, the American Joint Replacement Registry (AJRR), and the American Orthotic & Prosthetic Association (AOPA) to advance rehabilitation of individuals who have undergone limb loss and limb preservation surgeries.

TLI's scientific experts have worked for many years with civilian and military experts in limb loss and limb preservation to standardize, measure and report patient outcomes data. Our work supports evidence-based decision making, enhancing healthcare delivery and establishing and disseminating best practices to further reintegrate strategies following neuro-musculoskeletal injury or loss resulting from diseases, such as diabetes.

Each year, approximately 200,000 non-traumatic amputations occur, with African Americans four times more likely to experience diabetes-related amputation than whites. In the United States, every 17 seconds someone receives a diagnosis of diabetes, and every day 230 Americans with diabetes will suffer an amputation. Throughout the world, estimates show that every 30 seconds someone has a leg amputated, with 85% of these amputations the result of a diabetic foot ulcer.[1]

Supported by the NIH, the database will be the first national registry in the United States of its kind to include adults and children. Collecting data could lead to prevention of limb loss and improve pre- and post-surgical treatment and rehabilitation efforts for this population.

The LLPR, projected to be operational in 2022, will become available to researchers studying medical conditions that contribute to limb loss, such as diabetes and vascular disease. In addition, the research community will be able to analyze the data by age, gender and type of limb loss or preservation surgery to support decision making for long-term healthcare of these patients to enhance their functionality and quality of life.

The development of the LLPR will demographically and geographically represent the U.S. population. Improving the quality of healthcare for active military personnel and veterans, and highlighting the ongoing coordination and collaboration among federal partners in rehabilitation research will lead to one outcome.

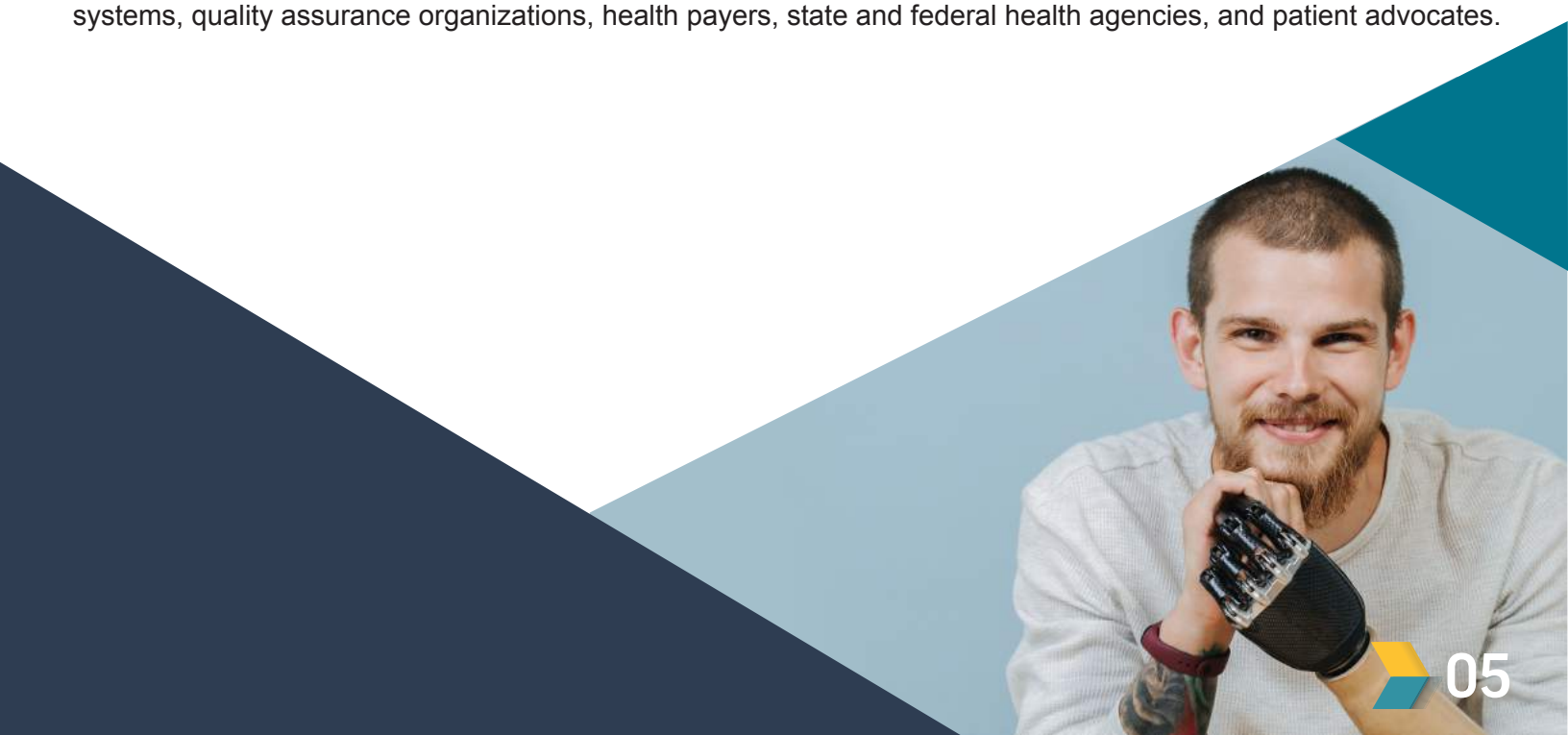
REPORT TO THE AMERICAN ORTHOTIC AND PROSTHETIC ASSOCIATION

TLI and the Mayo Clinic partnered in 2015 to submit a report to the American Orthotic and Prosthetic Association (AOPA). The purpose of our research and analysis focused on producing a preliminary list of data elements that can be used in a national orthotic and prosthetic (O&P) registry and assess the feasibility of populating the database with valid data. The report documented our findings regarding the initial concepts, feasibility and considerations necessary for the development and the operation of a National Orthotic and Prosthetic Registry (NOPR). Our research and analysis centered on the following primary areas of concern:

- **Data availability** – Can we get the data we need?
- **Data organization** – How should we organize the data effectively?
- **Partnership model** – Are there opportunities to leverage the experience and investment of others?
- **Technical model** – What technical considerations exist in our operating model?
- **Business model** – How should we operate and what is the sustainability model?
- **Impact** – What is the value to our O&P community and healthcare writ large of this effort?

The provision of O&P patient healthcare nationally represents an audit intensive environment in the post-Affordable Care Act time period. CMS/Medicare contractors have explicitly challenged O&P patient healthcare providers with pre-payment audits of every claim filed for more advanced prosthetic technology while less advanced prosthetics technology goes unchallenged. This has placed prosthetists in a difficult situation where they must face the choice between providing a less advanced technology, which may be less appropriate for the patient but would be paid without bureaucratic intervention. Or they may provide the patient with more advanced technology and face a potentially lengthy period of pre-payment audit. TLI and Mayo Clinic saw the need for a national database to document the quality of healthcare provided by orthotists and prosthetists.

Another driving factor: the need for improvement in the quality of healthcare provided in the healthcare industry. The Institute of Medicine report “Crossing the Quality Chasm” (2001) offered a set of performance expectations for the 21st century healthcare system, which included a set of new rules to guide patient-to-clinician relationships, align payment and accountability with improvements in quality, promote evidence-based practice and strengthen clinical information systems. To meet these expectations, we found it necessary to design a sustainable national registry and include collaboration among key partners in medical research and policy, healthcare providers, healthcare systems, quality assurance organizations, health payers, state and federal health agencies, and patient advocates.

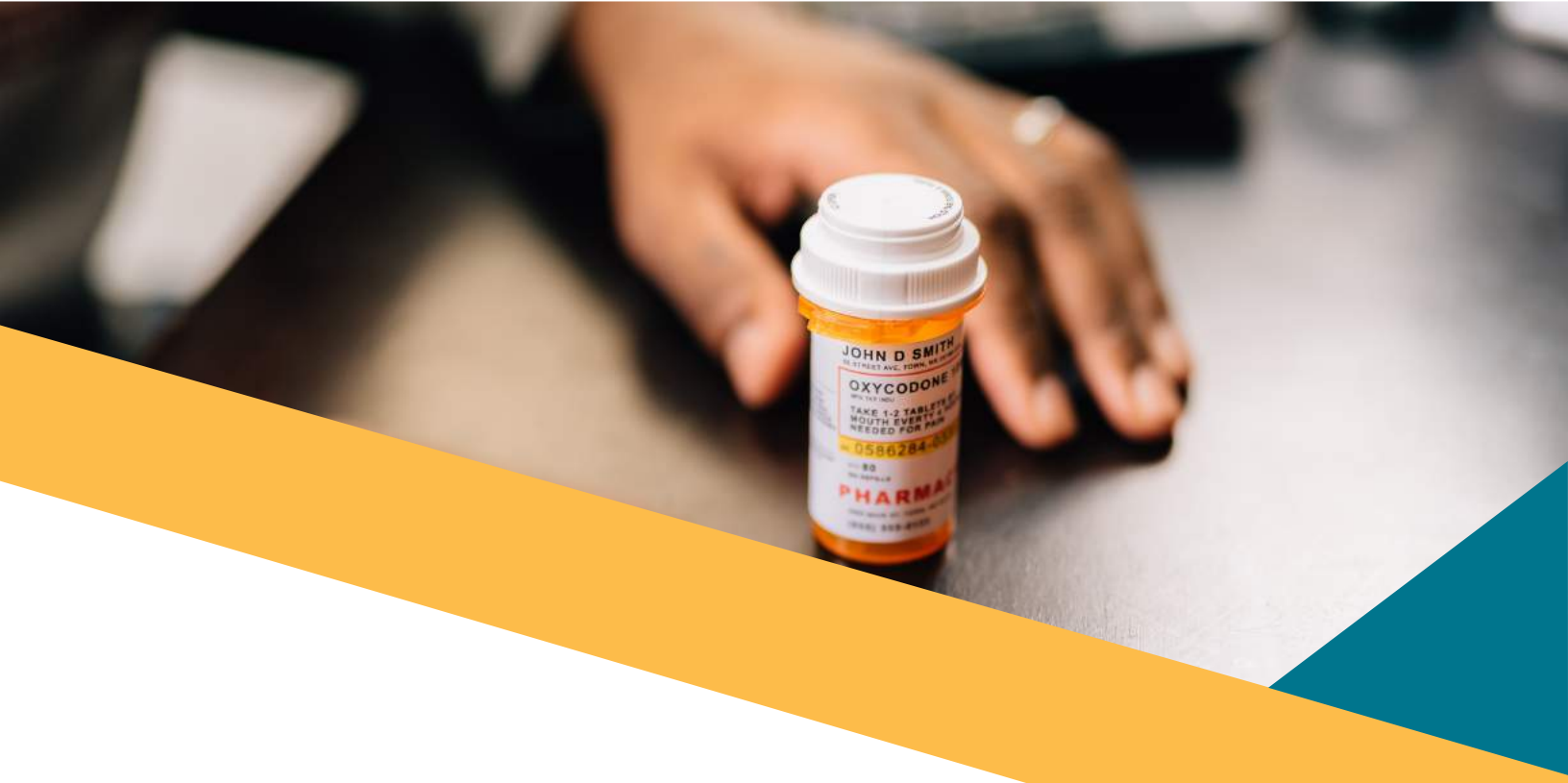


SOCIETAL LEVERS ACTIVATE THOUGHT LEADERSHIP & INNOVATION

With leadership transitions underway at many levels of local and national government, the opportunity and pathway to meaningful healthcare changes becomes more distinct. While elected officials debate the twists and turns of a regulatory environment, the fact remains that the United States spends substantially more on healthcare compared to other nations.

Despite these high costs, our healthcare system has failed to generate better health outcomes,[2] hindering efforts to mitigate the impact of the COVID-19 pandemic and leaving people unable to pay for tests or treatments.[3] Four chronic diseases—heart disease, cancer, stroke and diabetes—cause almost two-thirds of all deaths each year.[4] Chronic diseases account for 75% of the money our nation spends on healthcare, yet only 1% of health dollars are spent on public efforts to improve overall health. High healthcare spending does not necessarily represent a negative factor, especially if it leads to better health outcomes. In the United States, however, we lag behind other countries, despite higher healthcare spending.[5]

These results and rising healthcare prices are largely driven by the nation's aging population,[6] growth of Medicaid and indigent healthcare,[7] and a myriad of additional challenges, such as healthcare disparities, barriers to healthcare access, social determinants of health (SDOH), drug and alcohol abuse, and persistent behavioral/mental health issues.



LAC^3

The Los Angeles (LA) County Departments of Public Health and Mental Health worked with the Los Angeles County Community Collaborative (LAC^3), an incubator of innovation to address the nation's opioid crisis. LAC^3 partnered with the **LA County Department of Public Health**, the **Department of Mental Health** and TLI. Guided by a universal prevention framework, LAC^3 aims to promote social and environmental conditions that protect communities from the harms of opioid use.

This project builds on LA County's existing efforts, including the countywide opioid coalition known as Safe Med LA (**www.SafeMedLA.org**), to engage a wide range of sectors representative of the County's diversity. LAC^3 fosters public-private partnerships and supports key stakeholder actions via a community-based collaborative. The collaborative focuses on early drivers of this public health crisis, such as socioeconomic disparities, structural racism, resource inequities and social isolation.

LAC^3 brings together organizations throughout LA County to coordinate, collaborate and innovate to deal with the root causes of this public health crisis. The opioid crisis represents both a public health and community emergency requiring a response that depends on meaningful engagement with people struggling with substance use and their family members, healthcare providers, community leaders and the many neighborhood-based organizations that offer services and supports to residents. LAC^3 aims to build these partnerships and take collective action to address the upstream drivers of the opioid crisis.

LAC^3 takes a coordinated, community-centric approach to addressing the opioid crisis in the community and identifying a lasting solution for Los Angeles County. Every participant in this collaborative recognizes that a unilateral, top-down approach cannot solve a crisis this complex and pervasive within a community as large as Los Angeles County. They believe very strongly that a true solution to this crisis can be found only through robust collaboration with the community to find a community-based solution driven by mutual respect, understanding and awareness. Community partnership and shared purpose with healthcare providers are central to this endeavor.

REGENERATIVE MEDICINE AND CHRONIC DISEASE

With an emphasis on the discovery of infectious determinants of chronic diseases, a goal to reduce chronic disease worldwide and the dedication to make significant advances in regenerative medicine, TLI partnered with hospital systems and academic institutions and invited donor support for the continuation of vital research poised to lead to earlier prevention and treatment of infection, becoming the opportunity to avoid irreversible or severe chronic disease across large underserved populations.

While numerous causal relationships are scientifically established, chronic diseases often result from masked chronic infections, with the need for continued research to detect and confirm additional links. This project explores new capabilities to prove causality of chronic infection, open the door to new treatment plans and public health programs, and reduce the number and severity of chronic diseases globally. If only 5% of chronic diseases are attributable to infectious agents, in the United States alone, approximately 4.5 million of the 90 million people living with chronic disease might receive benefit from these new plans and programs.

Researchers have intently investigated infections caused by bacteria for well over 100 years, and modern treatments and medicines now control or have defeated those once considered deadly. However, most of the research conducted to date has targeted acute rather than chronic infections.

Current research conducted by TLI Fellows Dr. Bob Mozayeni and Dr. Marna Ericson indicate that biofilms play an important factor in chronic diseases, such as Lyme disease, Bartonellosis, rheumatoid arthritis, lupus, neuropsychiatric diseases and Crohn's disease. Experts now recognize that up to 80% of all bacterial infections in our bodies live in biofilms, which enable bacteria to grow in protective film-covered clusters. These biofilm bacteria often persist undetected and undiagnosed, causing chronic illness by fostering the growth of microbes that contribute to inflammation.

Researchers assert that biofilms may be unrecognized stages in the pathways from infection exposure to chronic illness and are likely to determine a substantially greater, and potentially preventable, number of chronic illness cases than currently thought. TLI has served as a partner in exploring biofilms as they relate to chronic disease for four years. Because new strategies must build on sound scientific evidence, TLI has established a Regenerative Medicine program with the infrastructure to support the continuation of this work, development of additional grant-funded research and other initiatives. Regenerative medicine entails the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage or congenital defects.

LOOKING AHEAD

A number of organizations striving to address healthcare issues falter at effectively collecting and analyzing the vast amounts of data they need to effect actual, sustainable change across communities in the United States. TLI's thought leadership and data expertise propels critical projects aimed at resolving intractable issues.

In part two of this two-part series, we explore critical areas for innovation, including societal factors that must be addressed, the impact of COVID-19 on behavioral health and our work with the U.S. military's Operation Live Well.

DOWNLOAD PART 2 OF "AT THE INTERSECTION OF THOUGHT LEADERSHIP & INNOVATION: WHERE MEANINGFUL HEALTHCARE CHANGES HAPPEN" HERE.

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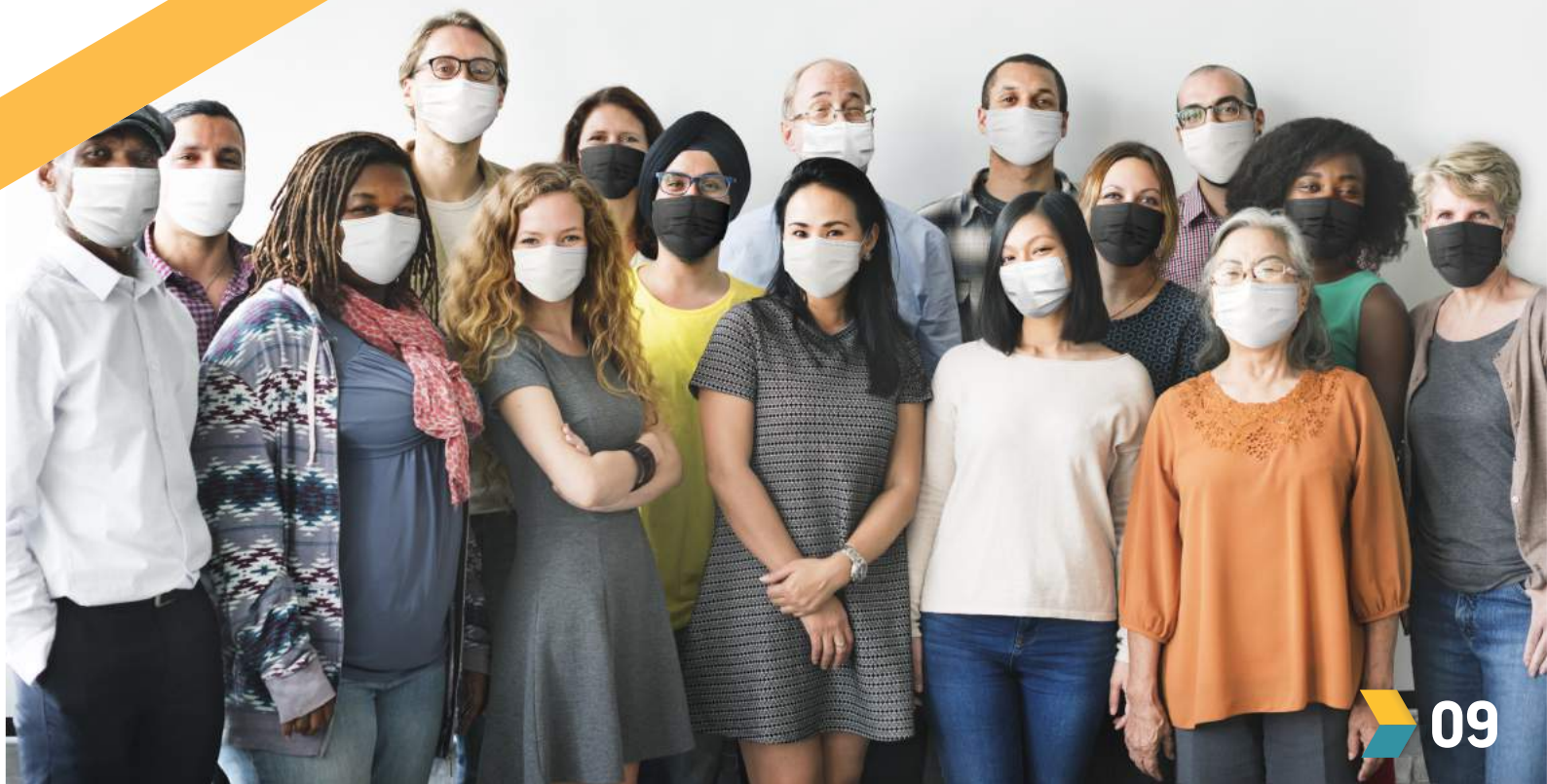

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[5] Kurani, 2020.

[6] Kurani, 2020.

[7] Kurani, 2020.

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