KNCV TUBERCULOSIS FOUNDATION

STRATEGIC PLAN 2020/2025

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***The marked text** in these chapters has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.*

Cover photo: Exceedingly joyous, back to singing again!, "How happy I was when I could return to my favorite hobby of singing!" **Photographer:** Enem Idiong, **participant KNCV's TB Photovoices in Uyo, Nigeria.**

‘Our mission is to end human suffering due to TB through the global elimination of tuberculosis’

Dr. Mustapha Gidado

1. PURPOSE, MISSION, VISION AND GUIDING PRINCIPLES

KNCV Tuberculosis Foundation is an international non-profit organization dedicated to the fight against tuberculosis. TB is the deadliest infectious disease in the world, 10 million new TB patients annually and over 1.4 million people dying from TB in 2018 alone, leaving families behind in despair and poverty.

WHO estimates that one quarter of the world population is infected with TB. However, preventive interventions to diagnose and treat latent TB infection are grossly underutilized worldwide.
A patient’s journey from infection to being diagnosed and started on the correct treatment is frequently unnecessarily protracted and incurring catastrophic costs for affected families. The treatment itself is long, difficult and expensive, especially for drug-resistant forms of TB.

KNCV has been fighting TB since its establishment in 1903 as a collaborative effort by several private local TB control initiatives in the Netherlands. Over the past 116 years, the organization has acquired indispensable knowledge and experience in the field of effective TB control, resulting in pre-elimination in the Netherlands and significant contributions to global evidence generation, policy development and TB program implementation worldwide.

KNCV track record includes over four decades of technical assistance to over 35 National TB programs (NTPs) worldwide. An important milestone was the development and the successful piloting of the DOTS strategy, which eventually was embraced by WHO as its core strategy to fight TB. In the 1990’s KNCV assisted countries with the countrywide introduction of ‘DOTS’, while developing strategies to prevent, detect and address the emerging TB/HIV and drug-resistant TB epidemics. Since the late nineties, KNCV has played a crucial role in leading the global response to multidrug-resistant TB (MDR-TB) through chair positions of global MDR-TB response mechanisms such as the WHO Green Light Committee for access to second line drugs and the Stop TB Partnership MDR-TB Working Group. KNCV contributed to virtually all WHO TB guidelines and was – and still is - member of the WHO Strategic and Technical Advisory Group. The combination of research, policy development and TB program expertise and experience under one roof, has allowed KNCV to test and bring innovations to scale within the context of country-specific strategic plans. This ability did not go unnoticed. Since 2000, KNCV has led four consecutive USAID-funded global flagship projects, with the last one covering 23 countries and $525 million budget ceiling. KNCV is proud of the sustainable capacity built at country level, while at the same time recognizing the challenges and opportunities still ahead to fulfill our mission. We will continue our journey to the elimination of TB with the same passion that laid the basis for our achievements thus far.

The **purpose** of KNCV is to contribute to a world free of tuberculosis.

Our **mission** is to end human suffering due to TB through the global elimination of tuberculosis.

Our **vision** is that KNCV will save lives and accelerate the decline of the TB epidemic through the development and implementation of effective, efficient and sustainable setting specific strategies that combine patient centeredness with epidemiological impact.

In the medium term, our goal is to reach the targets of the global END TB strategy and the health related Sustainable Development Goals (SDGs).

The KNCV Theory of Change is presented in Annex 1 on page 42.

The WHO END TB strategy aims for a 95% reduction in deaths and a reduction in the global incidence of TB to less than 10 cases per 100.000 population, all by 2035. In the longer term, KNCV strives for the complete elimination of TB worldwide (see figure 1).

KNCV contributes to these goals by
- Empowering patients and their families along the patient pathway ‘from infection to cure’
- Generating, applying and sharing new evidence for better results
- Designing, developing and implementing of evidence based, setting specific TB strategies
- Contributing to national and international TB policy development

DISCOMFORTED BY RULES,
"I always had to wear a mask when I went to the hospital to avoid spreading the disease."
Photographer: Uwem George, **participant KNCV's TB Photovoices in Uyo, Nigeria.**

KNCV guiding principles

In our work we are guided by six principles:

1. Alignment of the KNCV strategy with the Universal Health Coverage[1] agenda and SDGs;
2. Consider the legal and ethical issues of TB care and a human rights-based approach;
3. Identify the greatest impact at the lowest cost and least effort;
4. Ensure country ownership and country-specific design of interventions;
5. Value and build partnerships at all levels;
6. Ensure transfer of knowledge as an integral part of our technical assistance.

KNCV core values

These are the values that make us proud to be part of KNCV:

- Humanitarian, people-centered focus
- Delivering results
- Reliability and accountability
- Flexibility to respond to changing challenges and opportunities
- Drive for responsible innovation

Addendum (2023) to the KNCV strategic plan 2020-2025

In 2022 KNCV, with the support of external consultants from Management for Development Foundation (MDF), conducted a mid-term evaluation of the KNCV strategic plan 2020-2025. The process was all-inclusive and participatory with stakeholders at all levels. The evaluation confirmed that KNCV is well on track toward its 2025 goals and that KNCV's mission, strategy, and intervention approaches are in alignment with global needs.
Key strengths identified were the resilience and flexibility to adapt to the crises of both COVID-19 and war/crisis in different TB high-burden countries; the use of the innovation pathways as a principle for project acquisition and implementation; the value of working through the health system and respecting the leading role of the NTPs; and the internal assessment of KNCV organizational structures and system with an improvement plan.
Since 2020 when the KNCV strategic plan was developed, significant changes have occurred globally. and in the Netherlands, where the Center for Disease Control (Cib RIVMW) is now playing a coordinating role for TB prevention and care. Therefore, the following areas in the strategic plan were identified to be strengthened: the theory of change and the innovation pathways; strategic internal monitoring, evaluation, learning, and communication of results; the KNCV Network organization approach; development of a clear strategy for the hybrid work and working station outside the Hague; finally, the role of KNCV within the Dutch TB control.
With these revisions the KNCV Strategic plan 2020-2025 was updated; this updated plan will continue to guide KNCV operations for the next two years.

Figure 1: End TB Vision, goal, targets, milestones.

[1]The goal of universal health coverage (UHC) is to ensure that all people obtain the health services they need without suffering financial hardship when paying for them. UHC provides the broader context for our TB work and is the overarching agenda of the WHO as embraced by the World Health Assembly for the Post-2015 Sustainable Development Goals.

2. STATE OF TB CONTROL IN 2019

2.1 STATE OF THE EPIDEMIC

Tuberculosis (TB) is a communicable airborne disease that is a major cause of ill health, one of the top ten causes of death worldwide, and the leading cause of death from a single infectious agent. WHO estimates that one quarter of the world's population is infected with TB and thus at risk of developing the disease. Geographically, most TB patients are in South East Asia (44%), Africa (24%), and the Western Pacific Region (18%).

Globally, an estimated 10 million fell ill with TB in 2018 (WHO report, October 2019). In the same year, there were 1.2 million deaths among HIV-negative people and an additional 250,000 deaths among HIV positive people. The latter reflects a 60% reduction compared to 2000, but TB remains the number one killer among people living with HIV. Also, TB accounts for one in four Antimicrobial Resistance (AMR) fatalities per year.

Diagnosis and successful treatment of people with TB averts millions of deaths each year (an estimated 54 million over the period 2000-2017), but there are still large and persistent gaps in detection and treatment. Worldwide in 2018, about 7 million new TB patients were officially notified to national authorities and WHO – an increase from 6,4 million in 2017 and a large increase from the 5,7 million cases notified annually in the period 2009-2012. This increase does not reflect a deteriorating situation, but rather increased efforts to detect and report patients. However, as the data show, there is still a diagnostic gap of three million patients between the estimated 10 million patients in 2018, and the number of patients notified. This is due to a combination of underreporting and underdiagnosis, and possibly inaccurate WHO estimations in some settings.

MDR-TB and XDR-TB continue to pose a public health threat, both from a humanitarian and public health perspective. Although case detection of MDR-TB is increasing with the roll-out of rapid molecular resistance testing, it is still low. In 2018, there were half a million new cases with severe drug-resistant TB. However, only one in three of these patients were diagnosed and even less (156,000) patients enrolled in treatment. In 2018, the global treatment success rate of multidrug-resistant TB (MDR-TB) patients starting treatment in 2016 was still unacceptably low (56%); however, KNCV supported countries reported much higher rates for patient treated with the KNCV triage approach, using new drugs and regimens. The protection of these new(er) drugs are a great concern. Drug-resistance is man-made. Hence, inappropriate use of new(er) drugs and regimens will lead to the emergence of resistance to these drugs, and eventually to the spread of new forms of drug-resistance through airborne transmission.

Globally, the cumulative reduction of the TB incidence between 2015 and 2018 was only 6.3%, which is considerably short of the decline needed to realize the End TB Strategy. In that same period, the global reduction in the total number of TB deaths was 11%, also less than one third of the way towards the end TB strategy milestone of a 35% reduction by 2020. Likewise, substantial scale-up of preventive treatment will be needed to reach the targets set at the UN high level meeting in 2018.

But the promising news is that the WHO Europe region and seven high TB burden countries are on track to reach 2020 milestones for reductions in TB cases and deaths.

In summary, the latest available data show that progress is being made, but the pace is not fast enough. Global indicators are moving in the right direction and after 40 years of standstill in research and development, we finally see the promise of new game-changing treatments, diagnostics, a vaccine, and other technologies. These innovations hold the promise of bending the curve (figure 2).

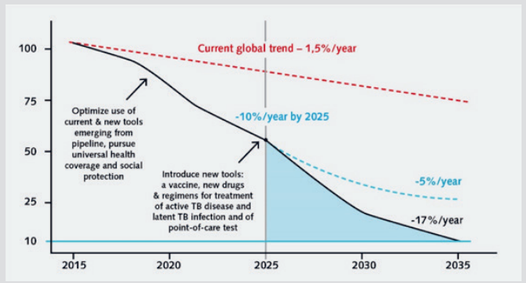

Figure 2: Current global trend with bending curve.

Countries require technical assistance to plan for the evidence-based introduction of these new tools and interventions and related change management. These need to address important challenges such as TB prevention; drug-resistance; TB co-morbidities such as TB/HIV co-infection and diabetes; and concentration of TB in vulnerable populations. WHO estimates that in 2018, 2.3 million TB patients were attributable to undernourishment, 0.9 million to smoking; 0.8 million to alcohol abuse, 0.8 million to HIV infection, and 0.4 million to diabetes, with most probably overlap between those groups

This strategic plan was writing in 2019, prior to the COVID-19 pandemic, which now threatens to derail the progress made over the past years by overburdening health systems and diverting attention and funds for TB Elimination. Global efforts are made to mitigate against this impact by adapting approaches and incorporating COVID-19 relevant interventions in TB programming; KNCV is in the forefront of taking up the challenge to maintain the momentum towards TB Elimination. The KNCV approach to an integrated response to the COVID-19 and TB pandemics are detailed in the COVID-19 Addendum, page 36.

2.2 STATE OF THE GLOBAL AND NATIONAL TB RESPONSES

We could significantly accelerate the decline of the epidemic and reach the global targets if all stakeholders: countries, donors, technical agencies, corporate sector, academia, civil society and patients alike would use their mandate, capacity and voice to approach the TB epidemic as a joint venture against a joint enemy. Even with the currently available limited arsenal of diagnostics and drugs, more progress could be made. And there is reason to believe that stakeholders are getting more aligned.

Since the development of the KNCV strategic plan 2015-2020, important steps have been made to increase political commitment globally, such as the Ministerial meeting on TB in 2017 and the first ever UN High Level Meeting on TB in 2018.

As explained in the previous chapter, the SDG 3 and 5 and END TB Strategy targets set for 2030 and 2035 cannot be met without further intensified research and development. Technological breakthroughs are required to accelerate the annual decline of TB incidence (figure 2). Priorities include, but are not limited to an effective vaccine, point of care diagnostics for latent tuberculosis infection (LTBI), TB and drug-resistant TB, and simpler and shorter treatment regimens. As of August 2019, there were 23 drugs, various combination regimens and 14 vaccine candidates in clinical trials. One of these, the M72/AS01E vaccine was found to be protective against TB disease in a phase IIB trial and thus brings a long awaited promise to transform global TB prevention efforts. Further research into this and other promising products is urgently needed.

But, ending the TB epidemic requires more than new tools and interventions. KNCV recognizes four domains that may undermine an optimal response. These represent political, technological, socio-economic and health systems challenges. Obviously, these all overlap and are interdependent. All will be addressed in the KNCV 2020-2025 strategic plan.

2.3 FUNDING FOR TB CONTROL

Funding for TB services has doubled since 2006, but still falls short of what is required to optimize the response. The amount in 2019 is US$ 3.3 billion less than the US$ 10.1 billion estimated to be required in the Stop TB Partnership's Global Plan to End TB 2018-2022, and only just over half of the global target of at least US$ 13 billion per year by 2022 that was agreed at the UN high level meeting on TB.

Most of the funding (78%) comes from domestic resources, but this aggregate figure reflects the domestic investments made by the BRICS group of five countries, that together account for 53% of the ▸

available funding. For instance, India quadrupled domestic funding between 2016 and 2019.

In other low and middle income countries (outside the BRICS), international donor funding still accounts for 38% of the available funding in the 25 high TB burden countries outside the BRICS, and almost half (49%) the funding available in low-income countries. In 2019, 72% of US $0.9 billion international donor funding came from the Global Fund. The largest bilateral donor is the US Government, which provides almost 50% of all international donor funding for TB (including funds channeled through the Global Fund). The new USAID strategy has moved away from the large global TB flagship projects that KNCV has led for twenty years. The new USAID development aid strategy aims at building local ownership and capacity through negotiating contracts with local institutions like NGOs, CBOs, academia (all eligible for the Local Organizations Network (LON) grants) and levels of Government (TIFA award). This essentially means that KNCV can only access USAID funding through bilateral grants and participation in LON coalitions, for instance through legally and financially independent NGOs that are affiliates of KNCV or were established with KNCV assistance.

The largest bilateral donor is the US Government, which provides almost 50% of all international donor funding for TB

As for research funding, the latest data showed an amount of US$ 772 million, which is far below the target of at least US$ 2 billion per year, set at the UN high level meeting in 2018.

There is broad consensus that we will not be able to end the TB epidemic as long as TB patients face catastrophic costs, meaning expenditures for the diagnosis and treatment of TB that are large in relation to households expenditures or income. Therefore, progress towards Universal Health Coverage (UHC) is key to success. The UHC service coverage index (SCI) increased steadily between 2000 and 2017. However, the SCI in the 30 high TB countries (with 87% of global TB cases) ranges between 40-60, showing that much remains to be done. ◄

3. A CHANGING GLOBAL ENVIRONMENT

Since 2014, there have been various external developments, both positive and negative, that influence the global TB response and the strategic directions of KNCV. The main challenges that KNCV sees in relation to effective TB control worldwide stem from developments in the socio-economic, technological, political, and health systems sphere.

3.1 POLITICAL BARRIERS

Key barriers are insufficient political commitment and country-ownership of the response to the TB pandemic, insufficient domestic and international funding for health systems, including TB control-till-elimination, insufficient funding for TB research and insufficient participation of affected populations in decision making.

Despite evidence of increasing global political commitment to TB Elimination, illustrated during the 2017 ministerial meeting, de G20 and the UN high level meeting (HLM) in 2018, as well as the successful Global Fund replenishment in 2019 political commitment and country-ownership of the response to the TB pandemic is still insufficient, leading to insufficient domestic and international funding for health systems, including TB control-till-elimination, insufficient funding for TB research and insufficient participation of affected populations in decision making, important for the development of effective legislation, accreditation, education, labor laws etc. TB patient organizations are rare, and broader civil society, professional (medical) associations, key affected populations and even national TB programs, do not succeed in attracting the attention of politicians for the humanitarian, economic and health systems costs of TB. The COVID-19 epidemic raised global and local attention for the importance of resilient, decentralized health systems; this is an opportunity not-to-be-missed for the TB community to make the case for more investment in TB control and further develop the TB effort into a community driven movement.

3.2 SOCIO-ECONOMIC BARRIERS

Key barriers are the catastrophic costs of TB, stigma of TB, insufficient community engagement and insufficient social protection, leading to lack of access to care.

Despite the fact that TB diagnosis and treatment are supposed to be free of charge in most developing countries, the patient pathway ‘from infection to cure’ comes with significant ‘out-of-pocket expenditures’ in most settings. This reality interferes with health seeking, the diagnostic process and treatment adherence. TB tends to concentrate in vulnerable groups that generally face challenges in accessing health services, insurance schemes, education, proper housing and peer support. They are more likely to remain undiagnosed and thus transmit the disease, and to buy over the counter TB medications which may not be effective or even create drug resistance. In most settings there is insufficient data available to quantify TB risk groups and thus to effectively design, implement and evaluate targeted interventions. Elimination of TB will require appropriate mechanisms to reach these groups with interventions that are tailored to their needs.
TB stigma remains a major problem around the world and seriously undermines patient empowerment, trust, health seeking behavior, diagnostic strategies, treatment adherence, quality of TB care, and political commitment. Indirectly, stigma also affects the financial situation of patients and their families.

Lack of patient awareness and empowerment results in insufficient demand generation for better and accessible services. We need to give a voice to TB patients and civil society to claim their rights to affordable and effective TB services. The latter is important to mobilize local politicians, parliamentarians and eventually Government ►

The text on the yellow pages, sections 3.1 to 3.4 have been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

to take their responsibility. On the other hand, the potential of community organizations is gaining recognition and will be an important advocacy tool in the coming years.

With over half of the world's population living in an urban areas with a diverse mix of public and private health sectors and broad access to a variety of medicines, specific approaches are needed to effectively organize urban TB control.

The highest burden of disease is in men (aged >15 years) who accounted for 57% of all TB cases in 2018, compared to 32% among women and 11% among children. As we know, male patients are known to be at higher risk of infection and developing disease and are better 'transmitters' than women and children; they deserve extra attention..
Also migration, with social instability and poverty, must be recognized as factors increasing vulnerability for TB and reduced access to care.

Many TB patients still face catastrophic costs, meaning expenditures for the diagnosis and treatment of TB that are large in relation to households' expenditures or income and incomplete UHC service coverage.

3.3 TECHNO-LOGICAL BARRIERS

Key barriers are the lack of effective TB vaccines and point of care diagnostics for TB and drug resistance as well as TB infection, and the lack of short, well tolerable treatments for all forms of TB.

New insights in the dynamics of the TB epidemic are putting more emphasis on identification and treatment of LTBI and early TB.

The promising pipeline of new drugs, diagnostics, and vaccines, as well as the digital revolution mark the beginning of a crucial era of retooling and change management. At the same time, uncontrolled use, especially of new drugs, has dramatic consequences such as the development and subsequent spread of resistance to new(er) drugs through airborne transmission. Globally, antibiotic stewardship is still weak and strengthening is needed to protect the few new drugs that are and will become available to end TB.

Technological advances in microbiology, including whole-genome sequencing and future point-of-care tests, are likely to become available for routine use, also in in low and low middle-income countries during the coming years. This will require a redesigning of diagnostic networks, related supply chain mechanisms, diagnostic algorithms and an adequate workforce.

The rapid development of internet and mobile phone systems in low- and middle-income countries opens up unprecedented opportunities for patients, healthcare workers and health care systems, including private sector, to benefit from digital solutions. These include, but are not limited to, patient education, patient referral, treatment adherence support, surveillance systems, supply chain management, laboratory connectivity, sample transportation, payment systems, and training.

3.4 HEALTH SYSTEMS BARRIERS

Key barriers are the underfunding and weak structures of health systems in many high TB burden countries, lack of well trained, supported health staff, insufficient integration of TB care in all sectors, incomplete use of data for strategic planning, leading to suboptimal quality and effectiveness of health services.

WHO and partners distinguish six building blocks that contribute to the strengthening of health systems in different ways.

Cross-cutting components, such as leadership/ governance and health information systems, provide the basis for the overall policy and regulation of all the other health system blocks. Key input components to the health system include specifically, financing and the health workforce. A third group, namely medical products and technologies and service delivery, reflects the immediate outputs of the health system, i.e. the availability and distribution of care.

Apart from the strengthening of these health systems building blocks, attention is needed for behavioral aspects and necessary actions by in other sectors to address the underlying social and economic determinants of health, as TB usually concentrates in marginalized populations.
In many countries an increased leadership role is needed by national TB programs, supported by increased funding and political support, as well as the development of data driven strategic plans for increased access to domestic and international funding and development of a strong workforce in both public and private sector at all levels of the health system.

Opportunities for TB control could be the current attention to COVID-19, AMR and UHC, and related initiatives such as health insurance schemes. In addition to economic aspects described in the chapter on funding, KNCV is considering the following socio-economic challenges.

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In most settings there is insufficient data available to quantify TB risk groups and thus to effectively design, implement and evaluate targeted interventions.
Elimination of TB will require appropriate mechanisms to reach these groups with interventions that are tailored to their needs.

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Lack of patient awareness and empowerment results in insufficient demand generation for better and accessible services. We need to give a voice to TB patients and civil society to claim their rights to affordable and effective TB services. The latter is important to mobilize local politicians, parliamentarians and eventually Government to take their responsibility. On the other hand, the potential of community organizations is gaining recognition and will be an important advocacy tool in the coming years.

Demographic developments need to be taken into account as well. At this moment, more than half of the world population lives in an urban area. In mid-2014, the United Nations reported that an additional 2.5 billion people are predicted to live in urban areas by 2050, making up almost 70% of the total world population. This is already having, and will continue to have, a major impact on the way TB will spread and on the way we will need to organize urban TB control.
Also, the highest burden of disease is in men (aged >15 years) who accounted for 57% of all TB patients in 2018, compared to 32% among women and 11% among children. As we know, male patients are known to be better 'transmitters' than women and children, and deserve extra attention to break the chain of transmission.

In today's increasingly mobile and interconnected world, with about 258 million international and 760 million internal migrants, migration must be recognized as a social determinant of health, impacting upon every individual's vulnerability and well-being. The way in which many migrants travel, live and work, can carry risks for their physical and mental well-being. Many work in dangerous, difficult and demeaning jobs, and live in isolation and sub-standard housing. Others may be detained in over-crowded detention facilities or live in camps as refugees or internally displaced persons. Migrants are thus among the vulnerable groups that face a particularly high level of TB risk factors. In addition, migrants face barriers to accessing health services due to language and cultural difference, and administrative hurdles. There are numerous reports of illegal migrants facing incarceration, deportation and even violence when presenting with TB.

Migrants are often excluded from social protection in health and are invisible to UHC programs. As a result, many migrants pay out-of-pocket to get the health services they need, which may result in catastrophic health expenditure, delayed and substandard care.

4. EXTERNAL STAKEHOLDERS

We believe that sustainability and partnerships are crucial to reach our goals of alleviating suffering, saving lives, and eliminating TB. That is why we strive to be a strong partner in relevant and occasionally unorthodox local and international alliances, and to share and exchange knowledge in order to strengthen local capacity.

Beneficiaries

KNCV aims to eliminate TB by contributing to the development and implementation of effective and efficient country-specific TB strategies and interventions at both global and country-level. We regard the patients, their families and infected people as our most important beneficiaries. Therefore we work with the leadership of the country's NTP, other parts of Government, health care workers, civil society, and patient organizations and other relevant local partners to design and strengthen setting specific TB control interventions. KNCV's capacity building approach is important to countries in order to enhance the self-sustaining and developing ability of their people and systems.

Partners and partnerships

KNCV works in a broad network of international and local technical partners, civil society organizations and research institutes, but also local and international development NGOs and professional organizations. We are partner in different coalitions to implement projects worldwide, under different grants. KNCV contributes to WHO TB policy development and has the status of WHO non-state actor. As a founding member of the global Stop TB Partnership (STP), KNCV has a seat at the STP Coordinating Board.

We also participate in Product Development Partnerships (PDPs) such as FIND, the TB Alliance, AERAS and the TB Vaccine Initiative. We will also partner with organizations and research groups that bring complementary expertise in laboratory strengthening, HIV control, pediatrics, and m- and e-health, among others. These may include collaborations with commercial partners under conditions of strategic and scientific independence.

AMR is a growing interest area in the global health security agenda globally. Also in the Netherlands there is a continued interest in AMR in the public and private sector. KNCV is a member of AMR Global, a partnership to strengthen the collaboration among public, private and academic partners around the promotion and use of AMR expertise and experience in the Netherlands internationally.

Donors

KNCV has diversified its funding sources and collaborates with a variety of donors, including but not limited to, USAID, WHO, Global Fund, Unitaid, EDCTP, TB REACH, the Bill & Melinda Gates Foundation, the Dutch Government and a number of foundations. KNCV's country approach has always been to work hand-in-hand with the MoH and NTPs specifically. As a trusted partner and advisor to the NTP, KNCV is seen as a strong in-country partner for local capacity building and the introduction and scale-up of new tools and interventions.
In addition KNCV is a beneficiary of private donations, directly or indirectly through lotteries (Nationale Postcode Loterij, VriendenLoterij, Nederlandse Loterij), Dutch TB foundations ("doelaanwijzers") and other private or corporate foundations.

Policy makers

KNCV responds to policies set forth by national governments, the WHO and other multilateral organizations and institutes. At the same time KNCV contributes to those policies through WHO STAG and guideline committees; global organizations such as the Stop TB Partnership; PDPs (for new drugs, diagnostics and vaccines); and participation in research consortia.

Influencers

With regard to policy influence KNCV operates in a broader landscape in which advocacy groups have become powerful players. Alliances with groups advocating for better TB control (politically, financially, technically) are valued elements of achieving KNCV's mission. Therefore, awareness raising and demand generation have become important components of our work in which we collaborate with both global and local partners. At the same time, we are aware that at the country-level, the advantages of such alliances can be further strengthened when supported by evidence based policymaking and community level engagement and monitoring. Public media are similarly powerful players and often allies in providing opportunities to keep the global TB problem on the public and political agenda.

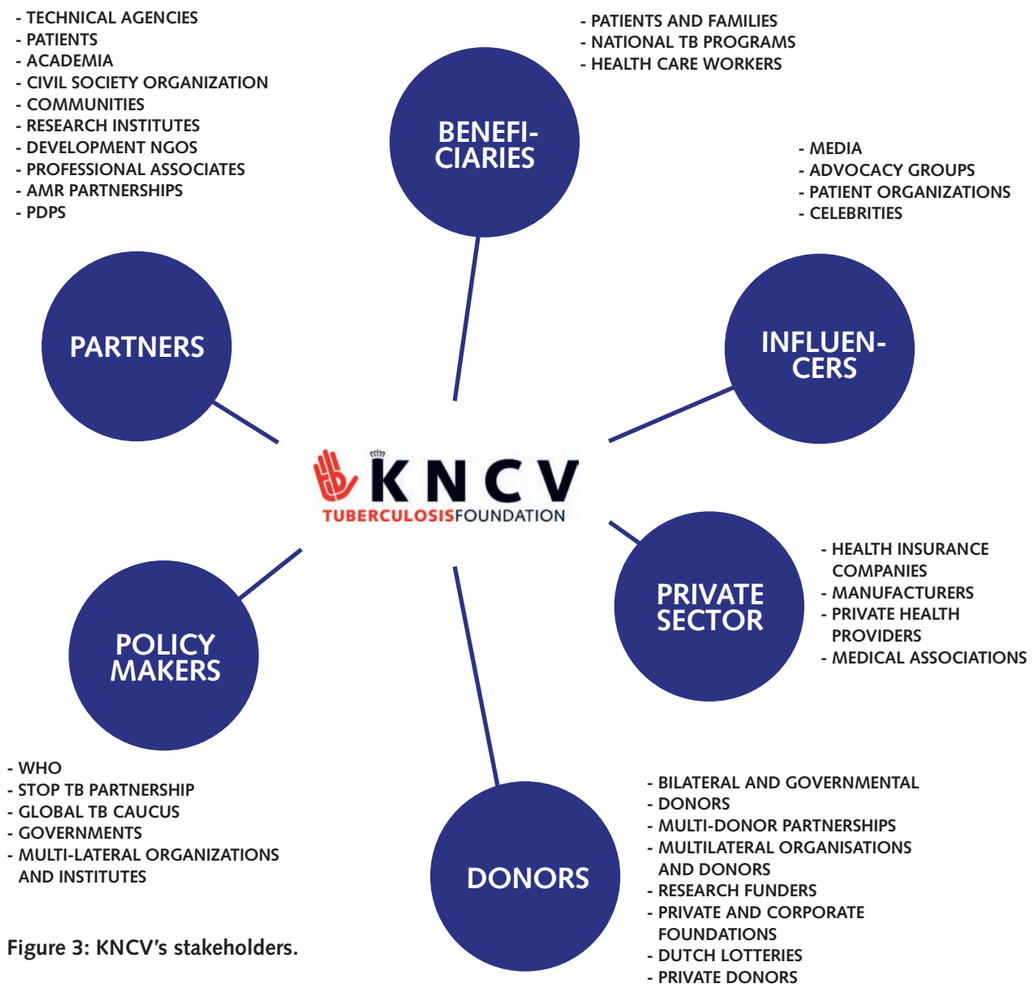


Figure 3: KNCV's stakeholders.

Private sector

Historically regarded as part of the problem (e.g. emergence of drug-resistance through inadequate TB treatment by private providers), the for-profit private sector is increasingly seen as an important contributor to the solution. This is true for for-profit health care providers, who as increasingly important players in diagnosis and treatment in many countries must be engaged as part of countries' national TB control efforts. Other important contributors can be health insurance companies in the context of UHC, as well as manufacturers of drugs, diagnostics and vaccines. KNCV develops partnerships with these players, building on previous public-private partnership successes in Indonesia, Vietnam and the Netherlands and geared towards aligning with KNCV's people-centered TB control and elimination mission. ◂

BEING ALONE DOESN'T MEAN LONELINESS,
"I was alone because of my TB, but it was my choice to do so. I maintained a distance from everybody else to be introspective. It might have seemed lonely, but it wasn't. For me it was a part of my recovery."
Photographer: Levi, **participant KNCV's TB Photovoices in Manila, the Philippines.**

5. KNCV STRATEGIC RESPONSE

The KNCV strategic response aims at addressing political, socio-economic, technological and health systems opportunities and barriers relevant to ending the TB epidemic (see chapter 4 and 5). We do realize that KNCV's mandate and strengths do not cover all these areas equally, and thus that KNCV will be able to have more impact in some areas than in others. For instance, our technical strengths, are at the core of KNCV capacities. Yet, our work at country and global level, provides us with ample opportunities to play a role in awareness raising and advocacy as well.

Recognizing the need to accelerate the decline in incidence of (MDR-)TB and bend the curve in figure 2 the promising pipeline of new tools and technologies; the challenges to introduce these innovations and bring them to scale; and KNCV's track record in assisting countries to innovate and generate evidence for policy development, KNCV will focus its future strategies on the responsible introduction of innovative approaches and improved use of existing, repurposed and new tools.

The KNCV focus on innovation reflects the importance of retooling to end the TB epidemic and KNCV's track record in this field. However, KNCV also recognizes that retooling should not be an aim in itself. In fact, setting specific evidence-based strategic planning may prioritize better use of existing tools rather than introduction of usually costly innovations. After all, existing tools and interventions are often underutilized because of systems weaknesses, that usually will not be resolved by adding tools.

During the period 2020-2025, KNCV will focus on assisting partners and countries along the innovation (retooling) pathway, distinguishing three areas of work, which of course partially overlap. The strategic plan divides the retooling pathway into three parts: 1) early recognition and evaluation of new promising tools and interventions, 2) evidence based global policy development and subsequent translation into local policies and strategic planning, and 3) health systems preparedness to introduce and integrate innovations in ▸

Figure 4: KNCV's strategic map.

KNCV STRATEGICMAP

Vision	End TB and related human suffering		
Focus areas	Evidence generation	Policy development & strategic planning	Supportive systems
Strategic objectives	Improve access to new and repurposed tools and interventions	Contribute to global and local guidance and strategic planning	Strengthen systems to deliver quality care and absorb innovations
Key result areas	Drugs/regimens, new diagnostics, digital solutions, ltbi management	Who guidelines, local guidelines, local epidemiology, strategic plans	Capacity building, surveillance/ mle, key affected populations, stigma reduction
Activities	Research, country support, knowledge sharing, advocacy, raising awareness, partnership building, policy dialogue		

KNCV ALONG THE INNOVATION PATHWAY

KNCV allong the innovation pathway	Contribution to product profiles	Acceptability and feasibility studies	Operational research for effectiveness, safety in local settings for national and global policy development	Scale-up planning, mobilization of (domestic and mainstream donor) funding
	Advocacy	Costing studies, cost effectiveness modeling	Operational research for patient/user and HCW/ user satisfaction	TA to management of delivery and scale-up, PSCM, EQA, …
		Facilitation of studies through country-offices and partnerships	Development of implementation approaches, generic implementation plans/ algorithms / SOP's/ jobaids etc	Surveillance, data analysis and use for decision making
		Refining innovations innovations	Training modules, capacity building, mentoring	Performance monitoring and feedback mechanisms, refresher courses, mentoring
KNCV key intervention areas across the innovation pathway				
New diagnostics and lab network design				
New drugs and treatment regimens				
ACF, diagnosis and treatment of latent TB infection				
HIS, Digital solutions				
Stigma reduction, patient empowerment				
Epidemiological measurement methodologies				
Patient Centered Framework for program management				
Blended learning platform & methodologies				

Figure 5: KNCV along the innovation pathway.

existing TB responses, while addressing general systems barriers. In short, we will refer to these as evidence generation, policy development and strategic planning, and supportive systems. These are supported by cross-cutting areas of work: awareness raising, advocacy, demand generation and capacity building (figure 4).

KNCV aims for TB Elimination in an integrated approach with HIV, Diabetes Mellitus (DM), COVID-19 and anti-microbial resistance (AMR). The COVID-19 pandemic occurred after the writing of this strategic plan. Therefore the KNCV approach to an integrated response to the COVID-19 and TB pandemics are detailed in the COVID-19 Addendum, page 36.

The evidence generation focus area covers deliverables that aim at connecting the R&D pipeline with the reality at country-level, and includes KNCV input in technical product profiles. This area includes, but is not limited to, building partnerships with R&D partners and donors; evidence generation (efficacy, feasibility, acceptability) through pilot and demonstration projects at country level for both new tools and underutilized/repurposed tools and interventions; and dissemination of these results (see 8.1).

The policy development focus area covers contribution to global and local policy development and guidelines, with focus on retooling and change management at country level in the context of evidence based strategic planning (see 8.2).

The supportive systems focus area covers a wide range of deliverables that aim at strengthening health systems to deliver high quality care along the patient pathway from infection to cure, in both public and private sectors. This involves different building blocks of the health system, and where relevant other parts of Government.

Essentially, the new strategic plan offers a continuum that starts with evidence generation (strategic objective 1), which leads to policy development and strategic planning (strategic objective 2) towards systems strengthening to bring innovation to scale (strategic objective 3).
KNCV will offer technical assistance through an effective mix of long term in-country technical assistance and short term consultancies by highly specialized experts. We will continue to build local capacity through KNCV offices in some countries and through local partner organizations in others.

KNCV aims to be a knowledge center by generating, sharing and applying experiences, expertise and evidence for TB control. In that context we will embark on new partnerships with academia and other R&D partners to facilitate early piloting, evidence generation and policy development related to new or repurposed tools. The evidence we generate in our research projects will be shared through scientific publications, conferences policy briefs and inputs in WHO guideline development.

Finally, KNCV will be actively engaged in policy dialogue and advocacy, both at the country-level and internationally. We will call on all of our experience, expertise and evidence to help generate policy recommendations and guidelines for various aspects of TB control, to share the policy insights, and to build the political support among governments, multilateral organizations and donors by informing and shaping policy dialogue and advocacy towards effective TB control with the required policies, legislation and finance. See for KNCV's role along the innovation pathway figure 5. ▸

KNCV aims to be a knowledge center by generating, sharing and applying experiences, expertise and evidence for TB control

5.1 FOCUS AREA AND STRATEGIC OBJECTIVE 1: EVIDENCE GENERATION

Strategic objective

Improve early access to new tools and interventions for people infected with TB and people with TB disease, for better individual health outcomes and public health impact.

Strategic approach

In recent years KNCV has built a track record introducing, evaluating and scaling-up new game-changing innovations such as molecular diagnostics (Xpert) and new drugs and regimens for the treatment of drug-resistant tuberculosis in many parts of the world. More recently, KNCV has successfully broadened its scope of work in the field of innovation through piloting of a new LTBI treatment regimen; field testing of digital adherence technologies; research into a diagnostic stool test for children; and preparations for a new injectable free regimen to treat XDR-TB. With regards to the latter two, KNCV has sought early collaboration with R&D partners such as the TB Alliance. Under this strategic approach KNCV will continue to contribute to formulation of product profiles and assist with design of projects to pilot and evaluate new and repurposed tools and interventions.

In summary, KNCV has shifted its primary focus from implementation under four consecutive USAID flagship grants to a more explicit role as innovator under new grants from Unitaid, the Gates Foundation, EDCTP and other foundations. This direction fits the capacity of KNCV as a center of excellence that provides specialized technical assistance, rather than supporting routine operations by local partners, including KNCV local offices and affiliates.

Key results areas

KNCV strives to generate evidence in the following technical areas.:

1. New drugs and regimens
2. New diagnostics
3. Digital solutions
4. Management of latent TB infection
5. Childhood TB

These technical areas may be expanded, depending on new opportunities such as the introduction of a new vaccine, biomarkers or better diagnostics for TB infection. However, phase three trials of promising candidates such as the M72 vaccine still have to start. Therefore, we initially limit ourselves to the abovementioned result areas.

Key result area 1: new drugs and regimens

After decades of relative stillstand in TB drug related R&D, the pipeline of new drugs is rather promising. In addition we realize that repurposed drugs can complement new drugs in regimens for treatment of TB infection and treatment of active TB. KNCV has been involved in the preparations for the introduction of a new game-changing injectable free regimen to treat XDR-TB. This involvement included both country preparedness studies and contribution to WHO guideline development (strategic objectives 2 and 3).

Under the Challenge TB project KNCV has proven capable of building the platforms for the responsible introduction of new drugs (bedaquiline, delamanid) and regimens (shorter regimen for MDR-TB). New drugs will enter the market, with again new options of designing regimens. KNCV aims at playing an important role preparing countries for their introduction with the ultimate aim of simplifying and considerably shortening tuberculosis treatment. Evidence generation and dissemination, as well as capacity building will be cross-cutting activities under this result area.

Key result area 2: new diagnostics

Still 3 million patients per year remain undiagnosed. This is a multifaceted challenge that requires many different actions, but most of all a reliable sensitive point-of-care test to rule in/out TB. Such test would come with the need to redesign the diagnostic algorithms and laboratory network. It even holds the promise of self-testing. In addition we will need rapid drug-susceptibility testing for the existing new drugs to inform individual patient decisions. The latter may include introduction of whole genome or targeted sequencing in high burden countries. Lastly, we urgently need a simple test for TB infection in high prevalence settings as both IGRA and tuberculin skin testing come with major operational challenges. The diagnostic network will require improved mechanisms for sample transport, digital connectivity, and laboratory related chain and supply chain management. Evidence generation and dissemination, as well as capacity building will be cross-cutting activities under this result area.

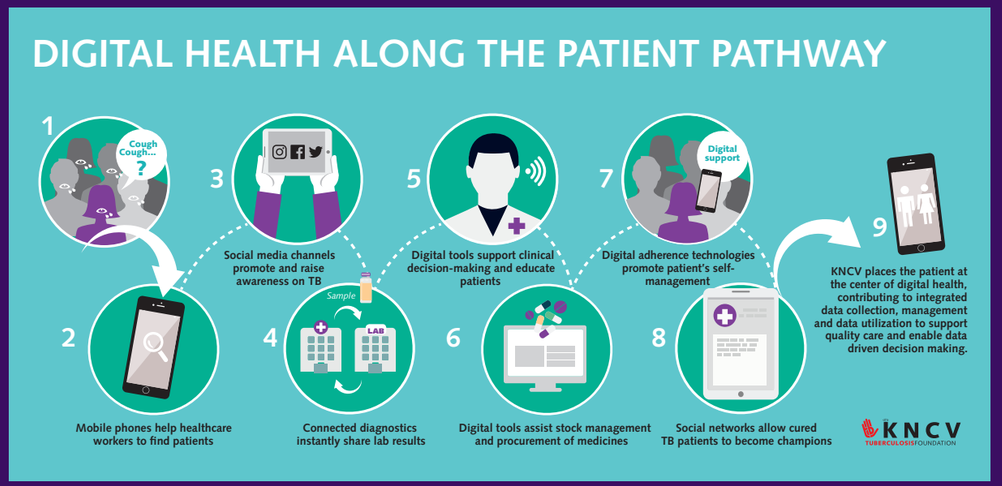


Figure 6: Digital health in the patient pathway.

Key result area 3: Digital solutions

KNCV will continue to invest in digital solutions along the patient pathway (figure 6). There are major opportunities to facilitate diagnosis, treatment and after care for patients and health care providers alike. Also broader health systems will greatly benefit, especially in the field of recording and reporting; surveillance; supply chain management; education; laboratory connectivity; referral systems; sample transportation; awareness raising; and private-public linkages. KNCV already plays a significant global role in introducing electronic surveillance systems and digital adherence tools. The latter under projects supported by Unitaid and TB REACH projects. We strongly belief that digital solutions are key to ending TB, provided that country context and prioritization, are well taken into account. Evidence generation and dissemination, as well as capacity building will be cross-cutting activities under this result area.

Key result area 4: Management of LTBI

LTBI diagnosis and treatment are routine interventions in industrialized countries such as the Netherlands, where KNCV has been supporting related policy development, implementation and evaluation for over five decades. KNCV has been advocating for LTBI management in high prevalence countries through the WHO Strategic Technical Advisory Group, which has finally resulted in new 2018 WHO guidelines that now recommend LTBI diagnosis and preventive treatment in low income countries. Obvious target groups include household contacts of infectious TB ▸

*This paragraph has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

index patients and HIV infected individuals, but other key affected populations may also benefit from LTBI management. Ideally, countries should develop national LTBI strategies which define target groups, diagnostic methods and treatment regimens. KNCV is in a perfect position to assist countries in designing, piloting, evaluating and scaling-up LTBI related interventions. Operational research will be important in this context, as LTBI diagnosis, information, education & communication (IEC), and treatment adherence pose significant challenges under routine program conditions. KNCV therefore offers a comprehensive technical assistance package, covering the full progression from policy-development to service delivery, evaluation and scale-up. Obviously, activities to identify LTBI among household contacts and TB key affected populations, may also lead to the diagnosis of active TB. KNCV will ensure adequate triage and (preventive) treatment of all detected by contact investigation and other forms of active case finding.

Key result area 5: Childhood TB

Our children determine the future, is often said. This also applies to the TB epidemic. In 2018, children accounted for 11% of the estimated 10 million new TB patients in that year. In addition, many more were infected and among them 5-10% of them will develop TB disease during their life.
In order to end the TB epidemic we must intensify efforts to reduce the pool of infected children to start with - infection prevention and early treatment of their parents - and make sure that all infected children get access to early and easy diagnosis of both infection and disease. However, to diagnose infection, we still rely on the very old tuberculin test which comes with ample interpretation and operational issues, and operational issues also apply to the newer but costly IGRA test. Clearly, we need better tests to detect (stages of) infection, that are easy and affordable to apply in a low-income country context. But we face similar challenges to diagnose active TB in children, especially as the clinical presentation may mimic many other childhood diseases and children do not produce sufficient sputum for diagnostic tests such as Xpert. That is why KNCV will evaluate new approaches for the diagnosis of childhood TB using other samples such as stool, and oral swabs. Finally, children and their caregivers require extra support to be able to take and provide the right treatment for long enough periods. KNCV will advocate for the development, introduction and use of child-friendly drug formulations and support the development of context-specific education materials for their caregivers.

***Organizational goal**
Our organizational goal for this focus area is to expand our retooling and change management track record by successful introduction and evaluation of new tools and interventions.

5.2 FOCUS AREA AND STRATEGIC OBJECTIVE 2: POLICY DEVELOPMENT AND STRATEGIC PLANNING

Strategic objective

To contribute to the development of global guidelines and local policy guidance and context-specific evidence-based prioritized and costed strategic plans.

Strategic approach

This strategic focus area forms the part of the KNCV strategic plan continuum that starts with evidence generation (strategic objective 1), which leads to policy development and strategic planning (strategic objective 2), towards systems strengthening to create an environment that can bring innovation to scale (strategic objective 3).
Elimination of TB will not be possible without new technologies (diagnostics, drugs, vaccines) and approaches to enhance their access and uptake. Over the last years WHO, countries, donors and technical partners have realized that the promising R&D pipeline comes with major opportunities but also challenges as far as revision of global and local guidelines and policies is concerned. For instance, the rapid technical changes during the last decennium have led to a certain level of 'change management fatigue' at country-level, with

both governments and donors facing reprogramming of approved grants. At the same time technical agencies – both at country- and global-level – are confronted with an increased demand for assistance to the rational phase-in, and phase-out of tools and interventions. KNCV's track record shows that KNCV is in a perfect position to play a global and local role addressing these challenges by contributing to global guidance evidence generation and contributing to global guideline development. KNCV brings a long history of participation in WHO guideline committees and WHO STAG. Moreover, we have a strong track record assisting countries 'translating' global guidance into local guidelines and plans, that are based on local epidemiology, the local health system and the needs of patients, communities and health care providers along the patient pathway in that particular setting. KNCV has the capacity to assist countries and donors with the retooling and reprogramming exercise in the context of sustainability and choices that bring value for money.

Key results areas

KNCV puts contribution to policy development and rational evidence-based strategic planning at the core of its strategic plan. In fact, KNCV leads the development of rational evidence and data utilization for TB programming through the People-centered framework approach, which is implemented in several countries in close collaboration with WHO, GF, and other partners. We are pretty much defining a new approach to surveillance, data and Expanded Program on Immunization (EPI) Reviews, program evaluation and planning.
These areas are the crucial connection between R&D and the reality in high burden countries:

1) **WHO guidelines**
2) **Local policy guidance**
3) **Local epidemiology**
4) **Strategic planning**

Key result area 1. Contribution to WHO guidelines

KNCV will continue to contribute to global guideline and policy development, especially in the context of WHO guideline and expert committees. We expect an increased pace of WHO guideline development given the promising pipeline of new diagnostics, drugs, treatment regimens and digital solutions. This will also come with a need for guidance on a wide range of related subjects, that may range from 'new ethical guidance in TB control' to 'pharmacovigilance'. In summary, we aim at contributions to WHO guidelines and STAG recommendations that combine both our scientific expertise and country experience.

Key result area 2. Local policy guidance

KNCV brings almost 50 years of experience with assisting countries 'translating' generic global guidance into country-specific guidelines or guidelines for very specific situations such as cross-border referral systems; TB in prisons; TB among migrants and so on. Of course, we always work hand in hand with national and subnational government, patient organizations and other stakeholders, who are the owners of the new guidance. Our assistance aims at balancing our ambition to step up the TB response with a critical eye for setting-specific issues such as local epidemiology, infrastructure, human resource capacity, acceptability, feasibility and cost-effectiveness. We expect that this activity will continue to require specialized state of the art technical assistance, which cannot be easily found at local level. However, this type of technical assistance will always include technology transfer to local staff to build capacity to follow-up on the implementation of new guidance.

Key result area 3. Population epidemio-logy to inform strategic planning

Over the years KNCV has acquired a wealth of expertise in surveys and surveillance to measure the extent and course of the TB epidemic and its aspects at the population level in a variety of settings. This includes technical assistance to building surveillance systems and analyzing surveillance data, as well as support to designing, conducting and analyzing TB prevalence surveys, surveys of LTBI in children, and drug-resistance surveys. This work is becoming increasingly important for a number of reasons. Indicators of TB control must be measured against targets set by the global TB community. There is an increasing demand for understanding the TB burden among specific risk groups ("know your epidemic"), primarily to target interventions wisely. Increasing attention to diagnosis and treatment of LTBI as a way of reducing incidence ▸

requires mapping of (recent) LTBI prevalence in various population segments. The advent of new drug regimens using existing or repurposed drugs (such as pyrazinamide and moxifloxacin) require detailed insight into the population distribution of resistance to these drugs and its course over time. And finally, new interventions ultimately need to be evaluated for their epidemiological impact, requiring the monitoring of trends in various indicators. There is also a need for methodological innovations in this field, which KNCV is well positioned to address. These include novel sampling approaches for TB prevalence surveys, especially for hard-to-reach groups (e.g. respondent-driven sampling), and for drug-resistance measurement; use of IT solutions in surveillance and surveys; molecular testing in prevalence surveys; including detailed patients costing in surveys to measure "catastrophic expenditures"; sequencing-based drug-resistance surveys and surveillance; real-time analysis of drug-resistance data to identify emerging outbreaks of multidrug-resistant TB; and novel approaches to testing for LTBI.

Key result area 4. Strategic planning 'new style'

Technically sound, prioritized and budgeted NSPs form the basis of any successful program and are a requirement for key donors such as the Global Fund. The previous result area 'population epidemiology' presents a crucial piece of evidence for any strategic plan, as it provides the figures on the burden and distribution of disease and drug-resistance. As such 'EPI-info' is invaluable for strategic planning, but not enough. KNCV recognizes that rational strategic planning also requires a full analysis of the patient pathway from 'infection to cure' in that particular setting: are eligible people screened for TB infection?; do infected people receive preventive treatment?; do people with symptoms reach the health system?; are those with TB diagnosed?; and if diagnosed, are they being cured? What are the root causes for the identified hurdles? What is the influence of the health system involved? For this epidemiological data is supplemented with evidence and data on patient perspectives and behaviors as well as overall health system context and performance. Planning will thus be targeted and responsive and resulting proposed interventions will be optimized using the latest epidemiological and economic impact modelling approaches (linked with focus area 3, key result area 2). The new system will further provide a custom-made, inbuild monitoring framework.

KNCV recognizes the importance of aligning TB-specific plans with approved broader national health plans and health systems developments, such as national directives to harmonize procurement and distribution of drugs, UHC and decentralized health budgets, or regulations in the field of staff transfers and retention. And of course, we take into account how the short-mid and long-term financial environment looks like, and how can we use modeling to prioritize tools and interventions to have maximum impact. The results of this will also inform donors and governments about their return for investment. KNCV is fortunate to be able to assist countries with answering these questions thanks to the support of donors who, like us, believes in comprehensive strategic planning.

KNCV will not limit itself to national plans, but also provide smaller-scale operational guidance. For instance, new tools only translate to improved patient outcomes if systems are ready to use them properly. This requires the early identification of systems requirements and timely preparatory interventions to meet these, such as adaptation of procurement and supply chain management, regulatory approval, or accreditation mechanisms. For instance, the introduction of rapid diagnostics, such as line-probe assays, only translate into rapid treatment initiation if referral and data feedback mechanisms are adjusted and clinicians demand the test and utilize the results. This also includes support in the field of staffing, ranging from HRD plans to guidance on HRD consequences of new interventions and tools.

*Organizational goal

Our organizational goal for this focus area is to be recognized as leading agency in translating both existing and emerging evidence into global and setting specific guidance and strategic planning.

*This paragraph has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

5.3 FOCUS AREA AND STRATEGIC OBJECTIVE 3: SUPPORTIVE SYSTEMS

Strategic objective

Governments adequately supported to design and implement a multisectoral approach to TB control, which results in early adoption of better tools and interventions, deployed in the context patien centered, high quality and affordable care.

Strategic approach

KNCV considers managerial support as well as transfer of knowledge and technology essential components of contemporary TB technical assistance. KNCV aims for empowerment of NTP central units to design, manage and report on inclusive TB control programs, which are not limited to MOH run operations only. We embrace a holistic approach that ensures optimal use of resources in the community, both financial and human, to support TB control. Ideally, all stakeholders in the public and private sector contribute to one comprehensive evidence-based national TB control strategy.

This approach contributes to better outcomes and prevents fragmentation and/or diverging policies. This vision is ideally suited to KNCV's history of providing technical assistance by working with and through governments, while at the same time linking up with private and public sector partners beyond the MoH, such as patient organizations, civil society organizations, relevant other ministries, academia and medical associations.

KNCV aims at assisting countries with strengthening all health systems building blocks in the context of TB, and with special attention to holistic patient management (addressing co-morbidities as well) and to vulnerable populations at increased risk of TB infection and TB disease. Obviously, strengthening a health system is a long and continuous process that will continue beyond the scope of this strategic plan. Ideally, efforts are coordinated, involving whole of government, donors, private sector and civil society. Therefore, KNCV aims at playing a facilitating and convening role where possible. KNCV will support outreach to relevant ministries such as Justice, Finance, Social Affairs, Labor, Education, Immigration and the Defense. Their involvement is crucial for reaching vulnerable groups by developing and enforcing laws and regulations, registration of new tools, ensuring sufficient staffing levels and facilitating public-public and public-private collaboration.

Key results areas

KNCV strives for assisting countries in the following four key areas:

1. **Capacity building**
2. **Governance and financing**
3. **Key affected populations**
4. **Stigma reduction**
5. **Antimicrobial Resistance**

Key result area 1: Capacity building

Capacity building has always been and will continue to be at the core of our work, and fully integrated in all activities under all three strategic objectives. However, recognizing the human resource crisis in health systems in general and the increased need for capacity building in the context of new tools and interventions, KNCV will invest in a systematic approach to the development of high-quality easy accessible educational materials that focus on new tools and interventions in the context of new WHO guidelines and KNCV innovations. This will involve collaboration with WHO and other relevant partners in order to ensure compliance with WHO guidance and to prevent overlap of investments and activities. KNCV recognizes that e-learning and training courses alone will not change health care worker behavior, and thus we will link these with mentoring, supervisory and consultation services, through local partners and using successful approaches such as ECHO.

Key result area 2: Health sector governance and finance

KNCV technical support towards effective, efficient and sustainable TB programs in the countries is increasingly embedded more broadly within overall ▸

health sector governance and financing. The context is rapidly evolving and marked by a need to accelerate transition from donor dependency to domestic funding and ownership. In many of the countries we support, TB budgets and investment agendas have been heavily donor-driven. For the 2020 – 2025 period pressure to transition to domestic (central and decentralized) budgets and integration of TB in broader health systems planning and UHC will grow and efficiency, prioritization and domestic political choices will replace donor-driven dialogues and re-shape health budget decision dynamics.

Connecting its technical and advocacy work for mutual reinforcement, KNCV can and will assert a more pronounced role in supporting countries to 'connect the dots' towards efficient and country-owned financing of TB programs. KNCV can technically and programmatically inform evidence-based advocacy, parliamentary engagement and administrative processes. Country-owned health governance and finance will strengthen if informed by insights from KNCV's domains of work described in 7.1 and 7.2: (1) technical work focused on early and rational adoption of better tools and interventions, (2) strategic planning 'new style' (technically sound, prioritized and budgeted national strategic plans - NSPs), (3) country support for smooth access to Global Fund funding on the basis of such NSPs.

Engaging in emerging advocacy collaborations, KNCV will develop its advocacy role building on its network and track record in the three civil society delegations to the Global Fund Board. Joint initiatives are currently explored on how to reinforce health sector governance, finance and accountability by a backbone of civil society advocacy (community-based as well as national level) for health budget allocations. KNCV seeks a role in connecting indigenous advocacy structures to global level advocacy and health financing and fiscal space work led by development partners.

Evolving KNCV's role in global level advocacy with the Stop TB Partnership, Dutch NGO partners and Global Fund governance enables KNCV to leverage its TB technical and programmatic insights by actively promoting accountability and transparency and informing country-level health governance and finance decision processes in a broader systems context and in line with the demands of the UHC, SDG 3 and SDG 5 and transition agendas.

Key result area 3: Key affected populations

Recent prevalence surveys in high burden countries and a vast amount of evidence gathered over the past few years have indicated that particular patient populations do not access, or have difficulties accessing, regular health care, or more specifically, HIV and TB care services. This applies to the elderly and young children (especially in remote areas), but also to specific groups that may not be large in size, but have a relatively high risk of suffering from TB. It is important to note that a country-specific analysis is required in order to identify which groups need tailored interventions, as situations differ significantly. However, in many countries these include the following groups: the very poor; slum dwellers; prisoners, mine workers (particularly underground miners and in combination with silicosis), (illegal) internal or foreign migrants, persons using drugs, injecting drug users. While these groups are often marginalized and/or stigmatized, with the associated socio-economical and legal complexities, other (mostly clinical) risk-groups may require special attention as well. For instance, the global increase of diabetes mellitus will have consequences that we must begin addressing today. KNCV will expand ongoing efforts to identify and target these special patient populations by designing, implementing and evaluating custom-tailored diagnostic and treatment modalities that fit the special needs of these vulnerable patients, including their financial needs and societal, legal and other barriers to access care.

Key result area 4: Stigma reduction

For more than a century TB has been one of the most stigmatizing diseases worldwide, with different expressions in different cultures, but all negative. Due to stigma, people with symptoms compatible with TB may not seek diagnosis, or when diagnosed not adhere with treatment modalities as proposed by NTPs. In addition to self-stigma and societal stigma, we also observe an increase of health care worker stigma, which is often associated with fear for drug-resistant forms of the disease. KNCV has developed tools to measure and address stigma at country-level and will seek opportunities and funding to introduce these in more countries while building on very successful experiences in several countries such as Kazakhstan, Nigeria and the Philippines.

*This paragraph has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

Key result area 5: Antimicrobial drug-resistance

Drug-resistant TB (DR-TB) is part of a broader global AMR threat which requires a multisectoral response, that includes a wide range of measures at national and global level. Examples are the regulatory environment; public-private partnerships to develop new drugs; strengthening of surveillance systems and laboratory networks; awareness raising, education and demand generation; and antibiotic stewardship. As such the fight against DR-TB will benefit from the broader AMR response, and vice versa. KNCV brings ample experience with designing and implementing country-specific plans to combat DR-TB, and will explore how KNCV can contribute to the broader AMR response both at global and local level.

***Organizational goal**

Our organizational goal for this focus area is for KNCV to be recognized as a technical agency that does not limits itself to technical aspects of TB control, but assists countries in addressing key (health) systems hurdles to optimize the TB response.

5.4 ENDING TB IN THE NETHERLANDS

KNCV has guided and supported TB elimination in the Netherlands for 120 years. Thanks to an active and structured approach as well as socio-economic development, the Netherlands is one of the countries with the lowest TB incidence in the world: only 4.9 per 100,000 people. However, the fight against TB continues as the disease is still diagnosed daily in the country, underscoring the need for sustained action. Currently, more than three-quarters of TB patients in the Netherlands are born abroad, in countries where TB remains a pressing concern. This positions TB as an international issue within the Dutch context.
KNCV has an active role in strengthening TB elimination strategies within the Netherlands, drawing on the expertise of professionals who not only bring insights from their Dutch experience but also bring lessons from their active involvement in global TB elimination initiatives..

As an important milestone, in 2021, in alignment with the Dutch public health strategy, KNCV handed over the central responsibility of supporting the policy making entity (Committee Practical TB control – CPT) in the Netherlands to the Center for Disease Control (Cib RIVMW). Yet, KNCV remains committed to Ending TB in the Netherlands. Since 2021, KNCV continues its support to the Dutch TB elimination strategy, policy development and organization of TB elimination in the Netherlands as a member of the National TB platform (responsible for developing and monitoring implementation of the National Strategic plan for TB Elimination in the Netherlands), member of the Central Committee Practical TB control (CPT) and member of the national governance advisory group of GGD GHOR Netherlands. KNCV also supports GGD GHOR Netherlands with organizing and documenting quality assessment visits of the regionally organized TB services of the municipal health services , in the framework of quality assurance.

Specific areas of support and advice are:
Cross-border TB control: Leveraging KNCV's extensive international network to facilitate seamless TB treatment continuation and patient support when migration is continuation of TB treatment and patient support in the destination country.
Identifying and mitigating financial barriers: KNCV systematically compiles anonymized case histories reported by the GGDs, exposing financial barriers to TB care, fostering shared learning, and spearheading stakeholder-driven solutions.

With the decreasing incidence of TB in the Netherlands it is vital to maintain expertise for high-quality TB control. Therefore, KNCV organizes training programs for doctors and public health nurses working in the TB field, and medical-technical assistants. Complementing capacity building initiatives, the online publication "Against Tuberculosis", provides Dutch professionals in the field of TB workers a platform for exchange of insights, best practices, scientific developments, and reflective analyses.

KNCV also provides information and education to patients and the public in general and organizes financial support to vulnerable TB patients and their families.

To further develop Dutch leadership in TB control and to adapt strategies in an ever evolving landscape, KNCV spearheads, coordinates and supports GGDs, chain partners and professionals to conduct operational ◂

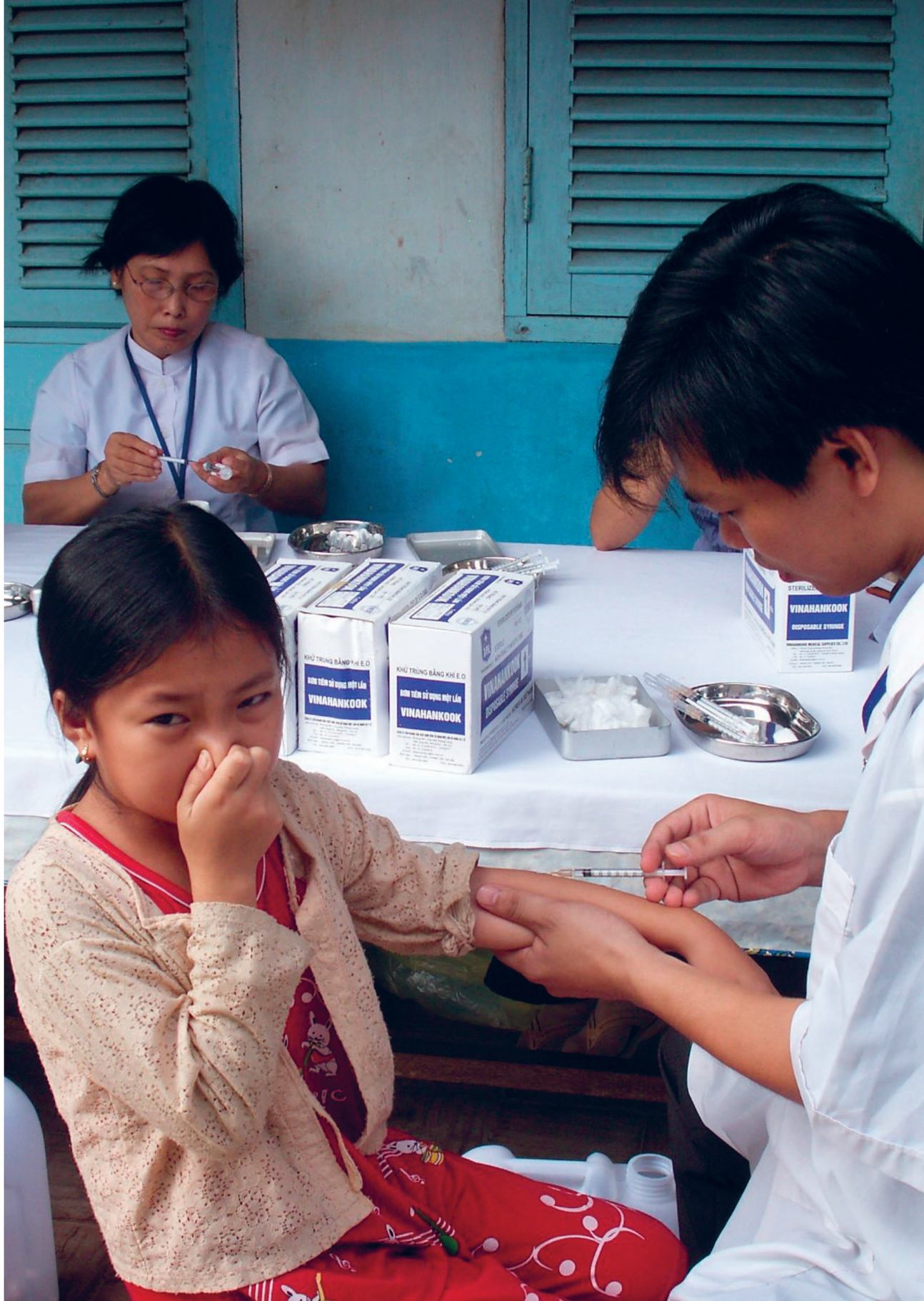
research and to develop and pilot effective innovations to end TB.
KNCV continues to develop broad collaboration for research on TB, AMR and related health conditions, with municipal health services, professional societies, Cib and RIVM, platforms of former and current TB patients, and research centers in the Netherlands, such as the Amsterdam Institute for Global Health and Development (AIGHD), the Medical Centers of Erasmus University in Rotterdam, Radboud University in Nijmegen, and the Universities of Groningen, Utrecht and Leiden. KNCV offers complimentary expertise and experience such as the programmatic introduction of new tools and interventions in high TB burden countries. KNCV brings to the table the country presence and links with governments to pilot new approaches or products of Dutch R&D and share results for R&D as well as global policy development, such as WHO guidelines.

KNCV also develops and conducts modules on various aspects of research methodology, TB epidemiology and interventions to end TB in accredited training courses for MSc and PhD programs, in collaboration with institutes for higher education in the Netherlands and abroad. Being committed to effective use of surveillance data, KNCV makes available part of the data from the Dutch Tuberculosis Register via the internet application TBC-online. This application is used by GGD regions to create their own figures and tables, based on their surveillance data. TBC-online also grants effortless access to the WHO country data on TB for to determine target groups for screening and vaccination and information on resistance.

In short, KNCV continues to be a catalyst in the journey toward elimination of TB in the Netherlands and abroad. Through its multifaceted initiatives, robust collaborations, and commitment to evidence generation and knowledge dissemination, KNCV stands as a cornerstone in the ongoing effort to safeguard public health and transform a TB-free vision into a tangible reality.

5.5 KNCV COUNTRY PRESENCE AND NETWORK ORGANIZATION

KNCV considers country presence in a limited number of high burden countries key to our strategic plan. Of course, in the period 2020-2025, KNCV is available to assist any country that requests our support. However, anticipating the end of the Challenge TB project, KNCV has identified a number of countries that we have prioritized for KNCV investments and projects. This attempt to channel funding to a limited number of countries for reasons of efficiency and technical coordination has resulted in a diverse ‘country base’ in this new strategic period: Ethiopia, Nigeria, the Philippines, Malawi, Tanzania, Vietnam, Tajikistan and Kazakhstan. This list may well expand and change due to the start or end of new projects. In addition to KNCV offices, we have and will develop affiliations with in-dependent local NGOs and academia, including organizations with which we have a ‘KNCV partnership agreement’, such as in Indonesia, Nigeria, Kenya and Kyrgyzstan.



5.6 UPDATED KNCV STRATEGIC M&E FRAMEWORK 2020 -2025

Introduction

The KNCV "theory of change" (TOC) shows how, with the available resources, and inspired by the KNCV philosophy, the identified implementation approaches enable KNCV's responsiveness to country needs. In this way, KCNV drives progress along the KNCV innovation pathways towards the intended results, achieving KNCV 2025 interim outcomes. Together with contributions by all stakeholders this eventually leads to achieving global goals of TB Elimination and a world free of TB.

An important aspect of KNCV responsiveness to country needs and global demand is the increasing role of KNCV as a knowledge institute, emphasized by the three implementation approaches: Technical assistance and research; Capacity building; Participating and advising in global forums.

Figure 7 (page 31): The updated KNCV TOC (May 2023), the basis of the KNCV strategic monitoring

KNCV monitors and reports the essential processes along the KNCV TOC for progress towards achieving the KNCV 2025 interim outcomes.
In separate chapters of the KNCV annual report, KNCV reports on the first elements of the TOC, the size and management of its resources:
1. The KNCV network and human resources
2. Financial resources
3. Systems and Operations

The M&E section of the annual report is dedicated to reporting progress towards the KNCV strategic goals, using outcome and process indicators.

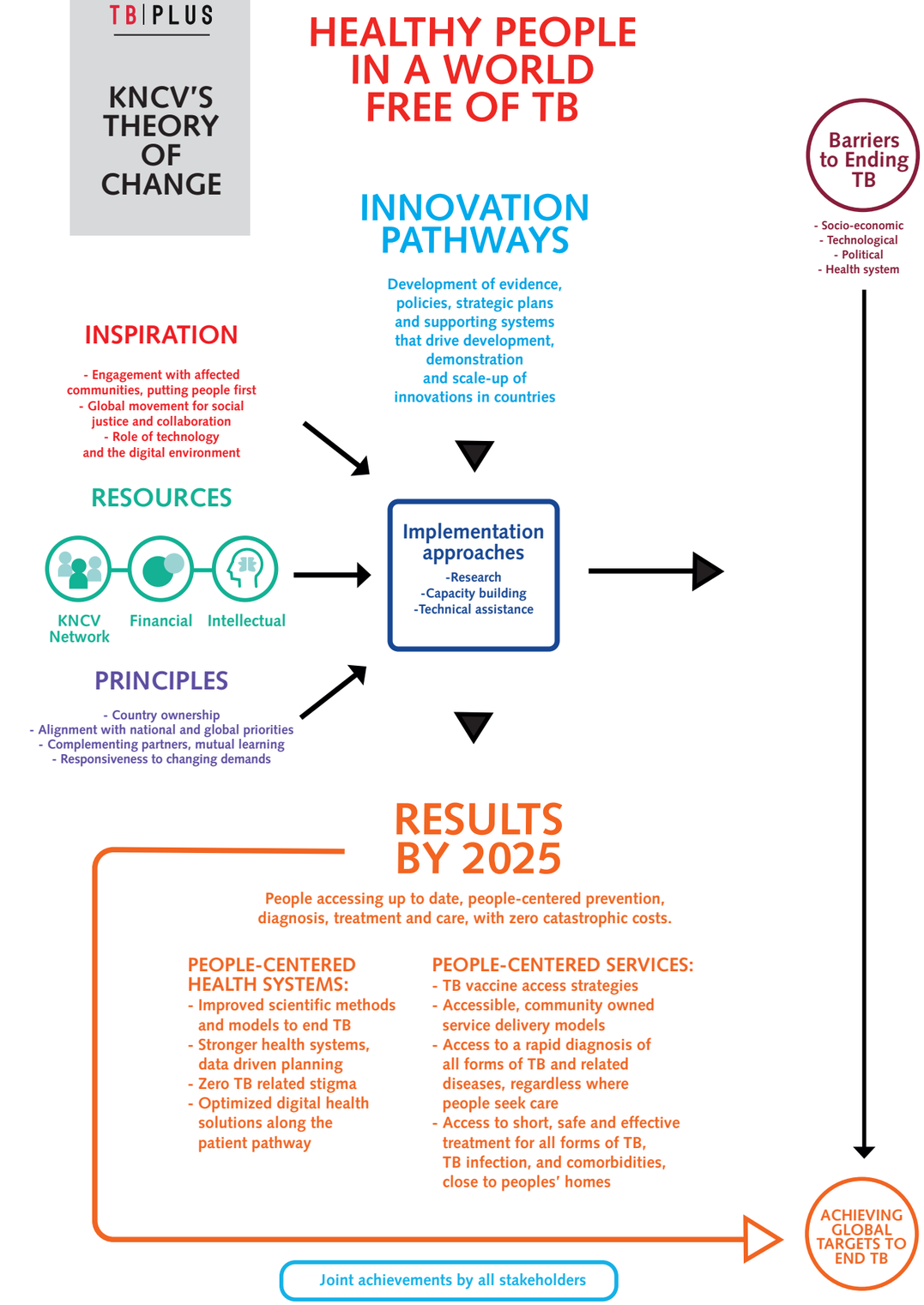
Outcome and process indicators for progress towards KCNV strategic goals.

Progress toward the KNCV interim outcomes is assessed annually by monitoring outcome and process indicators. Special attention is given to documenting and analyzing the elements identifying KNCV as a knowledge institute for TB and related health problems: scientific publications, the academic and post graduate education provided by KNCV, accredited courses developed by KNCV and national and international collaboration on research and institutional links established with other academic and research institutes.

Outcome indicators: KNCV uses four approaches to monitor progress towards achieving the KNCV 2025 interim outcomes:
1. Monitoring advances on the KNCV innovation pathways. Presenting novel interventions according to the innovation phase: conceptualization/development, demonstration or scale-up. For many innovations, an important milestone towards scale-up is WHO endorsement, so this is also indicated (see annex 2)
2. Monitoring the indicators of the global End TB strategy and UNHLM in the countries where the KNCV network is registered, as reported in the annual WHO Global TB reports (see annex 3)
3. Monitoring a specific set of project related output indicators of special interest in selected countries:
   a. The number of people in selected KNCV supported countries making use of digital adherence support tools during their treatment
   b. The number of people in selected KNCV supported countries accessing BPaL based treatment regimens.
   c. The number of people in selected KNCV supported countries accessing short TB preventive treatment (TPT) regimens
4. Monitoring the position of KNCV as a knowledge institute:
   a. The number of PhD, MSc and Bachelor candidates conducting research mentored by KNCV
   b. The number of knowledge institutes and universities with which KNCV has active research collaborations
   c. The number of downloads of KNCV knowledge products from the KNCV website
   d. The number of participants in webinars, workshops and symposia organized by KNCV.
   e. The number of times KNCV provides technical assistance to NTPs and their partners
   f. The number of times KNCV staff members participate in advisory bodies at global, regional and national level

KNCV TB PLUS

KNCV'S THEORY OF CHANGE



Process indicators: KNCV monitors and reports on several aspects of implementing the KNCV project portfolio (see annex 2 for the status per end 2022)

1) Collecting information on KNCV knowledge outputs:
   a) The number of accredited / informal trainings and courses provided by KNCV, with number and gender of participants
   b) The number of publications (co-) developed by KNCV staff and their distribution along the innovation pathways.
   c) The number of presentations by KNCV staff of KNCV work in scientific forums
2) The application of the main implementation approaches to the innovation pathways
3) The attention paid to crosscutting topics of interest (HIV, AMR, children and adolescents, COVID-19, DM)
4) The number of people trained (men/women)
5) The number of community representatives directly participating in events organized by KNCV (men/women/children)
6) The number of national TB programs, sites and partners participating in KNCV led activities.
7) The number of partners with whom KNCV collaborates in consortia
8) The number of media expressions on KNCV led activities.

The annual report also contains an overview (listing) of scientific publications, guiding materials, tools, technical briefs, best practices etc. published during the year, country and partner engagement, training conducted and a selection of media expressions on KNCV work.

Data collection

Data collection on TB program indicators is aligned with existing National TB Program (NTP) recording and reporting systems and follow WHO standard definitions. Where the national surveillance system does not provide the information required by a specific project, KNCV will define additional indicators and templates for data collection.
Data are collected from different sources and geographic areas, based on the specific results being measured, enabling comparisons of national to project area data where relevant
KNCV uses RedCap software to capture project level and organizational indicators throughout the organization. This facilitates analysis and visualization and allows for project specific adaptations, based on project, stakeholder, and donor requirements. M&E results are an integral part of the reporting to project partners and donors as well as the overall KNCV annual report.

Data use/Analysis

Collected data are analyzed and used in each project at both the implementation and research levels. Data are used to report progress and identify areas that require support or changes in implementation to achieve the planned milestones. To assess the impact of the project, at different stages of projects, collected data are compared to baselines. The data are also analyzed for trends disaggregated by relevant factors. When applicable, a TB care cascade analysis is performed to quantify the quality and completeness of implementation and outcomes of interventions.
Where possible KNCV incorporates collection of qualitative data in projects, through e.g., in-depth interviews, focus group discussions and observations. These are analyzed by thematic analysis. It enhances our understanding of key components, conditions, and underlying processes that make a project effective and impactful, potentially leading to adaptations.
The combined project results under KNCV are used to indicate progress towards the top 10 End TB and UNHLM targets, as well as the organization's strategic roadmap for 2020-2025 and beyond.

Organizational learning and dissemination

Progress reports are collected across KNCV projects on a quarterly basis, through narrative reports and quantitative and qualitative data collection.
Division meetings, KNCV network meetings, country focus meetings and lunch meetings are opportunities to share learnings across projects and professionals. In addition, every month a project of group of project is presented to the MT for in depth discussion.

Reorganization of the KNCV archiving system is conducted over the period 2023-2025, improving sharing of information among professionals, and across projects and network entities and enabling meta-analysis of KNCV activities for organizational learning.

Monitoring of M&E of KNCV internal processes

The above describes KNCV monitoring of progress towards project objectives and KCNV strategic goals. In addition, KNCV monitors, evaluates and reports internally progress on key performance indicators, identified every year based on annual plans.
These include indicators on project implementation, quality of reporting and knowledge products, indicators regarding human resources, financial management and resource mobilization as well as organizational developments.

Using a fixed format, short narrative reports are quarterly made on all projects using a format designed to capture achievements, progress made against technical and operational milestones, describing changes, challenges, risks, opportunities and lessons learned. These are summarized in the quarterly management report, indicating areas for necessary adjustments or additional needs.

The results are discussed quarterly by the management team and all divisions and shared for information with the board of trustees.

Where the national surveillance system does not provide the information required by a specific project, KNCV will define additional indicators and templates for data collection

NEVER LOSE HOPE!,
"This is what I kept telling myself back when I was on treatment. I have endured a lot (not only physically, but also emotionally) and hope was one of the things I held on to, as well as the fact that my family is always there to support me."
Photographer: Punay,
participant KNCV's TB Photovoices in Manila the Philippines.

6. RESOURCE MOBILIZATION

KNCV operates in a rapidly changing TB Control funding landscape that has become the domain of a small group of financiers, with the Global Fund, USAID in the lead and the Gates Foundation and Unitaid also offering significant support. See also chapter 4.3.

The new USAID development aid strategy aims at building local ownership and capacity through negotiating contracts with local institutions like NGOs, CBOs, academia (LON-mechanism) and levels of Government (TIFA mechanism). This essentially means that KNCV can only access USAID funding through bilateral grants and participation in LON-coalitions, for instance through legally and financially independent NGOs that were established with assistance of KNCV.

Anticipating these changes and a new strategic period 2020-2025 without USAID flagship funding, KNCV has successfully started diversifying funding with a focus on innovation and country support in the field of strategic planning. We have not only broadened our funding base, but also built and intensified strategic partnerships with relevant stakeholders such as the TB Alliance. We will continue to do so, also including financiers and private and corporate sector partners. In addition, we will further expand our local (country) partnership base and strengthen their (local partners) capacity to mobilize resources, for instance in the context of the new USAID LON mechanism.

KNCV will step up its efforts to diversify and maintain a healthy funding base in the strategic period 2020-2025 by:

1. Maintaining relations with current donors: showing results
2. Building relationship with new donors along the lines of this strategic plan
3. Increase capacity to innovate and mobilize resources through strategic partnerships
4. Strengthening efforts to optimize efficiency and internal resource mobilization capacity

In our resource mobilization efforts, we will focus on seeking and developing long-term and core funding for KNCV's priority countries (Ethiopia and Nigeria) and new projects for countries where we (would like to) have projects. KNCV will systematically develop short term TA and training packages in technical areas that require retooling and change management at country-level.
In summary, our resource mobilization initiatives will be informed by our new strategic objectives for the period 2020-2025 and explicitly linked to our track record in these areas thus far. Obviously, we will need to work with a much smaller budget compared to the last 20 years of consecutive USAID projects. But the funding base at the start of this strategic period suffices to implement the strategic plan, show results and further diversify our funding base.

Private fundraising

KNCV has a strong base in the Netherlands, where it was established as a collaborative effort by a group of civil society organizations. Our expertise and experience in organizing successful TB control in our own country was the starting point for KNCVs international role as a leading consultancy organization in the fight against TB. It is the cradle of our work and a testimony to our ability to effectively bring and keep TB under control.

The Netherlands is also our base for private fundraising, engaging private donors to help us with our mission. We are proud to be a beneficiary of the National Postcode lottery, VriendenLoterij and De Lotto. KNCV acknowledges the importance of campaigning and private fundraising for funding, but also for keeping TB on the Dutch public agenda. We will therefore not only continue to build on existing relationships, but also seek to expand with new audiences, building an even stronger base of support and engagement for advocacy and private fundraising in our home country. ◂

7. CONSEQUENCES FOR KNCV GOVERNANCE AND ORGANIZATION

Following the common principle of 'structure follows strategy' the KNCV organizational set-up has been adjusted in line with the new reality for the upcoming period 2020-2025. From 2020 onwards KNCV will work without a five-year flagship project, but still mostly based on project funding. KNCV will need to be responsive to changing demands and opportunities, both technically and managerial. Obviously, the organization will continue to diversify funding sources. Core funding will remain scarce and donor driven projects will be the core of our technical work for years to come. In order to implement the updated KNCV strategy the organization should be optimally geared towards delivering high-quality technical assistance, evidence and policy input in a dynamic and competitive environment.
The overall Governance structure remains unchanged, with the same roles and responsibilities for the General assembly, the Board of Trustees, the Executive Director, and the Management Team.

While the provision of technical advice, capacity building and development of evidence-based policies are KNCV's products, sound financial and project management are essential for good product delivery. Efficient, effective, conducive and facilitating mechanisms, such as finance and project management, fundraising and HRM, will facilitate the optimization of technical output of the organization. We need lean structures, pooling of activities, and a working environment in which different disciplines work together in a matrix structure. In order to minimize risks and increase the quality of technical outputs, KNCV works with multidisciplinary teams on different levels in the organization.

The main changes in the organizational set-up for the period 2020-2025 compared to the previous five-year period are:
KNCV moves away from the separate teams within the Technical Division; Within the pool of Technical consultants more flexible thematic taskforces will be set up including both KNCV staff in The Hague as well as technical staff from the different countries.
Merging of the Finance Division and the Operations Division into one Finance and Operations Division (F&O). In F&O financial management and operational and project management expertise and experience is bundled and will provide the same support and control packages as delivered over the past years ensuring successful implementation leading to results, and adequate monitoring and accountability.
In addition we will move from country teams to multidisciplinary project teams. The multidisciplinary project teams (with members from TD and F&O) will replace the CTB oriented country teams. However, country coordination will be ensured. For each project we will identify an individual technical project lead as well as a Grant Manager and they will jointly lead the project team ensuring good coordination and collaboration.

Technical Task Forces form the basis of KCNV knowledge sharing, idea generation and professional development system, ensuring the technical quality of KNCV work.

With the lower volume of funding, KNCV is not able to maintain as many country offices as before. However, KNCV presence in high prevalence settings remains necessary to test and evaluate innovations, build capacity and stay attractive to donors, especially taking into account new donor strategies. Therefore, KNCV will continue to strategically invest in selected country offices and further develop mutually beneficial collaborations with KNCV affiliated local NGO's.

Organizational chart

Starting the last quarter of 2019 KNCV operates in line with the revised internal structure. The organizational chart (figure 8) is characterized by separate departments (management lines) with technical, project management and financial responsibilities, respectively. A central element of the new organizational chart is the multidisciplinary project team with dual leadership by the Technical lead together with the Grant manager to coordinate and reconcile technical, project management and financial aspects of each project.

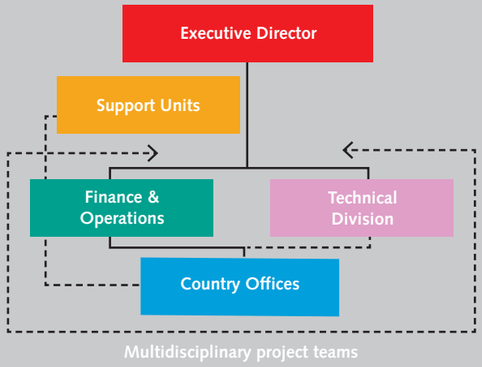


Figure 8: KNCV along the innovation pathway.

KNCV international presence and network

To create more resilience into the system and be fit for the future, and ready to anticipate on upcoming (funding) opportunities, KNCV envisions that implementing capacity on the ground in different countries remains key to success to complement specialized innovation capacity at KNCV in The Hague. However, recognizing that we can support fewer country offices resulting from lower budget volumes, we will also look for alternative ways of accessing local capacity, such as partnerships with local NGOs.
KNCV aims for an optimal mix of maintaining KNCV offices in prioritized countries, while building strong partnerships with (local) NGO's in others:

- Priority countries where KNCV will invest strategically (Nigeria, Ethiopia)
- Countries with fully project funded offices depending on project portfolio
- Countries where we will be working with partner organizations, either existing local organizations, or local entities being direct spin-offs of former KNCV staff in country

Recognizing the importance of our country offices and country presence (while considering different scenarios to achieve this), we will strive at further strengthening links between central office and country offices and country partners, ensuring a 'ONE KNCV' approach and feel. Country Directors will report to the Director Finance and Operations (F&O) They will also maintain strong functional links with the Director of the Technical Division and relevant project leads.

*KNCV workforce

The technical capacity of KNCV is key for pursuing our mission and reaching our organizational goals. In the new set-up KNCV has therefore maintained technical 'critical mass' to be able to contribute to these goals and stay attractive to donors and clients.
KNCV will need to be responsive to changing demands and opportunities, both technically and managerial. Like an accordion we need to be able to expand and (be) squeeze(d) and play different tones. In order to respond to emerging demands in specific technical areas, and recognizing the existence of a substantial international pool of specialized and highly qualified freelance consultants, KNCV will continue to make use of our flexible consultant network where needed.
KNCV's aging workforce called for a strategy for recruiting and retaining young technical staff. KNCV has been quite successful over the past years to attract young talent but this will remain on our strategic agenda for the coming five years as TB Control in general needs new and young talent.
Finally, KNCV, in compliance with labor and tax laws, will explore multiple complementary approaches to staffing within the strategic plan period. These will include a flexible layer/consultancy guided by a defined scope of work; application of duty station out of the Hague (need-based); and a strong partnership with other stakeholders both at the project and strategic levels. KNCV will continue with the phased implementation of diversification to other health-related areas, especially related to TB and the overall health system. Lastly, depending on the external environment and in close consultation with the general members, Board of Trustees, and the management team, merging with another organization with a shared vision and goal remains an option to ensure a healthy organization.

*This paragraph has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

8. STRATEGIC RISKS

KNCV has identified risks that may hamper the achievement of our mission or impact our long-term objectives:

Market risk

The countries we work in are susceptible to economical and geopolitical changes and our possibilities to support countries may change as a result of economic developments, changes in legislation and regulations, or political instability. In addition, the donor landscape is changing, with increased focus on self-reliance and funding streams to local organizations instead of INGO's. These changes may lead to increased competition or ineligibility for KNCV to apply for funding, which may result in lower income and activity budgets. We foster innovation, close relationships with NTPs and donors and a good knowledge of the field we operate in. Our strong relationships with the countries that we support and with our partners in the global network proximity enable us to anticipate changes early. Our Resource Mobilization team monitor trends to be able to adjust to developments in a timely manner. In addition, we update our strategy every five years and as needed intermittently to ensure that we optimally respond to and benefit from opportunities to fulfill our organizational mission.

Reputational risk

KNCV's name is used in all countries in which we operate. Damage to the brand in one country could have a serious impact on our reputation. Issues arising from fraud or non-compliance with laws and regulations may affect our reputation as a reliable, high-quality technical partner and that, in turn, could affect our ability to attract new projects and therefore to meet our strategic objectives. We protect our name by reaffirming our core values in a Code of Conduct and Partnership agreements. We also have control systems in place to help manage these risks. These include a whistleblower procedure, a safeguarding policy and selection criteria for selection of partners. Last but not least, we closely monitor progress of projects against commitments, which enables us to respond quickly to a variety of operational issues that may undermine timely delivery or program performance, and thus our reputation.

Financial risk

KNCV has a solid financial position and will need to maintain this position in other to be a reliable partner for donors. Besides having the highest accountability standards and solid internal controls this also means being cost effective and therefore having a continued focus on optimizing cost levels. KNCV's annual Planning & Control cycle safeguards proper planning and budget absorption as well as clear division of tasks and segregation of duties.

Organizational risk

Linking innovations to policy making and country-level implementation is at the core of KNCV's strategy. This requires a highly skilled and versatile team of technical consultants as well as a strong in-country presence in prioritized countries. Staff retention and maintaining a critical technical mass at both HQ and country level are achieved by prioritized investments in continued capacity building of all staff and effective recruitment of new staff.

KNCV operates with a risk framework that is updated annually and discussed with staff and Board of Trustees. ◄

9. FINANCIAL PLAN 2020-2023

Profit & Loss account	Budget 2020 *In € 1 mln*	Long-term forecast 2021 *In € 1 mln*	Long-term forecast 2022 *In € 1 mln*	Long-term forecast 2023 *In € 1 mln*
Organizational costs				
Personnel related costs	6,43	6,18	6,33	6,49
Other indirect costs	1,17	1,07	1,07	1,07
Subtotal organizational costs	7,60	7,25	7,40	7,56
Charged to projects	-7,02	-7,37	-7,74	-8,13
Total organizational costs not charged to projects	0,58	-0,12	-0,34	-0,57
Investment and general income	0,08	0,08	0,08	0,08
Net result organizational costs	-0,50	0,20	0,42	0,65
Activity costs				
Costs for fundraising	0,36	0,36	0,37	0,38
Other activity costs	0,07	0,07	0,07	0,07
Total Activity costs	0,43	0,43	0,44	0,45
Activity income				
Own fundraising	1,04	1,07	1,10	1,14
Lotteries	1,36	1,36	1,36	1,36
Total Activity income	2,40	2,43	2,46	2,49
Net result Activities	1,97	2,00	2,02	2,04
Project costs				
Charges organizational costs	7,02	7,37	7,74	8,13
Travel and accommodation	1,85	2,00	2,00	2,00
Other direct project costs	8,38	9,68	9,68	9,68
Total Project costs	17,25	19,05	19,42	19,81
Project income				
Funding donors - fee	4,81	5,05	5,56	5,83
Funding donors - travel and accommodation	1,70	1,85	1,85	1,85
Funding donors - other direct project costs	7,35	8,97	9,07	9,07
Endowment funds contribution	0,58	0,58	0,35	0,35
Other income for projects	-	-	-	-
Total Project income	14,44	16,45	16,83	17,11
Net result Projects	-2,80	-2,60	-2,59	-2,70
General Result (minus is a deficit)	**-1,34**	**-0,40**	**-0,15**	**-0,01**
Covered by earmarked reserves / donated to earmarked reser	**-0,52**	**-0,40**	**-0,30**	**-0,30**
Influence on/movements other reserves	**-0,82**	**0,00**	**0,15**	**0,29**

This financial outlook was developed in 2019 and is updated annually based on actual developments and updated expectations and available as part of the annual planning cycle.

10. COVID-19 ADDENDUM (SEPTEMBER 2020)

BACKGROUND

COVID-19

The Corona Virus Disease 2019 (COVID-19) caused by the Severe Acute Respiratory Syndrome Virus-2 (SARS-COV-2) has posed an unprecedented global challenge requiring a response package commensurate with its magnitude and seriousness. In just over nine months since COVID-19 was first recognized in China, more than 27 million people were diagnosed with the virus and nearly 0.9 million COVID-19 attributed deaths were reported as of September 7, 2020.[3] Of the over 7 million reported active cases at the time of writing, about 1% were reported to be in serious or critical condition. The overall mortality rate among closed cases was about 4%. Poor people, the elderly and people with co-morbidities are most at risk for unfavorable outcomes.

During the early months of the pandemic, most of the reported cases were among adults, and fatalities were largely among those in older than 65 years of age and in those with underlying health conditions such as diabetes, heart disease, hypertension or cancer.

The pandemic has now swept 199 countries. In some low income settings where other pandemics (TB, HIV, MERS) and epidemics are still ongoing, especially in most of Sub-Saharan Africa, the pandemic arrived late but is predicted to take a protracted course. Moreover, the interaction between other infections and COVID-19 remains to be understood.

Adapting to a changing global environment

The COVID-19 pandemic has rapidly impacted the global health environment. Many countries going into "lockdowns" and closing their borders for most of the international travelers, requiring KNCV to adapt the way it implements projects and provides technical assistance. KNCV immediately transitioned to supporting countries remotely, using a variety communication platforms, including e-workshops and e-learning with video feedback as integral parts of technical assistance. This has quickly become an acceptable way to organize technical assistance and exchange experience with partners abroad.

While saving resources on travel in projects, at the same time additional resources are needed to support and facilitate countries to mitigate the impact of the COVID-19 pandemic on TB control . Donors are showing flexibility in project adaptations and are freeing up resources for the necessary changes. In several cases COVID-19 specific activities are added on to existing projects.

The strain on the health systems, economies and social resources requires careful navigation to ensure essential services are maintained and adapted to the "new normal". This includes prevention control measures for both service providers and service users, local travel restrictions and other measures taken by governments to fight the epidemic.

KNCV will be using the following four pillars to responding to TB services (figure 9) during the pandemic with a focus on integrated and decentralized platforms.

Figure 9: Four pillars to responding to TB services during the pandemic.

Integrated and decentralized platforms	Infection prevention and control, diagnosis, surveillance, stigma reduction
Digital Solutions	Community empowerment, adherence support, M&E (including surveillance), Logistic Management Systems
Virtual Environment	Capacity building, Mentorship & supervision, Management
Leverage resources	TB to leverage resources for COVID-19 impact mitigation, including political commitment and domestic funding while sharing technical experiences from TB for application in the CO-VID-19 response

At the same time funding mechanisms for COVID-19 are established by the larger donor organizations, e.g. the COVID-19 response mechanism by The Global Fund. KNCV supports countries to make optimal use of these support mechanisms.

3: www.worldometers.info/coronavirus/

'Chapter 10: COVID-19 Addendum' has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

Situational analysis: COVID-19 and TB

Renewed country and donor commitment following the UNHLM in 2018 coupled with new diagnostics, drugs and treatment options and intervention strategies spurred an unprecedented progress towards achieving the End TB targets. The COVID-19 pandemic as well as the resulting severe strains on local health systems and economies have stalled the recent progress globally and threatens to reverse gains in many countries.[i,ii]

COVID-19 is impacting essential TB service provision in many low- and middle-income countries (LMIC) i,ii. Health systems resources (financial, human and infrastructure) are diverted towards COVID-19 reducing access to adequate TB care (diagnosis, treatment and support). Based on modelling , the WHO, STOP TB Partnership and other partners estimated an additional 6.3 million TB cases will occur between 2020 and 2025 and an additional 1.4 million TB related deaths, attributable to the COVID-19 pandemic. The predicted rise in TB incidence and death rates equates a setback of 5-8 years in the fight against TB.[i,ii,iii,iv,v]

The pandemic highlighted the need to invest in better emergency preparedness to ensure that essential services like TB programs will not be adversely affected. TB programs and health systems in general will take a considerable amount of time, resources and restructuring to recover from the initial strain of the COVID-19 burden as well as to adapt to the required "new normal" of service provision. As long as no effective and safe vaccine is available, infection prevention measures such as minimizing face to face interactions, strict physical distancing, the use of personal protection measures, strictly scheduled appointment systems to prevent crowded waiting areas, digital remote support tools for patients and health workers community-based approaches, etc. will have to be the norm.

The pandemic also highlights the need for better, integrated digital data and surveillance (DHMIS) systems and local data utilization to facilitate responsive evidence-based programming.

Lastly, the global COVID-19 response has set a precedent which could be harnessed for the fight against TB since it has managed to rally high level of international collaboration and coordination in information sharing and harmonizing a strategic response. It also opened avenues for fast tracked development and innovation and approval processes for guidelines, diagnostics, drugs and vaccines.

KNCV STRATEGIC RESPONSE

Focus area 1: evidence generation

Integrating COVID-19 in the mix of TB associated health problems, like HIV, Diabetes and anti-microbial resistance, KNCV continues to generate new evidence, combined with a firm commitment dissemination of the evidence to support optimal implementation and programmatic scale-up of effective interventions.

Transmission dynamics: Building on its TB-specific expertise and many years of providing technical support to countries with high burden of TB (and now COVID-19), KNCV will collaborate with national programs to study factors that affect transmission dynamics, disease severity and treatment outcomes with particular focus on households and communities at high-risk of COVID-19/TB infection.

Models of care: models of delivering integrated care for TB/COVID-19 including the optimal diagnostic algorithms using the existing platforms and adapting and optimizing service delivery modalities to the "new normal" of operation, including the increased level of distant support and operations will also be another key area.

Novel diagnostics: the occurrence of COVID-19 highlights the importance of the development and implementation of multi-disease diagnostic platforms, importantly also the introduction of genome sequencing; also studies on the impact of COVID-19 on diagnostic approaches and algorithms are needed.

Digital solutions: Due to the COVID-19 pandemic many countries are rapidly changing the way TB care is provided, especially relying on the use of a variety of innovative digital and mobile tools. These tools need rapid evaluation and evidence generation ▶

regarding their feasibility, acceptability, (cost-) effectiveness and optimal use, prior to scale-up.

Impact measurement and mitigation and cost effectiveness modeling: KNCV works with national TB programs and partners to monitor the impact of COVID-19 on existing services so to promptly identify and develop remedial actions where and when needed. At the same time KNCV is working with WHO and other partners on optimizing surveillance and data management systems and impact modelling for optimized TB programming (including assessing the COVID-19 impact on TB control at national and subnational level) to support countries in optimizing their response, develop contingency planning and emergency response strategies. Given the increased competition for scarce resources optimization of program efficiency and evidence-based investment cases are more important than ever to ensure the continuation of essential services and securing support for necessary innovations to continue on the road to TB elimination.

Focus area 2 and 3: Policy development, strategic planning of the TB response along the care continuum and strengthening of supportive systems

By developing and synthesizing evidence from ongoing studies and collaborating on guideline development processes, KNCV will contribute to evidence based policy development at global and national level, to adjust to the COVID-19 situation.

In addition KNCV will continue to support strategic planning and building resilient supportive systems, in response to countries need, especially regarding the following topics, making optimal use of lessons learnt.

Strategic planning, governance and health financing: The People-Centered Framework (PCF) approach for strategic TB planning and programming has proven itself as an accessible, user-friendly, and effective approach during the current TB NSP development and Global Fund application cycle. The approach has also already been shown to be adaptable for the use in other disease response programs (e.g. Leprosy in Uganda, Kenya and Rwanda). KNCV therefore intends to apply a slightly modified (shortened) version in combination with the above proposed surveillance approach, to facilitate country programs to perform a rapid assessment of the immediate impact of the COVID-19 pandemic on their TB epidemic response, identify and respond to emerging challenges and gaps in a timely and prioritized manner. We anticipate a demand for a rapid rollout of the PCF Approach as tool of choice for COVID-19 related mitigation planning and program adjustments over the period 2020-2022.

Prevention: Emphasis will be placed on measures limiting transmission of TB and COVID-19 in health facilities, congregate settings and home based care situations.

Diagnosis: KNCV will support the expansion and use of the Xpert platform for simultaneous COVID-19 testing, alongside testing for TB and HIV. Support to laboratory network strengthening, the introduction of genome sequencing, sample transportation systems, supply chain management and connectivity solutions will take into account the need to diagnose COVID-19 alongside TB.

Treatment and care with community engagement: Special attention will be placed on expanding community supported home based care with due attention to capacity building and safety of patients, community members and health workers regarding DS/DR TB and COVID-19. Also contact investigation and TB preventive treatment will be areas of attention for home based care. This will require extra attention and organization of supply chain systems to the grassroots level.

Digital health technologies: COVID-19 has increased the interest and provided opportunities for wider utilizing of digital health solutions to support patients' treatment at home, logistics, remote communication with patients and remote education of health staff and communities. COVID-19 has led to a rapid change in the standard of care in many countries, where NTP's moved away from facility-based care towards home-based treatment. KNCV supports the utilization of digital health tools to replace frequent face-to-face contact, supporting patients to complete their treatment at home while still keeping in close contact with their health care workers for counseling, monitoring and management of adverse events etc. KNCV will also support the development of digital platforms to optimize sample transportation and the distribution of medical supplies and drugs to health facilities, health workers and patients at home, critical to facilitate and ensure uninterrupted continuation of care; digital platforms will also facilitate community ▸

empowerment by providing information and enabling community based monitoring.

Stigma reduction: The COVID-19 pandemic has evoked a wave of stigmatization and discrimination against people perceived to be infected with COVID-19 or been in contact with infected persons (potentially able to transmit the infection) such as health care professionals, people displaying respiratory symptoms and people from certain associated ethnic backgrounds. Stigma drivers and stigma related adverse effects need to be carefully monitored and promptly mitigated. The KNCV TB stigma reduction and measurement tools can play a role to address COVID-19 related stigma and discrimination (and resulting increases in TB and other respiratory diseases related stigma and discrimination), which can provide valuable input into policies and guidance documents at global and national level

Surveillance and data management: Outbreak management and real-time monitoring of infections are becoming the standard in the COVID-19 response. TB surveillance is traditionally slow with aggregated quarterly reporting still the standard in many countries, often disconnected from the larger health system surveillance. The TB response can benefit from the way the COVID-19 epidemic is monitored and showcases the importance and effectiveness of rapid monitoring and response. This presents an opportunity to establish integrated infectious disease surveillance that builds on the lessons learned from COVID-19 data reporting : (a) define a unified response rather than diverse disconnected strategies and (b) leverage the innovative technologies such as web based patient support systems and simple dashboards using easy to collect indicators. KNCV is preparing the development of a National Patient Based TB & SARS -Cov-2 Surveillance System to facilitate combined surveillance.

Healthy Workforce and Capacity Development: The COVID-19 pandemic is not just a physical health issue but also affects mental health. This holds true for affected populations, care providers as well as the general population. The new way of (remote) working requires remote meetings, delivering webinars, e-seminars, e-workshops and actively facilitated peer-to-peer learning as well using e-tools and digital platforms as integral part of technical assistance and mentoring. At the same time, digital health approaches are also becoming the norm in service delivery and care provision. Adding computer/ digital literacy, therefore, has become an urgent priority when developing staff technical competencies. The changes in policies, guidelines and ways of working require responsive and accessible communication, information management, and staff support systems. Digital communication and notification systems using mobile phone technology linked to digital learning platforms like the one KNCV is currently developing with WHO form an invaluable backbone to this approach.

Key affected populations: COVID-19 pandemic has created many challenges for the world's population. However, these challenges are inordinately more severe for most marginalized and vulnerable populations. COVID-19 mitigation strategies with strict lock-down measures with subsequent loss of income, lack of public transport, reduced public services (e.g. health & social services), etc. has led to a severe increase in socio-economic hardship for many vulnerable and marginalized populations - pushing many (further) over the poverty line. This has also further reduced their access to health, social and legal services and substantially increased their risk of contracting COVID-19 and/or TB through crowded living conditions (inability to physically distance during lock-down). Trying to access health services or trying source basic supplies has put these populations at risk of further discrimination and even violence (for "breaking lock-down"). This has discouraged timely health care seeking for both TB and COVID-19 and led many people to hide their symptoms putting themselves and their contacts at risk of adverse outcomes. TB programs need to urgently put emergency measures and contingency plans for vulnerable and marginalized key affected populations in place to ensure sustained and safe access to essential services and care. These needs to also include enhanced additional socio-economic support packages for patients and their families.

Resource mobilization- opportunities and risks

The changed "post-COVID-19" landscape and resulting new operating environment challenges country programs and their national and international partners as well as global policy makers and donors to take stock, re-assess strategies against resources, challenges and opportunities and creatively re-imagine approaches.

10. COVID-19 ADDENDUM (SEPTEMBER 2020)

Currently, at the start of the COVID-19 pandemic an overall a shift in focus and resources from TB towards COVID-19 is taking place. The international donor-community, through the Global Fund, has made emergency grants available (COVID-19 -response mechanism) to allow countries to mitigate the impact of the pandemic on their disease programs and strengthen their health systems. Furthermore, countries were encouraged to reprogram savings of their ongoing grants and work on portfolio optimization for their new grants.

Substantial additional resources will be needed to safeguard current achievements towards the End TB targets (and the corresponding HIV and malaria program targets) and catching up with those targets which stalled or reverted during the pandemic.

There remains a risk of further challenges to achieving End TB Targets brought on by localized and regional next COVID-19 waves and outbreaks. However, these could be outweighed by unprecedented opportunities to utilize additional funds, new technologies and implementation pathways strategically to rapidly advance the fight against TB. KNCV is well positioned and equipped to play a key role in supporting this drive both at national and international level.

KNCV is continuing to monitor funding opportunities for COVID for possibilities to fund KNCV support to the combined TB-COVID and health systems strengthening approaches described above.

Consequences for KNCV governance and organization

KNCV regularly reviews the COVID-19 situation in the offices in The Netherlands and the country offices, keeping open lines of communication and supporting and enabling staff to adhere to safe working practices and government advice and regulations regarding COVID-19.

Domestic and international travel are restricted in the Netherlands and KNCV supported countries and many countries limit the number of people in physical meetings. Therefore the way technical assistance, training and capacity building is provided needs to adjust to this situation. KNCV rapidly switched to utilization of remote support technologies, including e-workshops and e-learning as integral parts of providing technical assistance.

The impact on how we travel, work, and interface with health system will guide the revision of KNCV travel and safety policies at all levels. The work environment is being upgraded with appropriate digital (IT) infrastructure and staff capacity to enable provision of services in the changing world and effective communication across projects and countries. ◄

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i The potential impact of the COVID-19 response on tuberculosis in high-burden countries: a modelling analysis. Stop TB Partnership, Geneva: Stop TB Partnership, Geneva; 2020. Available from: http://www.stoptb.org/assets/documents/news/Modeling%20Report_1%20May%202020_FINAL.pdf

ii Information Note. Tuberculosis and COVID-19. Geneva, World Health Organization; 2020. Available from: https://www.who.int/tb/COVID_19considerations_tuberculosis_services.pdf

iii Predicted impact of the COVID-19 pandemic on global tuberculosis deaths in 2020; Glaziou P. Epidemiology; 2020 May [cited 2020 May 6]. Available from: http://medrxiv.org/lookup/doi/10.1101/2020.04.28.20079582

iv Potential impact of the COVID-19 pandemic on HIV, tuberculosis, and malaria in low-income and middle-income countries: a modelling study Alexandra B Hogan, Britta L Jewell, Ellie Sherrard-Smith. Lancet Glob Health 2020; 8: e1132–41 Published Online July 13, 2020 https://doi.org/10.1016/ S2214-109X(20)30288

v The potential impact of the COVID-19 response related lockdown on TB incidence and mortality in India; Anurag Bhargava, Hemant Deepak Shewade; Indian J Tuberc. 2020 Jul 10; doi: 10.1016/j.ijtb.2020.07.004

ANNEX 1

Annex 1 has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

ANNEX 1: KNCV THEORY OF CHANGE 2020 – 2025

INTRODUCTION

1.1 KNCV mission and vision

The KNCV Theory of Change presented here is a way to operationalize the KNCV mission and vision for the period 2020-2025:

- Our mission is to end human suffering due to TB through the global elimination of tuberculosis
- Our vision is that KNCV will save lives and accelerate the decline of the TB epidemic through the development and implementation of effective, efficient and sustainable, setting specific strategies that combine patient centeredness with epidemiological impact.

1.2 KNCV goals

The long term goal of KNV TB Foundation is ending TB and related human suffering as a global public health problem by 2035, and TB Elimination by 2050

Strategic goals: *KNCV aligns with UNHLM targets for 2022 and the End TB strategy milestones for global TB elimination by 2035 and 2050*
Interim goal: *in 2025 the world will be in a good position to work towards elimination of TB and related human suffering in line with the global UNHLM 2022 and 2035 / 2050 milestones*

The strategic plan 2020-2025 covers a pivotal era in Global End TB strategy, during which optimization of the use of existing and innovative approaches has to take place as well as universal health coverage and social protection, while preparing for the introduction of game-changing innovations by 2025 (vaccine, new drugs for treatment of TB infection and active TB disease and a point of care test).

The COVID-19 pandemic threatens to derail the progress made over the past years by overburdening health systems and diverting attention and funds for TB Elimination. Global efforts are made to mitigate against this impact by adapting approaches and incorporating COVID-19 relevant interventions in TB programming; KNCV is in the forefront of taking up the challenge to maintain the momentum towards TB Elimination.

1.3 Barriers to Eliminate TB

People are still suffering and dying of TB because there are significant socio-economic, technological, political and health systems barriers to eliminate TB:

Technological barriers

- Lack of effective vaccines, POC diagnostics for TB, drug resistance and TB infection, lack of short, well tolerable treatments for all forms of TB; insufficient use and availability of e-Health and mobile tools along the patient pathway to facilitate community health management, TB care provision, treatment adherence etc. ▸

Figure 10: KNCV's strategic goals aligned with the UNHLM targets for 2020 and the End TB Strategy milestones for 2035 and 2050.

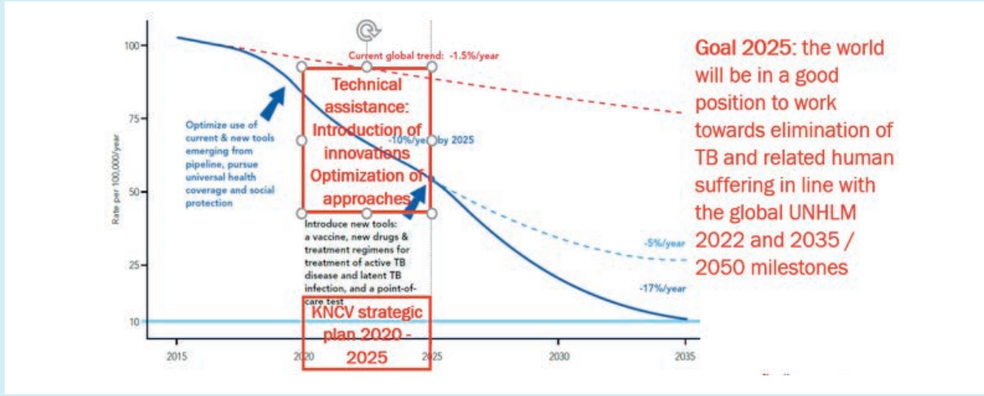
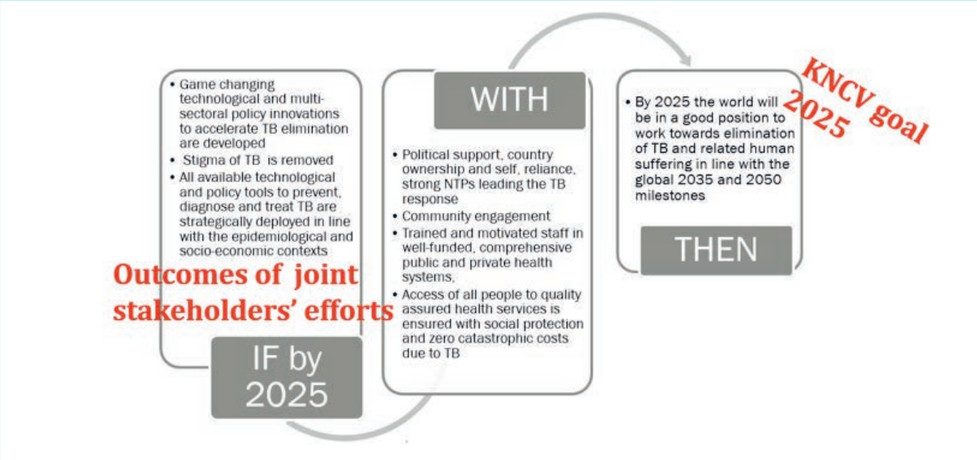


Figure 11: Global interim goals leading to the intended TB Elimination situation by 2025.



Socio-economic barriers
- Stigma of TB and associated health problems, insufficient community engagement, insufficient social protection, leading to lack of access to care

Health system barriers
- Underfunded, weak health systems, lack of well trained, supported health staff, insufficient integration of TB care in all sectors, incomplete use of data for strategic planning, leading to suboptimal quality and effectiveness of health services

Political barriers
- Insufficient of political commitment and country-ownership of the response to the TB pandemic, insufficient domestic and international funding for health systems, including TB control-till-elimination, insufficient funding for TB research, insufficient participation of affected populations in decision making

1.4 KNCV engagement with stakeholders in TB Elimination

Stakeholders are governments and regulators, managers in health and health workers in public and private health sectors, the broader community and patients, scientific communities, NGO's and technical partner organizations, corporate sector and funders (including governments).

KNCV THEORY OF CHANGE

2.1 Interim goals leading to the intended TB Elimination situation by 2025

As illustrated below in figure 11, in line with the Global End TB strategy, KNCV believes that IF game changing technological and multi-sectoral policy innovations to accelerate TB elimination are developed by 2025 AND stigma of TB is removed and IF all available technological and policy tools to prevent, diagnose and treat TB are strategically deployed in line with the epidemiological and socio-economic contexts WITH political support, country ownership and self-reliance, strong NTPs leading the TB response and community engagement AND implemented by trained and motivated staff in well-funded, comprehensive public and private health systems, AND access of all people to quality assured services is ensured social protection is in place and zero catastrophic costs due to TB THEN by 2025 the world will be in a good position to work towards elimination of TB and related human suffering in line with the global 2035 and 2050 milestones.

KNCV will work towards these interim goals in collaboration with stakeholders in TB Elimination.

2.2 KCNV strategies and positioning along the innovation pathway towards achieving the global interim goals

The three overarching implementation strategies KNCV uses to work towards realization of its goals are:
1) Evidence generation
2) Policy development and strategic planning and
3) Development of supportive systems

KNCV considers these strategies to be mutually reinforcing, see figure 12.

Figure 13 shows how the three implementation strategies are applied along the innovation pathway, which stretches from the early development of the innovations to demonstration pilots and eventual scale-up.
While developing and generating evidence around innovations, leading and learning from demonstration projects and providing technical assistance to measuring and documenting the impact of scale-up of innovations, KNCV supports countries and partners to prepare the regulatory frameworks and strategic plans that are to guide and realize the in-country innovation pathways. At the same time KNCV provides technical assistance to the development of the platforms, tools, the organization of care and engagement of communities and other stakeholders that are needed for effective uptake and roll-out of the intended innovations.

Figure 12: Three overarching implementation strategies

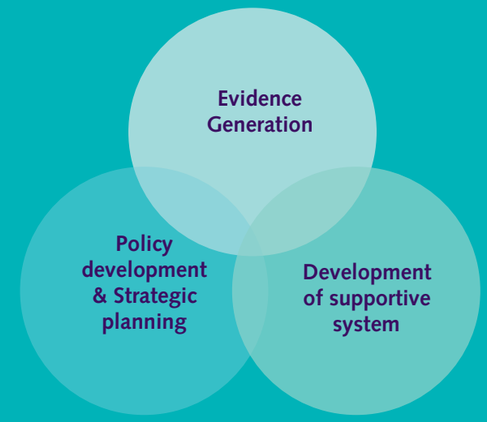
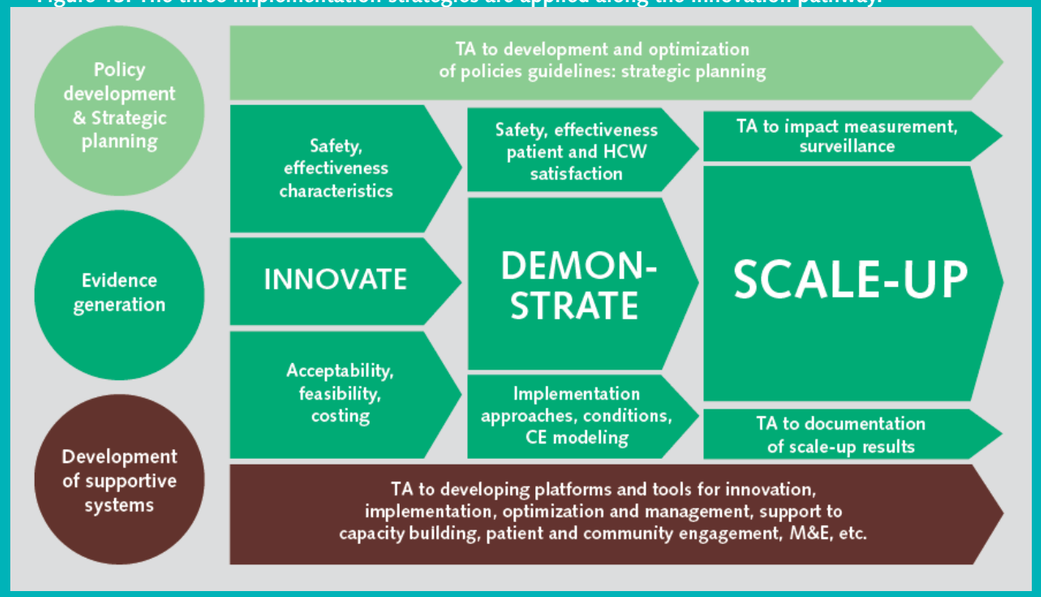


Figure 13: The three implementation strategies are applied along the innovation pathway.



2.3 The KNCV strategic roadmap 2020-2025

The KNCV roadmap consists of detailed pathways for KNCV's contributions to achieving the global interim elimination goals by 2025. This roadmap guides KNCV priority setting in acquisition and communication and are a basis for monitoring and evaluation of the KNCV strategic plan 2020 -2025. Updates to the roadmap are made based on new developments.

KNCV aims for TB Elimination in an integrated approach with HIV, Diabetes Mellitus (DM), COVID-19 and anti-microbial resistance (AMR), following nine pathways that constitute the KNCV roadmap towards the KCNV strategic goal:

1) Improving and developing the evidence base for TB Elimination including methodologies for epidemiological measurements and integrated disease surveillance systems
2) Building system-readiness for the deployment of new or improved TB vaccines
3) Improving early management of TB infection
4) Early identification of all patients with all forms of TB in all age groups and vulnerable or at-risk populations
5) Reducing stigma
6) Innovation and optimization of diagnostic technologies and strategies, especially the use of multi disease testing platforms
7) Improving patient centered treatment of active TB, including drug resistant TB
8) Development of electronic information systems and digital health solutions along the patient pathway
9) Strengthening of health systems and multisectoral solutions along the patient pathway, including health financing and country ownership

The detailed pathways for 2020-2025 on the road map towards KNCV goals are the following:

1) Improving and developing the evidence base for TB elimination at national and sub-national levels. This evidence will support advocacy, country program planning and policy development at global, national and subnational levels on the best possible policies, algorithms and methods for primary and secondary prevention of TB, active case finding, diagnosis and treatment of TB infection and disease and the prevention and management of AMR in TB. This includes improvement of TB burden estimation tools, innovative methods for surveillance of TB and associated diseases, TB drug resistance patterns and early management of TB INFECTION in adults, adolescents and children. Development of the evidence base regarding effectiveness, acceptability, feasibility and cost-effectiveness of new interventions and approaches as well as epidemiological and cost-effectiveness modeling for subnational, national, regional and global TB elimination planning and modeling of impact of relevant factors (e.g. COVID, HIV, DM and AMR). The pathway also includes capacity building in key countries to demonstrate and disseminate the use of these tools and methodologies.

Expected landscape by 2025: countries will have the tools to make valid TB burden estimates, perform meaningful surveillance of TB (and HIV, DM, COVID and AMR as needed) , evidence and models will be available to design an optimized mix of interventions for TB elimination and capacity will be present in key countries for their use.

2) Building system - readiness for the deployment of new or repurposed TB vaccines by contributing to multi-disciplinary research for the development of late-stage tuberculosis vaccine candidates and repurposed vaccines; contributing to the knowledge base for the population distribution of TB infection, to inform late stage TB vaccine research and development and demonstration of information systems capturing age specific TB infection rates in selected countries, with publication of results, experiences and lessons learnt for advocacy and policy development.

Expected landscape by 2025: Evidence and tools to develop vaccine delivery strategies will be available for countries to prepare the deployment of new or repurposed vaccines

3) Improving the early management of TB infection by using all relevant evidence and practical experience to identify and focus on populations with high prevalence of TB infection and populations vulnerable to TB (including e.g. PLHIV), optimizing models of care and service delivery systems. This includes the deployment of digital tools to facilitate diagnosis and treatment of TB infection; the development of situation specific decision guidance for identification ►

of priority populations for TB infection, testing and treatment options; introduction of effective and patient friendly treatment regimens and formulations, including treatment options for TB infection in people exposed to drug resistant TB.
The pathways also includes support for scale up of innovative TB preventive treatment in demonstration projects in key countries, including building on community resources, combined with enhanced strategies for active case finding (also see 4), with publication of results, experiences and lessons learnt for advocacy and further policy adjustments.

Expected landscape by 2025: Tools and guidance are developed and implemented widely, such that safe and effective TB preventive treatment is provided to all people who may benefit according to their risk of developing TB, with service delivery models following a people-centered approach.

4) **Early diagnosis of all patients with active TB**, by applying standardized methodologies to identify the gaps in diagnostic services and treatment coverage (such as patient pathway analysis (PPA), prevalence surveys, inventory studies, sub-national TB prevalence estimations in key countries) and data driven design of strategies, models of care and service delivery systems to effectively find and treat patients with TB at the earliest possible moment. This will be achieved by making optimal use of the private and public health sectors, corporate sector and communities and by integrating these approaches with programs for HIV, DM, COVID-19 and AMR, mother and child care programs etc.

Expected landscape by 2025: Evidence based methodologies and models of care will be available for diagnosis and treatment follow-up of people with TB and TB infection, as close as possible to the homes of the patients, with community ownership

5) **Reducing stigma of TB** and comorbidities by advocating for mainstreaming of stigma reduction in NSPs and grant applications and making tools available for stigma measurement and assessment as well as tools to raise awareness about stigma and stigma prevention & intervention packages; capacity building and evidence generation on the use of stigma reduction tools in key countries for advocacy and policy development; collaborating on use of TB stigma reduction tools for application in other diseases like COVID.

Expected landscape by 2025: the application of evidence stigma reduction tools is mainstreamed in National Strategic Plans and major donor funded programs

6) **Innovation and optimization of diagnostic technologies and strategies** for diagnosis and treatment for TB infection, TB, DR-TB in health facility and community settings. We will be involved along the spectrum of TB infection, incipient disease and active disease for diagnosis as well as treatment & post-treatment monitoring. We will collaborate on development and support of early implementation and evidence generation on innovations e.g. alignment of diagnostics with the treatment regimens used. We will leverage synergies from multi-disease platforms and anti-microbial resistance (AMR) as well as emerging infections (e.g. COVID) and co-infection (e.g. HIV) testing capacity increases. We will strengthen diagnostic networks in key countries, including the use of artificial intelligence e.g. in chest X-ray reading, and ensuring access to diagnostic tools for all ages and gender sensitive. We will have a patient-centered care approach with diagnostic capacity as close to their homes as possible by optimizing the mix of technologies newly introduced or currently used in key countries. We will design diagnostic algorithms and quality management systems. We will document results, experiences and best practices for advocacy and policy making.

Expected landscape by 2025: Evidence-based methodologies and algorithms will be available for diagnosis and treatment follow-up of people with TB, DR-TB and TB infection of all ages as close as possible to the homes of the people seeking care.

7) **Improving patient centered treatment of active TB, including drug resistant TB**, by introducing new drugs and novel, all oral and shorter treatment regimens in key countries, including child friendly formulations, for well selected patients under appropriate drug safety monitoring conditions; patient centered care, including HIV, DM, COVID care and AMR stewardship; studies to provide evidence for policy ▸

development, advocacy and scale-up; dissemination of results of these studies and lessons learnt in the form of SOP's and implementation tools, training packages, publications and webinars; improvement of treatment results and patient experiences by introduction of blended packages of patients support, with health worker and community patient support contacts supplemented by on line and mobile patient support options.

Expected landscape by 2025: BPaL and subsequent fully oral DR TB regimens are implemented in key countries and up to date generic implementation tools packages for regimen change are available for all countries

8) Development of electronic information systems and digital health solutions along the patient pathway: We will achieve this through development & implementation of diverse people-centered computer, mobile, diagnostic, and other innovative information and communication technologies (ICTs) to support patients, health care providers, and decision-makers. Integrated in this work will be policy guidance on the use of digital innovations, established though evidence-building efforts around the impact of these solutions in reducing TB.

   These approaches include: defining a framework for a surveillance and health information systems with potential linkages to national systems (such as DHIS2), as well as strengthening community-led health surveillance using mobile tools; strengthening diagnostic networks through ICT-enhanced sample transportation and laboratory connectivity systems while building human and network capacity to support these; incorporation of digital adherence support tools in funding mechanisms and country policies for improved TB treatment outcomes for TB, DR TB and TB infection; and building data visualization pipelines and platforms for countries and internal KNCV M&E use.

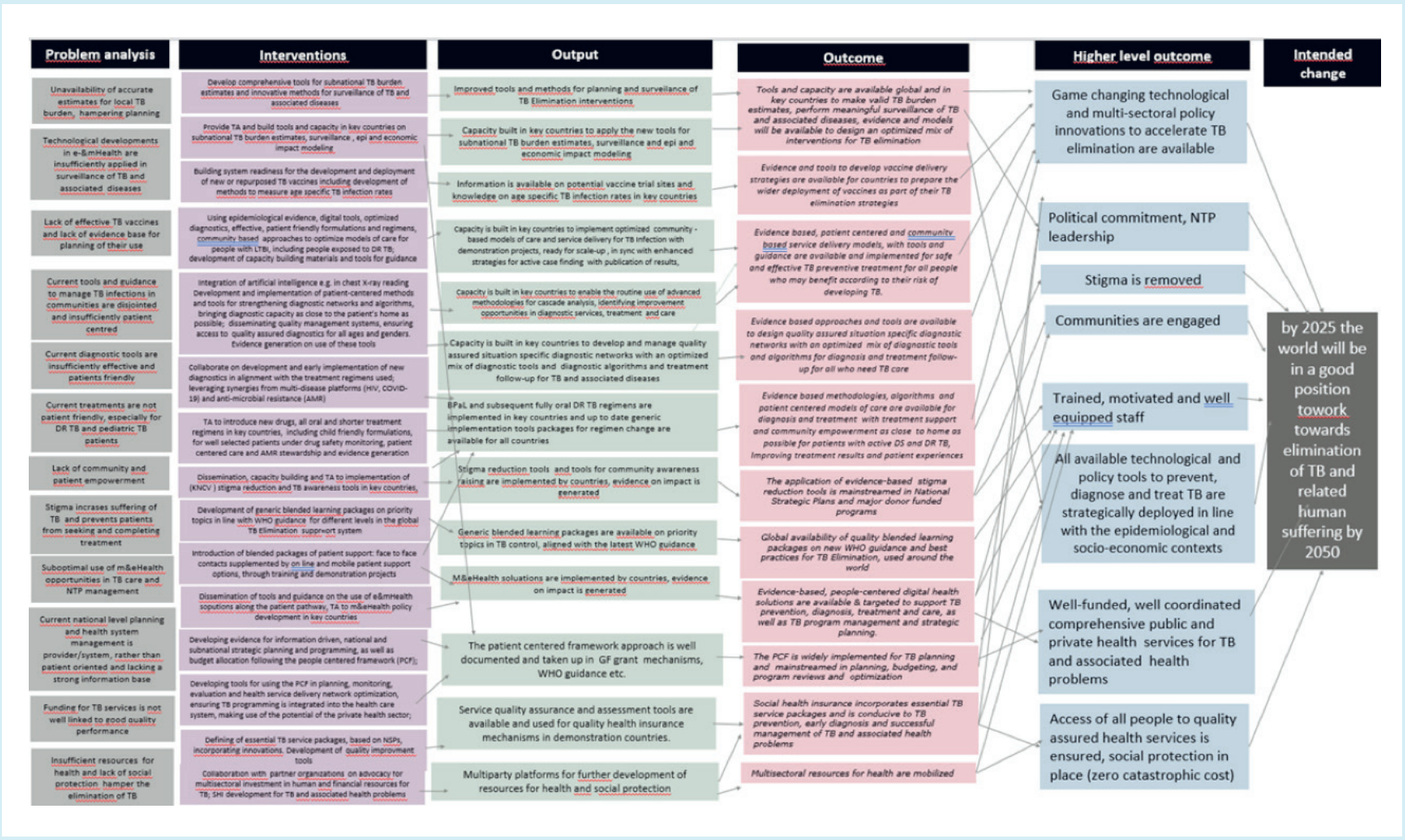
Expected landscape 2025: Evidence-based, people-centered digital health solutions are available & targeted to support TB prevention, diagnosis, treatment and care, as well as TB program management and strategic planning.

9) Strengthening of health systems and multisectoral solutions along the patient pathway by developing evidence for information driven, national and subnational strategic planning and programming, as well as budget allocation following the people centered framework (PCF); developing tools for implementation of the PCF in planning, monitoring, evaluation and health service delivery network optimization, ensuring TB programming is fully integrated into the overall health care system, making full use of the potential of the private health sector; promoting a multi-sectorial approach and accountability, underpinning strategic national and decentralized health financing as well as social and economic protection for all in need; development of essential service packages, quality assessment and improvement (QA/QI) tools to ensure availability of services to patients' preferences, pathways and priorities and to link service quality to health financing strategies in collaboration with health finance partners.
   The pathway also includes improving unified and rapid global dissemination of new policies and best practices for TB elimination by development of the WHO digital learning platform for TB, strengthen capacity building of the global health workforce on TB by collaboration with global partners and ensuring a healthy workforce and safe working environments as per international guidelines and standards (WHO, UNAIDS, ILO).

Expected landscape by 2025:
- *The patient centered framework approach is well documented and mainstreamed in planning, budgeting and program optimization; the PCF is widely implemented for all aspects of TB programming beyond the first adopter countries;*
- *Service quality assurance and assessment tools are available and used for quality health insurance mechanisms in demonstration countries.*
- *WHO and KNCV have strong ongoing collaboration on the provision of quality blended learning packages on best practices for TB Elimination, used around the world.*

The pathways are further detailed in figure 14 on the next page, showing the relation between the problem analysis to the interventions which are needed, outputs and outcomes of KNCV work, indicating the higher level outcomes and the change to which KCNV aims to contribute. ◂

Figure 14: Further detailing of the innovation pathways.



ANNEX 2

Annex 2 has been added (and approved) after the initial Strategic Plan was approved by the Board of Trustees in November 2019.

ANNEX 2: STRATEGIC PROGRESS INDICATORS KCNV STRATEGIC PLAN 2020-2025

KNCV STRATEGIC PATHWAYS

Innovation pathways A to D are focused on increasing sustainability and resilience of people-oriented health systems

A. Improving and developing improved methodologies for epidemiological measurements and models for optimized programming towards ending TB and related health problems
B. Strengthening of health systems and multisectoral solutions along the patient pathway, including integrated disease surveillance systems
C. Reducing stigma of TB and related health problems
D. Development of electronic information systems and digital health solutions along the patient pathway, including integrated disease surveillance systems

Innovation pathways 5 to 9 are focused on the development and optimization of people centered TB services.

1. Building system-readiness for the deployment of new or improved TB vaccines
2. Improving early management of TB infection
3. Early identification of all patients with all forms of TB in all age groups and vulnerable or at-risk populations, with community ownership
4. Innovation and optimization of diagnostic technologies and strategies, especially the use of multi disease testing platforms
5. Improving patient centered treatment of active TB, including drug resistant TB

ANNEX 2

Legenda for the interpretation of the color coding	
Color coding:	The intervention is in the following phase:
	Conceptualization phase
	Proof of concept phase
	Demonstration phase
	Scale-up phase
	The intervention received WHO endorsement

A. NTPs apply improved methods and user-friendly tools to develop valid TB burden estimates and to optimize their TB response	2020	2021	2022	2023	2024	2025
Improved tools for TB prevalence surveys	Proof of concept	Demonstration	Demonstration			
			WHO endorsed			
Tools for subnational disease burden estimates	Demonstration phase	Scale-up phase				
Development of novel, user friendly modeling approaches			Demonstration			
B. Stronger health systems, applying data driven approaches to planning and evidence based services delivery for TB and related health problems	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
PCF framework approach	Proof of concept phase	Demonstration phase	Scale-up phase			
		WHO endorsed				
PCF dashboard	Conceptualization phase	Proof of concept phase	Demonstration phase			
COVID-19 self testing, linkage to care and therpeutics		Conceptualization	Demonstration			
AMR stewardship - evidence generation on effective approaches		Conceptualization				
C. NTPs apply proven effective tools to reduce TB related stigma in health facilities, patients and communities.	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Stigma section WHO guideline on solcial protection		Conceptualization				
Allies approach	Proof of concept		Demonstration			
TB Photo Voices	Proof of concept					
Inside out	Proof of concept					
D. NTP's apply evidence based digital tools to facilitate people's access to information, health services and effective care for TB and related health problems, fitting each person's needs.	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
DAT's	Proof of concept	Demonstration	Demonstration			
			WHO endorsed			
Home based ECG recording	Proof of concept	Demonstration	Demonstration			
Mobile and e-health faclitating health seeking, diagnosis and linkage to care			Demonstration			

1. Designing approaches to ensure access to new or repurposed TB vaccines, through people centered vaccine delivery strategies	2020	2021	2022	2023	2024	2025
Asessment tool for countries' TB vaccine preparedness	Conceptualization	Proof of concept				
Understanding role of BCG re prevention of infection and/or disease						
2. People have access to short, effective and safe TB preventive TB preventive treatment, tailored to their needs	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Use of 3 month once weekly treatment regimen 3HP	Demonstration	Demonstration	Scale-up			
		WHO endorsed				
Use of 1 month daily treatment regimen 1 HP		Demonstration	Demonstration			
		WHO endorsed				
Infection prevention and control			Scale-up			
3. People access to TB services through community owned approaches for active case finding and linkage to care.	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Women engagement in family TB care	Proof of priniciple	Demonstration	Scale-up			
Involvement of urban ccommunities in TB service delivery and care			Demonstration			
Involvement of HIV support groups in TB service delivery and care			Scale-up			
TB- Diabetes bidirectional screening	demonstration	Demonstration	Scale-up			
TB COVID bidirectional screening			Demonstration			
Novel approach to engaging adolescents in HIV care		Proof of priniciple	Demonstration			
4. People access diagnosis of TB close to their homes through evidence based, rapid diagnostics, through optimized diagnostic networks	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
SOS stool processing methods to diagnose (DR) TB in children and PLHIV	Demonstration	Demonstration	Scale-up			
			WHO endorsed			
Point of Care (POC) TB triage test	Proof of concept	Proof of concept	Proof of concept			
Decentralized use of sequencing for TB, other infectious diseases and AMR	Conceptualization	Proof of concept	Demonstration			
Roll-out of rapid molecular XDR testing			Scale-up			
			WHO endorsed			
Quality assurance for non bacteriological laboratories			Demonstration			
5. People receive effective, short and safe treatment for TB and drug resistant TB close to their homes with support tailored to their needs.	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Treatment of pre-XDR TB by BPaL	Demonstration	Demonstration	Scale-up			
	WHO endorsement OR		WHO endorsement			
Treatment of MDR TB by BPaL based fully oral treatment regimens			Scale-up planning			
			WHO endorsement			

ANNEX 3

ANNEX 3 UNHLM AND STRATEGIC PROCESS INDICATORS

KNCV STRATEGIC PATHWAYS

UNHLM and End TB top 10 indicators and global targets, monitored in countries with KNCV network presence.

1. TB treatment coverage (End TB target ≥90%)
2. TB treatment success rate Percentage of notified TB patients who were successfully treated. (End TB target ≥90%)
3. Percentage of TB-affected households that experience catastrophic costs due to TB (End TB target 0%)
4. Percentage of new and relapse TB patients tested using a WHO-recommended rapid diagnostic (WRD) at the time of diagnosis (End TB target ≥90%)
5. Latent TB infection (LTBI) treatment coverage (End TB target ≥90%)
6. Contact investigation coverage (End TB target ≥90%)
7. Drug-susceptibility testing (DST) coverage for TB patients (End TB target 100%)
8. Treatment coverage, new (since 2010) TB drugs (End TB target ≥90%)
9. Documentation of HIV status among TB patients (End TB target 100%)
10. Case fatality ratio (End TB target ≤5%)

Additional KNCV strategic indicators:

1. The number of projects addressing the different innovation pathways
2. The number of projects addressing identified crosscutting topics of interest.
3. The number of publications (co-) developed by KNCV staff and the number of publications addressing questions along the different innovation pathways.
4. The number of people trained (men/women) in KNCV led projects.
5. The number of community members engaged (men/women/children) in KNCV led activities.
6. The number of countries/sites/partners directly participating in KNCV led activities.
7. The number of collaborating partners
8. The number of media expressions on KNCV led activities.

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