Sector: Infectious disease control (CRS Code: 12250)
Programme/Project: Strengthening tuberculosis control programme in North-West Pakistan (2000 66 290)*, FC/TC cooperative programme
Implementing agency: Government of Khyber Pakhtunkhwa province, represented by the Ministry of Health and its Provincial Tuberculosis Programme (PTP)

Ex post evaluation report: 2015

<table>
<thead>
<tr>
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<th>Project (Planned)</th>
<th>Project (Actual)</th>
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<tbody>
<tr>
<td>Investment costs (total)</td>
<td>EUR million</td>
<td>10.1</td>
</tr>
<tr>
<td>Counterpart contribution</td>
<td>EUR million</td>
<td>1.5</td>
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<tr>
<td>FC financing (BMZ funds)</td>
<td>EUR million</td>
<td>6.1</td>
</tr>
<tr>
<td>TC (BMZ funds)</td>
<td>EUR million</td>
<td>2.5</td>
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*) Random sample 2015

Summary: The FC/TC cooperative programme was designed to support the fight against tuberculosis (TB) in Khyber Pakhtunkhwa (KP), formerly North West Frontier Province (NWFP), and in the Federally Administered Tribal Areas (FATA) in accordance with the DOTS strategy (directly observed treatment, short-course) recommended by the WHO. The elements of the Financial Cooperation (FC) included the procurement of TB drugs, constructing and equipping laboratories (especially diagnostic equipment) as well as training and administrative buildings, supplying vehicles for supervision and teaching aids for health awareness and consulting services. The priorities of the Technical Cooperation (TC) were to strengthen the diagnostic and treatment capacities of doctors and medical-technical personnel in accordance with the DOTS strategy, and to improve the management of the TB control programme and educational work.

Objectives: Improving the diagnosis and treatment of the various forms of TB (programme objective) to contribute to the reduction of TB transmission (ultimate objective).

Target group: The target group was the entire population living in the programme region (today roughly 25 million people). As TB particularly affects people with poor social living conditions, it was assumed that the poor population would benefit from the project in particular. Security risks meant the project could not be implemented in the FATA. The planned inclusion of prison inmates, a group particularly at risk of TB, was also not possible due to a lack of cooperation from the security forces.

Overall rating: 2

Rationale: In spite of the difficult security situation, significant progress was made in Khyber Pakhtunkhwa with fighting TB in the public health sector. The population in the conflict-ridden region has improved and free access to diagnoses and treatment, and public institutions were strengthened. The national tuberculosis programme is deemed a success story in Pakistan.

Highlights: The unregulated private health sector, where the treatment and diagnosis of TB generally does not follow WHO recommendations, still presents a major challenge for TB control overall in terms of the detection and treatment of TB cases and the avoidance of drug resistance. In the current phase (BMZ No. 2009 66 143) this is being tackled by involving non-governmental organisations.
Rating according to DAC criteria

Overall rating: 2

Classification of the project

Khyber Pakhtunkhwa (KP) and the Federally Administered Tribal Areas (FATA) represent the regional focal point of terrorist attacks carried out by the Pakistan Taliban and other extremist groups in Pakistan. The precarious and volatile security situation caused by attacks, abductions and military operations has made it impossible to implement the project in FATA and has rendered large parts of KP inaccessible time and again. Despite slight improvements in recent years, KP was nevertheless the region with the highest number of victims of terrorism in 2014. Against this backdrop, in addition to the achievement of the objectives specific to each measure which were set at the project appraisal (PA), the role of the project in terms of stabilisation and capacity-building in this particular conflict-ridden region is also taken into account in the evaluation.

Relevance

Pakistan is one of a number of countries experiencing a significant burden of tuberculosis (TB). In global terms, Pakistan is fourth in the rankings of countries with the most incidences of TB, with an estimated 500,000 newly diagnosed cases in 2013. This burden of disease is compounded by TB strains that exhibit resistance to standard TB drugs. According to a national prevalence study from 2010/2011, TB prevalence is at 342 per 100,000 people, meaning that approximately 620,000 residents are suffering from TB. The proportion of multidrug-resistant TB (MDR-TB) amongst new TB cases is 4.3 % according to the first national study on drug resistance (2012), and is thus higher than previously assumed. It is estimated that TB is responsible for about 5 % of the national burden of disease in Pakistan.

The project evaluated here is the first FC project to combat tuberculosis in KP, Pakistan. Support was continued in a second phase (BMZ no. 2009 66 143), which is expected to be completed at the end of 2015. At the time of the PA in 2002, the Pakistani Ministry of Health had just declared TB a national emergency and the DOTS strategy (Directly Observed Treatment, Short-Course) to combat TB recommended by the WHO had been introduced nationwide. The FC project was thus consistent with the Pakistani government's objective to combat TB. In KP, the project region, the introduction of the DOTS strategy was initially financed by means of public funds. These were and still are, however, very limited. Only with the beginning of the FC financing in 2006 did the Provincial Tuberculosis Programme (PTP) gain momentum, widen its reach and achieve greater quality. The first phase of the FC support focused initially on the diagnosis and treatment of uncomplicated TB and included the procurement of first-line drugs, construction work (including construction of the reference laboratory and of the PTP office and training building), equipping the reference laboratory and 48 peripheral laboratories, as well as the supply of 28 vehicles for supervision, materials for training courses and consulting services. In addition, the PTP has received technical assistance from German TC in order to strengthen the diagnostic and treatment capacities of doctors and medical-technical personnel in accordance with the DOTS strategy, as well as to improve educational work and the management of the TB control programme. This broad approach was suited to addressing the bottlenecks in the diagnosis and treatment of TB which were evident at the project appraisal and to helping combat TB. As the major donor to the TB programme in KP, German Development Cooperation had the potential – through a combination of FC and TC – to expand and reinforce standardised TB control in accordance with WHO guidelines in the public health sector. By selecting the province of KP and FATA, Pakistan's poorest regions were selected at the PA. The relevance of these regions continued to increase during the course of the project as a result of the worsening security situation and the increased number of Afghan refugees and internally displaced persons.

The large proportion of thus far unregulated private healthcare providers who do not comply with WHO recommendations on the diagnosis and treatment of TB, as well as the option of buying anti-TB drugs in pharmacies and shops without a prescription, represent considerable difficulties for the fight against TB in Pakistan. The successful treatment of TB patients cannot be guaranteed in the private sector, and a treatment which is ineffective, interrupted or terminated early promotes the emergence of resistance. Although this fact had already been recognised at the project appraisal, the action taken to involve the pri-
vate sector only began towards the end of the second phase. However, the strengthening of the PTP and the consolidation of the basic processes of standardised TB control in the public sector was a necessary condition for the subsequent involvement of the private sector. The same applies to the treatment of MDR-TB, which also started in the second phase of FC support. The fight against TB is an aim of the Millennium Development Goals (MDGs), to which Germany and Pakistan have committed themselves. In addition, health was a focal sector of German-Pakistani cooperation during the project. Overall, we assess the relevance as very good.

**Relevance rating:** 1

**Effectiveness**

The programme objective was to improve the diagnosis and treatment of different forms of TB in KP. This objective is appropriate from today’s perspective. The following indicators were selected at the project appraisal to measure the achievement of objectives: (1) the widespread implementation of the DOTS strategy; (2) the increase in the proportion of smear-positive cases among the total number of expected smear-positive TB patients (case detection rate) to at least 70 %, and (3) the increase in the proportion of successful treatments by means of DOTS therapy in new smear-positive cases (treatment success rate) to at least 85 % by the end of the programme period. Indicator (4), the proportion of MDR-TB among new TB cases falling to under 3 %, was added during the course of the project.

**Indicator 1: Implementation of the DOTS strategy**

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<th>Objective:</th>
<th>100 % in the public sector</th>
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Status ex post evaluation: 100 % in the public sector

According to PTP the DOTS coverage rate of 100 % in the public sector was achieved in 2004, and thus even before the start of the FC project. During the course of the FC project, however, substantial qualitative and quantitative advances were made in diagnosis and treatment. Microscopic diagnosis takes place today in around 230 public health facilities in KP, while outpatient treatment of uncomplicated TB takes place in around 800. Supervision of treatment is not carried out in health facilities, but instead conducted by “treatment supporters” in patients’ residences. Currently around 300 private clinics in KP cooperate with the PTP in TB control. The contribution made by private healthcare providers to case detection in KP is around 26 % and is mainly attributable to NGOs with their own clinics.

**Indicator 2: Case detection rate**

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<tr>
<th>Objective:</th>
<th>at least 70 %</th>
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Due to significant uncertainties regarding the actual TB incidence in the population, this indicator is no longer recommended by the WHO. A recently conducted and very reliable national survey estimates, however, that the case detection rate is only 58%. Pakistan is responsible for 7 % of all undetected TB cases globally and is thus ranked 3rd behind India and Nigeria. However, case detection development also shows that Pakistan has made great progress in the diagnosis of TB. In KP, the number of registered TB patients (all TB forms) rose from 8,010 in 2002 to 42,400 in 2014, while the case detection rate per 100,000 people rose from 39 to 169. Since 2002, over 300,000 TB patients have been treated in KP.
Indicator 3: Treatment success rate in new smear-positive TB cases

Objective: at least 85 %

Status ex post evaluation: 96 % (cured and treatment completed) (MDR-TB: 70 % in the 2012 cohort)

Since the introduction of the DOTS strategy in 2002, the treatment success rate in KP has been above the WHO target of 85 %. While the treatment success rate for MDR-TB is considered very reliable, there are doubts concerning the treatment success rate for uncomplicated TB. Given the MDR-TB rate among new cases of 4.3 %, the very high mobility of the population, the difficult access to health services – at least in mountainous regions – and the weaknesses in the lowest level of healthcare, a treatment success rate of 96 % seems unlikely. Moreover, it should be noted here that the treatment success rates relate only to the public sector. There is no information on the treatment success rates for patients who are treated by private healthcare providers.

Indicator 4: Proportion of MDR-TB among new TB cases

Objective: under 3 %

Status ex post evaluation: 4.3 % (national); 19 % among retreatment cases

The objectives set at the PA were thus partly achieved. The project has led to a significant expansion in free medical care for the whole population in KP, including refugees in a conflict-ridden region. In addition,
the skills and capacities of the PTP were established and strengthened by the project, thus promoting the state’s ability to provide public services to the population. The effectiveness is therefore assessed as good.

**Effectiveness rating: 2**

**Efficiency**

The project experienced considerable delays, particularly early on (four years between PA and project start). The reasons for this are varied and include the critical security situation, the effects of the flood disaster of 2010, uncertainties and coordination problems between KfW, the consultant and PTP (e.g. regarding the financing agreement) as well as changed WHO guidelines concerning the requirements for laboratory safety. Overall, less was implemented in phase 1 than planned. An example of this is the considerable delay in the construction of the BSL-3 laboratory. This was initially delayed until phase 2 and is now expected to be completed in the last six months prior to the discontinuation of FC financing. Not only is the delay associated with additional costs, but it also has implications for the effectiveness and sustainability of TB control (see below).

The DOTS strategy in itself is considered an efficient method for the treatment of TB. Sputum diagnostics and outpatient treatment with TB drugs are the core components of the DOTS strategy and are relatively inexpensive, while at the same time offering a high degree of reliability for the results and a high treatment success probability. The standardised reporting enables improved monitoring of the course of the disease, both for the individual patients as well as nationally and worldwide. DOTS was successfully introduced in the public health sector in KP as well as throughout Pakistan. Sputum diagnostics are carried out in separate laboratories in 230 health facilities; the treatment of uncomplicated TB also takes place at the lowest level of the public health sector, i.e. in around 800 facilities. This integration avoids costly parallel structures, however, TB treatment at the lowest level is also affected by the general weaknesses of these health facilities (e.g. absence of staff). Access to treatment for MDR-TB has thus far been limited to just 4 hospitals throughout the entire province. The treatment of both uncomplicated TB and MDR-TB is carried out on an outpatient basis. Treatment is not directly monitored in health facilities. The patients receive the anti-TB drugs for a month and are supported and supervised by their chosen “treatment supporter”, who will be a family member or someone who lives with them. This reduces costs for the healthcare system and the patient; the effect on the patient’s intake of drugs remains unclear.

TB treatment is free for patients. Support services in the form of food provisions and transport costs are available only for patients with MDR-TB. Multi-drug resistant forms of TB result in significant costs for the healthcare system: while the cost of medication for the treatment of uncomplicated TB is approximately USD 100 per patient, this increases to approximately USD 5,000 per patient in the case of MDR-TB.

The procurement of first-line medicines was implemented through the Global Drug Facility, a mechanism for the procurement of prequalified TB drugs in accordance with WHO standards, which was launched as part of the ‘Stop TB Partnership’. Since the beginning of the FC funding, there has been no shortage of drugs. The current inventory will be sufficient until April 2016 for adults and until August 2015 for children. The medication is stored appropriately in a new ventilated warehouse and is managed by an accurate system. It is delivered quarterly as needed to the health centres of the province. The on-site visits revealed that the FC-financed buildings, equipment and vehicles are of good quality, are in good condition and are in use. According to statements made by the PTP, all 48 equipped peripheral laboratories are still in operation. KP is currently the only province with a web-based reporting system. At the lowest level, treatment is documented on paper and recorded in the system at district level. Until recently, case detection was mainly passive, meaning that options for efficient case detection in high-risk groups were not being fully utilised. This relates in particular to investigating the contacts of diagnosed persons. Currently, patients in public health centres are asked about their contacts, but the rate of follow-up is low. There is, for example, still no register for contacts. Active case detection was introduced earlier this year by involving NGOs.

**Efficiency rating: 3**
Impact

The overall developmental objective was to contribute to the reduction of TB transmission. According to the current global TB report, conducted by the WHO, Pakistan is not on course to meet the MDG targets as regards TB (falling incidence rate, halving of TB mortality and TB prevalence in comparison to 1990). In the ex post evaluation we consider the trends in incidences of TB and TB mortality.

Indicator 1: Reversal of trend in incidence of TB

Pakistan is part of a small group of “high TB-burden countries” in which the rate of new infections is not yet declining. The estimated incidence rate is around 275 per 100,000 inhabitants and has been stable since the 1990s. Furthermore, no reversal in the case detection rate – which would suggest a decrease in the rate of transmission given the same diagnosis – has yet been detected.

Indicator 2: Reduction in TB mortality

National TB mortality has been decreasing since 2000. In recent years, however, it has stabilised at around 55 per 100,000 inhabitants.

Unfortunately, no data are available at provincial level. On a national level, it was not possible to break the chain of TB transmission during the course of the project. There is, however, a high probability that the decline in mortality is linked to improved diagnosis and treatment in accordance with the DOTS strategy also in KP. Despite ongoing conflict, stable provision has thus been achieved in the fight against TB, which has led to health improvements in the population. We therefore assess the overarching developmental impacts as satisfactory on the whole.

Impact rating: 3

Sustainability

Pakistan has made considerable progress in the fight against TB in the last 15 years. In KP, this progress has been made feasible in large part thanks to German support. The national TB programme is considered the most successful disease-specific programme in Pakistan and KP has stood out particularly in certain ways. The project evaluated here was continued in a second phase and expanded to include the treatment of MDR-TB and measures aimed at involving the private sector, for example. FC support is anticipated to finish at the end of 2015. Ownership and the institutional capacities of the NTP and PTP in KP are high. The staff are well trained and are characterised by high levels of motivation and commitment. Many have been involved in the fight against TB for years. Once the FC support comes to an end, the PTP will receive public funding and will become a sub-recipient of the Global Fund’s new commitment. First-line drugs and healthcare professionals in the diagnosis and treatment centres are paid for by the state, while Global Fund funding is needed to pay for expensive second-line drugs and the treatment of MDR-TB. The MDR-TB patients who currently receive treatment within the framework of the FC project
will also be taken on by the Global Fund. There is therefore a high probability that the basic established processes of TB control will be maintained after the end of support.

More critical is the situation as regards necessary progress in the field of MDR-TB diagnosis. As a result of the considerable delays, the BSL-3 laboratory is still not completed. At present, drug-susceptibility testing is carried out in the reference laboratory – a process which does not sufficiently meet the safety standards of WHO. What is more, only patients whose treatment has failed or who have to be treated again are tested for resistance. Once completed, the BSL-3 laboratory will be the lab with the highest safety standards in the country. Given the tight budget and the fact that the second phase is coming to an end, there are concerns whether the capacities and potential in the field of drug-susceptibility testing can be fully exploited. There are currently no sources of financing for the maintenance of the equipment required for such testing and supplied under the FC project. The early implementation of drug-susceptibility testing for 100% of new sputum-positive cases, which has been defined as an objective of the second phase, appears unlikely. As a result of the high rate of MDR-TB infection and low access to MDR-TB treatment, as well as the still insufficient involvement of the private sector in standardised TB control, this represents a risk for the sustained fight against TB. The ongoing critical security situation also continues to represent a risk for TB control, as this impedes access to health facilities not just for patients, but also for staff.

**Sustainability rating: 3**
Notes on the methods used to evaluate project success (project rating)

Projects (and programmes) are evaluated on a six-point scale, the criteria being relevance, effectiveness, efficiency and overarching developmental impact. The ratings are also used to arrive at a final assessment of a project’s overall developmental efficacy. The scale is as follows:

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<tr>
<th>Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Very good result that clearly exceeds expectations</td>
</tr>
<tr>
<td>2</td>
<td>Good result, fully in line with expectations and without any significant shortcomings</td>
</tr>
<tr>
<td>3</td>
<td>Satisfactory result – project falls short of expectations but the positive results dominate</td>
</tr>
<tr>
<td>4</td>
<td>Unsatisfactory result – significantly below expectations, with negative results dominating despite discernible positive results</td>
</tr>
<tr>
<td>5</td>
<td>Clearly inadequate result – despite some positive partial results, the negative results clearly dominate</td>
</tr>
<tr>
<td>6</td>
<td>The project has no impact or the situation has actually deteriorated</td>
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Rating levels 1-3 denote a positive assessment or successful project while rating levels 4-6 denote a negative assessment.

**Sustainability is evaluated according to the following four-point scale:**

Sustainability level 1 (very good sustainability): The developmental efficacy of the project (positive to date) is very likely to continue undiminished or even increase.

Sustainability level 2 (good sustainability): The developmental efficacy of the project (positive to date) is very likely to decline only minimally but remain positive overall. (This is what can normally be expected).

Sustainability level 3 (satisfactory sustainability): The developmental efficacy of the project (positive to date) is very likely to decline significantly but remain positive overall. This rating is also assigned if the sustainability of a project is considered inadequate up to the time of the ex post evaluation but is very likely to evolve positively so that the project will ultimately achieve positive developmental efficacy.

Sustainability level 4 (inadequate sustainability): The developmental efficacy of the project is inadequate up to the time of the ex post evaluation and is very unlikely to improve. This rating is also assigned if the sustainability that has been positively evaluated to date is very likely to deteriorate severely and no longer meet the level 3 criteria.

The **overall rating** on the six-point scale is compiled from a weighting of all five individual criteria as appropriate to the project in question. Rating levels 1-3 of the overall rating denote a "successful" project while rating levels 4-6 denote an "unsuccessful" project. It should be noted that a project can generally be considered developmentally "successful" only if the achievement of the project objective ("effectiveness"), the impact on the overall objective ("overarching developmental impact") and the sustainability are rated at least "satisfactory" (level 3).