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SIXTH SIX-MONTH PROGRESS REPORT FOR PROJECT D2-4

RE-ESTABLISHING THE NATIONAL DRUG QUALITY CONTROL PROGRAMME IN IRAQ

REPORT COVER PAGE

Operationally Closed

<p>Participating UN Organization: WHO</p>	<p>Cluster: D: Health and Nutrition</p>
<p>Project No. and Project Title: D2-4: Re-establishing the National Drug Quality Control Laboratory Programme</p>	<p>Report Number: 6</p>
<p>Reporting Period: 1 January to 30 June 2007</p>	<p>Project Budget: US\$ 5,977,090</p>
<p>List Implementing Partners: - Ministry of Health Iraq - Local Iraqi contractors</p>	<p>Project Coverage/Scope: The project is physically based in Baghdad, but the scope of the project is of nationwide nature in terms of services provided</p>
<p>Abbreviations and acronyms:</p> <ul style="list-style-type: none"> - MOH: Ministry of Health - WHO: World Health Organization - NDP: National Drug Policy - NDQCL: National Drug Quality Control Laboratory - NCDRCR: National Centre for Drug Control and Research - NMP: National Medicines Policy - SOPs: Standards Operating Procedures, - GLP: Good Laboratory Practices - QC: Quality Control 	<p>Project Duration/Closed Project:</p> <ul style="list-style-type: none"> • The project duration, including extensions is about 32 months from its inception on 17 August 2004 until 30 April 2007 which is the date on which the project is considered as operationally closed. • The initial project duration was for 12 Months starting from 18 August 2004. In between three extensions all at no cost were obtained, including one with a slight budget revision (extension up to 30 June 2006, the second up to 31 December 2006 and the last one up to 30 April 2007).



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- Add additional information including charts, graphs, etc as annexes to the report and clearly reference the annexes using footnotes or endnotes within the body of the narrative
- Number all sections and paragraphs as indicated below
- Format the entire document using the following font: 12point _ Times New Roman & do not use colours.

NARRATIVE REPORT FORMAT

I. Purpose

1.1 Provide the main objectives, outcomes, outputs of the programme/project

The purpose of the programme was to assist the MOH/Iraq in re-establishing the national drug quality control laboratory, with the overall developmental goal of ensuring quality, safety and efficacy of drugs used in Iraq.

Main objectives of the project were to:

- Rehabilitate and re-establish the functionality of the national drug quality control laboratory (NDQCL) also known as the National Centre for Drug Control and Research (NCDCR);
- Provide laboratory equipment, supplies and reference standards;
- Provide computer hardware and software, as well as communication equipment to increase and enhance connectivity;
- Build capacity by the provision of training courses and fellowships;
- Develop guidelines and standards operating procedures (SOPs) related to quality control procedures.

The expected outcomes are:

- National drug quality control laboratory modernized and fully operational;
- Obsolete and defect equipment replaced by new and up to date highly efficient and most precise;
- Well trained professional staff to carry out quality control (QC) analyses and reporting;



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- Guidelines and SOPs for the NDQCL developed and implemented.

The main activities were:

- Physical rehabilitation of the NDQCL.
- Establishing policies, strategies, SOPs and guidelines;
- Building the capacity of the personnel of the NDQCL;
- Strengthening and implementing state of the art technology in drug quality control, through the provision of new laboratory equipment and the provision of computer hardware, software and connectivity tools;

1.2 Explain how the programme/project is relevant to the following benchmarks:

- **UN Assistance Strategy for Iraq,**
- **UN Millennium Development Goals,**
- **Joint Needs Assessment ,**
- **Iraqi National Development Strategy**

The overall goal of the project is to provide to the country with means and tools enabling the Ministry of Health to ascertain quality, safety and efficacy of medicines and other pharmaceutical products before these are allowed to be used in Iraq. In this context, the re-establishing of the functionality of the NDQCL is relevant to the four benchmarks stated in the UN Assistance Strategy for Iraq, UN MDGs, the UN World Bank Needs Assessment and the Iraqi National Development Strategy.

The laboratory is now fully functional and hence is contributing to ensuring that drugs used in the country are safe and effective. The use of safe medicines assists in improving the health status of the population and thus contributing to addressing the following Millennium Development Goals (MDGs) and Iraq's National Development Goals stipulated in the National Development Strategy (NDS):

- (a) Reduce child mortality (MDG4 and Goal 4 of NDS) and Improve maternal health and hence reduce maternal mortality (MDG5 and Goal 5 of NDS).
- (b) The project indirectly will contribute to (1) eradicating extreme poverty (MDG1 and Goal 1 of NDS).

This project is also in line with the UN Assistance Strategy to Iraq and the UN Health Cluster matrix, as it addresses the outcome related to increasing access to quality health care services especially for vulnerable groups and the un-reached through access to safe and effective drugs.



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The project has also provided opportunities of employment during the rehabilitation phases of the buildings used for drug quality control laboratory and hence is in line with the priorities identified through the joint UN and World Bank needs assessment.

1.3 Indicate the main implementing partners, their roles and responsibilities, and their interaction with the Agency

The main implementing partner is the Ministry of Health in particular the Directorate of Technical Affairs and Engineering Department which oversee the implementation of the rehabilitation projects within the MOH and the National Centre for Drug Control and Research (NCDRC) whose role was to implement with the support of WHO the technical and software aspects of the programme as primarily beneficiary of the programme.

The other partners were the two local Iraqi contracting firms who carried out the physical rehabilitation/construction of the laboratory facilities and its Annex buildings. The first contractor carried out the rehabilitation of the main laboratory building whereas the second contractor carried out the second phase which included the rehabilitation of animal unit and the sampling section and the construction of a new lab space for research and bio-equivalence studies,

The work of the contractors was overseen by the MOH Engineering Department supported by a WHO multi-disciplinary engineering team of civil engineers and architects. Furthermore, the progress of work was monitored by MOH and WHO engineering teams.

During the whole period of project implementation, regular technical and coordination meetings organised/supported by WHO were held through various means, including videoconferencing, meetings/seminars in Amman and field visits to the project site inside Iraq.

II. Resources

Financial Resources:

2.1 Provide total funds provided, disbursed and committed

The total project approved budget is US\$ 5,977,090 and was received in WHO account on 17 August 2004. As of 30 June 2007, of this amount, US\$ 5,628,376 have been disbursed and the difference (US\$ 348,714) is still committed but in the process of disbursement.



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2.2 Highlight any variation(s) in projected versus actual spending for the reporting period indicating the reason for such variation(s).

There has been no variation between the actual budget expenditures and the spending which were projected between 1 January 2007 and 30 April 2007 which was the operational closing date of the project.

2.3 Explain programme/project expenditures within the 10 budget categories, including security expenditures.

The budget allocation breakdown within the 9 budget categories mentioned below is summarized below. Please note that the budget lines for equipment, supplies and commodities have been merged as the procurement of specific equipment is done together with the relevant reagents for that specific equipment.

S/N	Budget category	Allotted budget (after revision) (US\$)	Funds still committed (US\$)*	Funds Disbursed (US\$)*
1	Personnel, including consultancy	145,000		145,000
2	Contracts:	2,250,000	230,777	2,019,223
3	Training:	470,152	14,588	455,564
4	Equipment, Supplies/commodities	2,837,848	113,349	2,724,499
5	Transport:	0		0
6	Travel:	10,000		10,000
7	Miscellaneous	0		0
8	Security:	100,000		100,000
9	Agency Support Cost	174,090		174,090
	TOTAL	5,977,090	358,714	5,628,376

NB *: The figures above are indicative as some of them are based on records at the field level and not yet necessary reflected in the Agency's financial systems. Certified financial figures will be provided separately.



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2.4 Indicate other funding sources, if applicable.

There are no other funding sources. However, additional resources which are on the top of the project funding were provided to support the implementation of the project, which are not included in the above mentioned budget. These include:

- Logistics and administrative facilities of WHO, such as videoconferencing tools which have been key to coordination and interaction with the MOH and other partners involved in the project;
- Technical support and backstopping received from the regional and headquarters offices outside the agency management support framework;
- Additional MOH and WHO personnel involved in the project implementation, monitoring, evaluation and reporting.

2.5 Provide details on any budget revisions approved by the UNDG ITF Steering Committee, if applicable

The initial project duration was for 12 Months starting from 18 August 2004. However, due to different factors mainly linked to the security situation in the country, the project could not be completed during the planned period. Instead, it was operationally completed after about 32 months. Within this period, there have been in total three extensions, all at no cost, including one with a slight budget revision. The first one was an extension up to 30 June 2006, the second extended the project up to 31 December 2006 and the last one up to 30 April 2007.

The slight budget revision was operated in December 2006 by a transfer of \$43,460 from the procurement budget line to the capacity building. This was necessitated by the fact that under capacity building there was no more funds to cover newly identified training needs. This amount was within the limit of the 10 percent budget revision which can be operated without any formal approval by the Steering Committee provided the Committee is kept informed.

2.6 Project expenditures for the 1 January to 30 June 2007.

During the period between 1 January and 30 June 2007, funds committed amount at US\$ 125,140 against US\$ 537,917 disbursed funds.



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Human Resources:

2.7 National Staff: Provide details on the number and type (operation/programme)

Three national officers, including one civil engineer, one biomedical engineer have supported the implementation of the project.

Also, expertise of national specialists was used time to time, to carry out defined specific tasks under special services agreement contract type. Their knowledge of the local environment and context has helped to implement the project without major obstacles.

2.8 International Staff: Provide details on the number and type (operation/programme)

One international technical officer based in WHO/Iraq Office in Amman has managed and coordinated the project throughout the entire implementation period. It is worth noting that other WHO international staff, including a Senior Health Facility Architect and a Biomedical Equipment Specialist have been regularly providing technical support on the physical rehabilitation component and on developing and or reviewing the specifications of lab equipment, overseeing the installation and commissioning of equipment as well as organising capacity training activities with regard to use application.

III. Methods of Operating

3.1 Summarize the implementation mechanisms primarily utilized and how they are adapted to achieve maximum impact given the challenging operating context.

The project has been primarily implemented through the use of national expertise available within the Ministry of Health and local market (local construction and engineering contractors).

The use of local contractors to carry out the physical rehabilitation works is a mechanism which has proved to be successful taking into consideration the current deteriorated security situation. Indeed, the deep knowledge and awareness of local contractors with regard to the security environment on the ground has increased the possibility to adapt quickly to changing and volatile environment.



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To ensure quality services and accountability, the work of the contractors was overseen by the MOH Engineering Department supported by a WHO multi-disciplinary engineering team of civil engineers and architects. Furthermore, the progress of work is being monitored by MOH and WHO engineering teams.

Like all other rehabilitation projects supported by WHO, these are implemented based on the “Physical Rehabilitation Guidelines” agreed upon by the Ministry of Health, Ministry of Environment, and WHO earlier in 2004. These guidelines provide detailed information on how each stage with its micro-steps is dealt with for each WHO supported project with a physical rehabilitation component.

In the case of the NDQCL rehabilitation projects, WHO Technical Team made an assessment of MOH request to rehabilitate the physical structure of the NDQCL in term of functional, structural, electrical, mechanical and sanitation systems.

Technical documents (i.e. Bills of Quantities and drawings) were prepared jointly by WHO and MOH engineers inside Iraq, reviewed and approved by WHO Iraq Technical Team in Amman.

Bidding document (Instruction to contractors, Obligation of contractors, Invitation, etc.) were prepared jointly by WHO and MOH Team. Announcement was done in more than one local newspapers by MOH and the bids opening and bid analysis were done by MOH/DOH committees and checked by WHO engineers inside Iraq. The whole process is again re-checked in Amman by WHO Iraq review team and then sent to WHO regional Office to be checked by the Regional Contract Review Committee.

Once approval was obtained from the regional office the MOH is informed and signs the contract with the winner and the later will start the implementation works.

During the implementation process, there are two committees nominated by MOH, one stays on the site to supervise the implementation works and undertake daily measurements and the second follows up and supports the first committee on weekly/fortnightly basis based on the needs. WHO assigns an engineer to join the first team and to check the quality and quantity of executed items.

Once the work is completed, payment documents are prepared jointly by MOH and WHO engineers inside Iraq and checked by WHO Team (Engineer and Finance) in Amman in order to release payment to the contractor. Additional items (more than 20%) or new items or change of specifications where justified by joint committee of WHO and MOH. When there are several payments, 10% of each interim payment are kept with WHO



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Upon total completion of the works, the first acceptance certificate is issued by the MOH Committee and from that time the maintenance period which is 12 months starts to count. When the final payment is released to the contractor, 5% of the cost of the executed works is kept as warranty and will be released upon issuance of final acceptance certificate after one year.

3.2 Provide details on the procurement procedures utilized and explain variances in standard procedures.

For the purchasing and delivery of quality control laboratory equipment and supplies, WHO procedures for tendering and contract awarding were applied.

Organisation manuals providing strict guidance and procedures on invitation to bids, bids opening, bids analysis, bids review and contract award, including conditions abiding both parties (the successful bidder and the organisation) are available for international and local procurement. There are specific committees at each stage of the bidding process.

3.3 Provide details on the monitoring system(s) that are being used and how you identify and incorporate lessons learned into the ongoing programme/project.

For monitoring the project implementation, a strong team of national staff, which includes pharmacists and engineers, was closely monitoring the work accomplished in collaboration with MOH staff. These teams visited the NDQCL site on a regular basis and produced regular progress reports. They also took photographs to support the narrative observations. In many instances video-films were also taken to show the progress in the implementation.

Among the lessons learnt was about the process of importing some of the civil engineering construction equipment - not locally available in the country which had taken longer than anticipated.

Also the security has made some times difficult the timely despatch of experts to the site to install equipment. In some case the solution was to bring the technicians in neighbouring countries where similar equipment were being used.

During the project implementation, frequent visits to assess the project implementation progress (monitoring and evaluation) were regularly made by WHO and MOH engineering team to the project sites. This is in addition to several face to face meetings between WHO and MOH/NDQCL senior management staffs which were held in



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Amman. These meetings assisted in ensuring that any arising issue during the implementation is timely addressed.

Also, internal audit team from WHO/HQ has visited the Country Office in March-April 2006 to assist the Country Office in assessing and identifying bottleneck if any that may hamper or have negatively impacted on the implementation of UNDG ITF projects implemented by WHO. The progress made in the implementation of the NDQCL project was also monitored

3.4 Report on any assessments, evaluations or studies undertaken.

A desk review study on quality control tests performed between 2003 and 2006 as well as tests which could not be performed due to lack of appropriate equipment or lack of proper skills conducted in December 2006. It was found that the number of tests performed per year by the NDQCL between January 2003 and November 2006 has increased by about three times and the number of tests that could not be performed because of lack of equipment has steadily been decreasing (from 156 tests in 2003 to 80 tests in 2006).

An evaluation mission to assess the progress made in the implementation of the project and to identify any gaps comprising of the WHO Representative for Iraq and the International Project manager was accomplished in April 2007. During the mission, field visit to the project site was made on 11 April 2007. It was found that the project was almost complete. Guidance was given for a smooth closing of the project. The ceremony to celebrate the formal opening of the newly rehabilitated National Center for Drug Control and Research (NCDCR) was held on 7 May 2007 in Baghdad under the auspices of the Iraqi Ministry of Health (MOH) in partnership with the World Health Organization (WHO) and a press release to this effect has been posted.

IV. Results

4.1 Provide a summary of programme/project progress in relation to planned outcomes and outputs; explain any variance in achieved versus planned outputs during the six month reporting period.

There are four outcomes which were expected at the end of the project:

- National drug quality control laboratory modernized and fully operational;



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- Obsolete and defect equipment replaced by new and up to date highly efficient and most precise;
- Well trained professional staff to carry out quality control (QC) analyses and reporting;
- Guidelines and SOPs for the NDQCL developed and implemented.

All the four outcomes have been achieved. The lab is now fully functional since Nov 2006 and is equipped with modern equipment and infrastructure. All the defect laboratory equipment and devices have been replaced by state of art equipment.

With regards to capacity building, over 75 lab technologists and lab managers were trained in different centres including WHO collaborating centres in the region and are now capable of performing various methods and techniques for drug quality control and in the management of the laboratory, development of guidelines and SOP. This is well above the total number of 44 staff who were initially scheduled for training when the project started.

Different guidelines and standard operating procedures have been developed and are being used to guide the works performed by lab technicians

4.2 Report on progress made toward the achievement of specific medium-term outcomes of the programme/project as a result of the achieved short-term outputs during this reporting period.

As indicated in section 4.1 above the project has come to its operational completion. All the specific mid-term outcomes have been achieved.

4.3 Report on the key outputs achieved in the six month period including # and nature of the activities (inputs), % of completion and beneficiaries.

The two priority activities which were planned between January and April 2007 included (1) the completion of the physical rehabilitation and furnishing of the main laboratories and their Annexes and (2) the finalization of the remaining capacity building programs. These two activities were fully accomplished during the reporting period.

Additionally, during the same period, efforts were exerted to ensuring that all the new equipment and lab devices installed are tested for their functionality and that appropriate standards operating procedures for the lab are developed. This also has been fully accomplished.



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4.4 Explain, if relevant, delays in programme/project implementation, the nature of the constraints, lessons learned in the process and actions taken to mitigate future delays.

Through the implementation period, the deteriorated security inside the country has been the main constraint that has hampered the timely implementation of the programme.

For instance several security incidents were reported during the implementation process and led to occasional stoppage of works. Some of these incidents were severe and have led to the unfortunate loss of two innocent lives who were killed on the project site. Also some other security related incidents of kidnapping of relatives of one of the contractor and two car bombs explosions led to some delays.

Also, in some cases the project implementation was slowed down by (a) the lack of appropriate construction and engineering systems on the local market and the long time needed for their importation and (b) the impossibility for international engineering teams to enter Iraq to train staff on the installation and use of sophisticated procured equipment.

Despite these challenges, most of the planned activities have been successively completed and the quality of outputs has been confirmed as meeting the expected standards by several monitoring and evaluation teams, including an external audit which was conducted on all UNDG ITF projects led by WHO, including the NDQCL project.

To mitigate and reduce the potential negative impact of the above mentioned challenges WHO has been using a combination of innovative implementation modalities. For instance, the use of local contractors familiar with the local security context has assisted to minimize the risks inherent to the current situation in the country. Also frequent visits to assess the project implementation progress (monitoring and evaluation) were regularly made by WHO and MOH engineering team to the project sites. Also, the extensive use of WHO global procurement facilities and WHO collaborating Centers has assisted in finding alternative solutions to issues related to unavailability of some construction materials on the local market and training of staff on application use of equipment.

Also, support from the WHO international team based in Amman, backstopped by the regional and headquarter offices, has regularly been provided through the coordination maintained by the international project manager. This is in addition to the regular meetings and other opportunistic meetings between WHO and MOH/NDQCL senior management officials which have been frequently held in Amman.

4.5 List the key partnerships and collaborations, and explain how such relationships impact on the achievement of results.



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The main implementing partner of the entire project is the Ministry of Health through the National Centre for Drug Control and Research (NCDCR) which is the main beneficiary of the programme. For the physical rehabilitation component, the local construction firms who have signed contractual agreements with the Ministry of Health to carry out the necessary civil engineering works on the building of the NDQCL. The MOH Engineering Department is also a key partner as it oversees the quality of the work performed by the local contractors and the progress of work was being monitored by MOH and WHO engineering teams.

Other important partnerships include the local pharmaceutical industries as well as Kimadia, the state company for drugs and medical appliances. These are the main end users of the services rendered by a functional national quality assurance system. The drugs and other pharmaceutical products tested are either imported through Kimadia or locally produced.

WHO has been interacting with those different partners at various levels in term of coordination of the project as well as in term of providing technical normative guidance in the different areas of work of each partner.

4.6 Summarize achievements against planned results for cross cutting issues: security, gender, human rights, employment (including # of short and/or long-term jobs created), and environment.

The project has led to the creation of job opportunities for about 15 skilled labors (WHO national staff, MOH and Contractors' engineers) and over 50 seasonal labors working on the rehabilitation of the main laboratory building and its annexes through two local contracting firms.

The training activities organized during the reporting period has also taken into consideration the gender balance where possible. All the technical staff of the NDQCL (female and male) has undergone different training packages.

The NDQCL is the national body which constitutes the legal instrument to ensure that drugs consumed in the country are safe. The services provided by the lab have a nationwide impact on entire population of Iraq regardless of gender.

The NDQCL is providing services which have a nationwide impact on entire population of Iraq with regard to the population rights to have access to safe and effective drugs as part of the patient satisfaction needs and part of the national drug policy.

V. Future Work Plan



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5.1 Summarize the projected activities up to the end of December 2007.

The project has been operationally closed. The focus now will be put in ensuring that the financial transactions are complete and that the final report of the project is produced.