CAPABILITIES OF VETERINARY LABORATORIES IN THE MIDDLE EAST: NEEDS TO IMPROVE ANIMAL DISEASE DIAGNOSTIC

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Summary: The humanity's knowledge about infectious diseases everyday develops new technologies to improve the public and agricultural health situation. In order for the Middle East region to follow the international development trend, it is necessary to understand the current level of capabilities of the laboratories in the region.

The information received from the countries participating in the 10th Conference of the OIE Regional Commission for the Middle East, indicated that most laboratories have necessary but not sufficient development capabilities. After analysing the information gathered, the author has come to the following results:

- Not all laboratories have laboratory's quality system policies and objectives.
- Most laboratories have insufficient technical and managerial staff.
- Not all laboratories apply a monitoring for the control of the environmental conditions, and this influences the quality of the results.
- All laboratories need to train their staff on biosafety and biosecurity programme.
- Few laboratories perform formal, documented biosafety and biosecurity assessments.
- Most laboratories do not have BSL-3 biosecurity facilities.
- Most laboratories do not have ISO 17025 certificate.
- Equipment calibration procedures are performed in most laboratories but there is no equipment maintenance plan in many laboratories.
- All laboratories have sampling plan and procedures, but most of them are not collecting a sufficient number of samples annually.
- In the majority of laboratories there is no standardised official reporting protocol including all the relevant information.
- Only few laboratories share in network for information exchange and timely notify the OIE about the diagnostic of epidemic diseases.
- Appropriate methods and procedures for all tests within laboratory scope are applied in the majority of laboratories.
- Confirmed relevant diagnostic results need to be applied by the laboratories either by making proficiency tests (inter-laboratory comparison) or making systemic assessment of the factors influencing the tests.
- All laboratories are interested in entering in a twinning training project with existing OIE Reference Laboratories and are looking forward to the OIE support in developing international standards on laboratory diagnostic tests.

Key words: Middle East – veterinary laboratory – diagnostic – biosecurity – biosafety – quality assessment – certification – international standard

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Introduction

Animal disease diagnostic is considered to be an important issue in the Middle East due to its implication for animal and poultry wealth, which is one of the most important sources of national income for the countries in the region. Due to the risk of exotic diseases that are considered the most important problem facing this wealth, it is necessary to accelerate the evaluation of the level of animal disease diagnostic laboratories in order to insure the safety and protection of human food as one of the top priorities. To protect animal and poultry industry from endemic and exotic diseases, quick, efficient and accurate diagnosis of the causative agents should be performed.

To cover some technical items applied in these laboratories, a questionnaire was designed and sent to the members of the OIE Regional Commission for the Middle East. The information collected help understanding and evaluating all levels of animal disease diagnostic capabilities and can be used as a working tool against diseases and for predicting the evolution of a recently introduced disease emergency.

The presentation covers the following headings:

- 1. Laboratory, policies, structure and management.
- 2. Human resources.
- 3. Facilities and environmental conditions.
- 4. Laboratory equipment.
- 5. Sampling.
- 6. Results reporting.
- 7. Test methods and validation.

The questionnaire was mailed to all 20 countries member of the OIE Regional Commission for the Middle East. The completed questionnaire was returned by a total of 14 countries (see <u>Appendix I</u>).

1. Laboratory policies, structure and management

1.1. Policy

The information collected show that none of the Member Countries indicated the policy of the National Veterinary Laboratory. This lack of information about the policies indicates weakness in the laboratory operation.

Views and comments:

The laboratory's quality system policies and objectives should be defined and documented in a quality policy statement. It should include at least the following:

- The laboratory management's commitment to good professional practice.
- The objective of the quality system.
- A requirement that all the personnel concerned with testing activities within the laboratory familiarise themselves with the documentation and implement the policies and procedure.
- The laboratory management's commitment to comply with the international regulation.

1.2. Structure and organisation

It was found that 13 countries (Bahrain, Cyprus, Iran, Iraq, Jordan, Kuwait, Lebanon, Oman, Qatar, Sudan, Syria, Turkey, United Arab Emirates) defined the organisation structure of their National Veterinary Laboratory and determined its position within the structure of the Veterinary Services (VS).

Views and comments:

The laboratory of which it is part should be an entity that can be held legally responsible.

Where the laboratory is a part of a larger organisation, the organisational arrangement should be such that departments having conflicting interests —such as production, commercial marketing or

financing— do not adversely influence the laboratory's compliance with the requirements of the international standards regulation.

The laboratory should have different departments that cover its activities and responsibilities in the field of diagnosis. If the laboratory is part of an organisation performing activities other than testing, the responsibilities of key personnel in the organisation that have involvement or influence in the test activities of the laboratory shall be defined in order to identify potential conflicts of interest.

1.3. Activities and responsibilities

From the reported activities (see <u>Table 1</u>), it appears that many countries have shortage in diagnostic activities.

Table	1.

Activities and responsibilities	No. of countries	Countries
Diagnostic of animal disease	13	Bahrain, Cyprus, Iran, Iraq, Jordan, Kuwait, Lebanon, Oman, Qatar, Syria, Sudan, Turkey, United Arab Emirates
Surveillance of infectious disease	7	Cyprus, Iraq, Kuwait, Oman, United Arab Emirates, Qatar, Syria
Monitoring of vaccine programme and vaccine evaluation	5	Bahrain, Iraq, Jordan, Kuwait, Qatar
Training staff	3	Jordan, Oman, Turkey
Examination of animal food origin	5	Cyprus, Iran, Iraq, Jordan, Lebanon
Vaccine production	2	Sudan, Turkey
Perform research field animal disease	5	Bahrain, Iraq, Qatar, Sudan, Turkey
Produce biological substance and diagnostic kits	1	Turkey
Standardise the laboratory procedures with the international regulation and the international Ref. Lab.	1	Qatar

It was found from the information collected that 10 countries (Bahrain, Cyprus, Iran, Iraq, Jordan, Oman, Qatar, Sudan, Syria, Turkey) have got the book entitled *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases* published by the OIE.

Views and comments:

The VS should implement a system to monitor the use of medicines, veterinary biologicals and their side effects.

The VS should have a comprehensive residue testing programme performed for all animal products for export and internal consumption and subjected to routine quality assurance and regular evaluation.

<u>Table 2</u> shows that 10 countries (71.43%) have an OIE quality standard and 8 countries (Cyprus, Iran, Jordan, Oman, Qatar, Sudan, Syria, Turkey) have a quality system.

Answer	Using OII	E standard	Quality s	system
	Number	%	Number	%
Yes	10	71.43	8	57.14
No	3	21.43	5	35.71
No comment	1	7.14	1	7.14
Total	14	100	14	100

Views and comments:

The VS should have implement, control and eradication programmes for all relevant diseases with scientific evaluation of their efficacy and efficiency consistent with the relevant OIE international standards.

The VS should keep up to date the latest scientific advances and should comply with the standards of the OIE —and the Codex Alimentarius Commission where applicable.

<u>Table 3</u> shows that 10 countries (71.43%) specified their responsibilities and 11 countries (78.57%) have policy and procedures for protecting the electronic storage.

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	Specified the responsibilities		Policy and procedure for protected electronic storage		Identify, collection, indexing recorded and during of disposal record			
	Number	%	Number	%	Less than 2 years	2-3 years	3-5 years	More than 5 years
Yes	10	71.43	11	78.57			2	5
No	3	21.43	2	14.29	2	4		
No comment	1	7.14	1	7.14	2	2 4	5	
Total	14	100	14	100				

Views and comments:

The laboratory should specify the responsibilities, authority and inter-relationships of all personnel who manage, perform of verify work affecting the quality of the tests.

The laboratory should have policies and procedures to protect and back-up record stored electronically and prevent unauthorised access to or damage or amendment of these records during storage.

1.4. Internal audit

<u>Table 4</u> shows that only 6 countries (Cyprus, Iran, Qatar, Sudan, Syria, Turkey) out of 14 responding countries conduct internal audit. Also 7 countries (Bahrain, Cyprus, Iran, Iraq, Jordan, Sudan, Turkey) out of 14 responding countries review of testing activities and apply the proficiency test.

Table 4.

	Internal	audit and h	10w often c	conduct it	Review of testing actualities and proficiency test			
Answer	At least once a year	Once every 2 years	Once every 3 years	More-than- 3-year interval	At least once a year	Once every 2 years	Once every 3 years	More-than- 3-year interval
Yes	3	2	1		4	1	1	
	(Cyprus,	(Iran,	(Syria)		(Bahrain,	(Iran)	(Turkey)	
	Sudan,	Qatar)			Iraq,			
	Turkey)				Jordan,			
					Sudan)			
No		(6		6			
	(Bahrain, Ir	aq, Jordan, I	Kuwait, Leł	oanon, UAE)	(Cyprus, Kuwait, Lebanon, Qatar, Syria, UAE)			Syria, UAE)
No comment		2	2				2	
		(Oman, S	Somalia)		(Oman, Somalia)			
Total		1	4				14	

Views and comments:

The VS should carry out auditing of their compliance programmes consisting of inspection, and verification of compliance with regulations relating to animals and animal products and report instances of non-compliance. The cycle of the internal audit should be completed in one year.

The VS should consult with stakeholder to ensure that strategic issues are identified, to provide leadership and to ensure coordination among national delegation as part of their participation in relevant meeting.

The public sector of the VS should carry out audits of its accreditation, authorization, delegation programmes in order to maintain the trust of their trading partners and stakeholders.

2. Human resources

Many countries have not enough managerial and technical personnel, as shown in Table 5.

able 5.									
Damand	•	Veterinarians working at the laboratory							
Respond	ing countries	Veterinarians	Veterinarians Vet. with Msc. degree						
1. Bahrai	n	No enough managerial a	and technical personnel						
2. Cyprus	5	9	3	2					
3. Iran		17	4	5					
4. Iraq		180	48	9					
5. Jordan		12	8	3					
6. Kuwai	t	3	0	7					
7. Lebano	on	1	0	1					
8. Oman		No enough managerial a	and technical personnel						
9. Qatar		3	3	8					
10. Somali	ia	No comment							
11. Sudan		80	62	82					
12. Syria		58	4	6					
13. Turkey	1	227	227 138 for both Msc and PhD degree						
14. United	Arab Emirates	0	2	2					

A total of 10 countries (Bahrain, Cyprus, Iran, Kuwait, Oman, Qatar, Sudan, Syria, Turkey, United Arab Emirates) out of 14 responding countries have a current job description for managerial, technical and key support personnel.

A total of 12 countries (Bahrain, Cyprus, Iran, Iraq, Jordan, Kuwait, Oman, Qatar, Sudan, Syria, Turkey, United Arab Emirates) have a training programme.

Views and comments:

The laboratory should have enough managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system.

It is important that the laboratory management could ensure the competence of all staff who operate specify equipment, perform tests, evaluate results and sign test reports certificates.

3. Facilities and environmental conditions

It was found that 10 countries (Bahrain, Cyprus, Iran, Iraq, Kuwait, Oman, Sudan, Syria, Turkey, United Arab Emirates) have laboratory facilities sufficient to facilitate correct performance of the test and 7 countries (Bahrain, Cyprus, Iran, Jordan, Kuwait, Turkey, United Arab Emirates) out of 14 responding countries monitor, control and record the environmental condition as required by specification methods and procedures.

Views and comments:

The laboratory should ensure that the laboratory environmental conditions do not invalidate the results or adversely affect the required quality of any measurement.

A total of 11 countries (Cyprus, Iran, Jordan, Kuwait, Lebanon, Oman, Qatar, Sudan, Syria, Turkey, United Arab Emirates) separate neighbouring areas to prevent cross-contamination and apply biosecurity measure, while 3 countries (Iran, Sudan, Turkey) perform formal, documented biosafety and biosecurity assessment to evaluate its effectiveness.

The laboratory should be effective separation between neighbouring areas in which there are in compatible activities. Measures should be taken to prevent cross-contamination.

It is essential that each laboratory organisation has a comprehensive safety policy, a safety manual and supporting programmes for their implementation. It should conduct in compliance relevant OIE standards (including WTO SPS Agreement² obligations where applicable) and base their management decisions on the outcomes of their risk assessments.

² WTO: World Trade Organization; SPS: Sanitary and Phytosanitary

Laboratory biosafety and biosecurity manage the risk of working with dangerous materials in bioscience laboratories.

<u>Table 6</u> indicates that only few countries can implement the biosafety and biosecurity measures. Only 2 countries are aware of the CEN biorisk management standard³. This table shows also that only 1 country got ISO 17025 certificate⁴; the other 3 countries that got the ISO certificates did not mention the type.

Table 6.

							ISO Certification			
	Challen	ges for blo	security imple	CEN BIOFISK		ISO 17025		ISO ?		
Answer	Lack of funds	Lack of training	Lack of equipments	Unsuitable lab. design or location	Number	%	Number	%	Number	%
Yes	3	5	3	2	2	14.29	1	9.09	3	27.27
No	0				10	71.43	9	81.82	0	0
No comment	1				2	14.29	1	9.09	0	0
Total	14				14	100		100		100

Views and comments:

The international standard (ISO) specifies the general requirement for the competence to carry out tests including sampling. The international standard is for use by the laboratories in developing their quality system, administrative and technical system that govern their operation.

All the laboratories used by the public sectors VS and most or all private laboratories should use formal quality assurance programmes that meet OIE, ISO 17025 or equivalent quality assurance standard guidelines.

Biosafety level and disposal of waste materials

<u>Table 7</u> shows that 4 countries (28.57%) have a BSL-3 laboratory⁵ and that 10 countries (71.43%) have a plan and procedure for disposal of the waste materials either by using chemical disinfectant or by autoclaving or using incinerator. Some countries contract with special company specialised on waste disposal.

Answer	BSL-3	facility	Waste disposal procedures and plan		
	No.	%	No.	%	
Yes	4	28.57	10	71.43	
No	9	0.00	3	0.00	
No comment	1	7.14	1	7.14	
Total	14	35.71	14	78.57	

Table 7.

Views and comments:

An identification and separation system for infectious materials and their containers should be adopted. National and international regulations must be followed. Categories should include:

- Non-contaminated (non-infectious) waste that can be reused or recycled or disposed of as general, "household" waste.
- Contaminated (infectious) 'sharps'-hypodermic needles, scalpels, knives and broken glass; these should be collected in puncture-proof containers fitted with covers and treated as infectious.
- Contaminated material for decontamination by autoclaving and therefore washing and reuse or recycling.

³ CEN: *Comité européen de normalisation* (European Committee for Standardization)

⁴ ISO: International Organization for Standardization

⁵ BSL-3: biosafety level 3

- Contaminated material for autoclaving and disposal.
- Contaminated material for direct incinerator.

4. Laboratory equipment

<u>Table 8</u> indicates that 13 countries (92.86%) have suitable equipment; 9 countries (64.29%) calibrate their equipment before being used and also made a maintenance plan; 6 countries (42.86%) apply the measurement traceability to the SI units⁶.

Table 8.

Answer	Laboratory equipments		Equipment calibration		Mainten	ance plans	Traceability measurement	
	Number	%	Number	%	Number	%	Number	%
Yes	13	92.86	10	71.43	10	71.43	7	50.00
No	0	0.00	3	21.43	3	21.43	6	42.86
No comment	1	7.14	1	7.14	1	7.14	1	7.14
Total	14	100	14	100	14	100	14	100

Views and comments:

The laboratory should be furnished with all items of sampling, measurement and test equipment required for the correct performance of the test. Each item of equipment and its software used for testing should be uniquely identified.

All equipment should be calibrated before being used and the laboratory shall have an establish programme and procedure for calibration of its equipment.

5. Sampling

<u>Table 9</u> illustrates that 11 countries (78.57%) have a sample plan and system for physically identifying as well as electronically registering sample and that 13 countries (92.86%) have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test items and samples during storage, handling and preparation.

Answer	Sampling plan		Sample r	egistering	Sample storage		
	No.	%	No.	%	No.	%	
Yes	11	78.57	10	71.43	13	92.86	
No	2	14.29	3	21.43	0	0.00	
No comment	1	7.14	1	7.14	1	7.14	
Total	14	100	14	100	14	100	

Table 9.

Views and comments:

Sample is a defined procedure whereby a part of substance material is taken to provide for testing. Sampling may also be required by the appropriate specification for which the substance is to be tested.

Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample.

The laboratory should have a procedure for the transportation, receipt, handling, protection, storage, disposal of test items.

<u>Table 10</u> indicates that the most frequent source of samples is from the official veterinarians, since 12 countries receive their samples from them, while the less frequent sources are farmer or private pet owners.

⁶ SI: *Système international d'unités* (International System of Units)

Source ranking	Official veterinarians		Private veterinarians		Other laboratories		Farms	
Source running	Number	%	Number	%	Number	%	Number	%
1 Most frequent	12	85.71	0	0.00	0	0.00	0	0.00
2	0	0.00	4	28.57	4	28.57	3	21.43
3	0	0.00	8	57.14	0	0.00	3	21.43
4 less frequent	0	0.00	0	0.00	5	35.71	6	42.86
5	2	14.29	2	14.29	5	35.71	2	14.29
Total	14	100	14	100	14	100	14	100

Table 10.

Views and comments:

The VS should conduct active surveillance for most or all relevant diseases and apply its to all susceptible populations. The surveillance programmes are evaluated and meet the country's OIE obligation.

The VS should have national contingency plan for all diseases of concern. They should have an established procedures to make timely decisions on whether or not a sanitary emergency exists. Also, they should have the legal framework and financial support to respond rapidly to sanitary emergencies through a coordination actions with all stakeholders through a chain of command.

6. Results reporting

Most Member Countries issue their test report that contain all the data and information about the owner, animal, region, type of test and the result.

<u>Table 11</u> shows that 4 countries (28.57%) are network sharing with other laboratories while, 13 countries (92.86%) have public health laboratory coordination.

A 1991/01	Network	sharing	Public health laboratory coordination			
Answer	Number of countries	%	Number of countries	%		
Yes	4	28.57	13	92.86		
No	9	64.29	0	0		
No comment	1	7.14	1	7.14		
Total	14	100	14	100		

Table 11.– Network sharing laboratories

Views and comments:

The VS should have a well developed communication plan provides up-to-date information, accessible via the internet and other appropriate channels, on activities and programme and actively and regularly circulate information to the stakeholders.

The VS should act with its neighbouring countries and trading partners to respond to emerging issues, including audits of each other, ability to detect and address emerging issues in their early stages.

The VS should have management implementation and coordination under full conformity with international standards for products at all levels of distributions (throughout the national and local markets and direct sales.

In case of new and emerging disease in the region or world, the VS should have access to and use a network of national or international reference laboratories (e.g. OIE Reference Laboratory) to obtain correct diagnosis.

The VS should have the capability to certify animal and animal products, services and process, under their mandate in accordance with the national legislation and regulations and international standards.

The VS pursue the development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners on all maters relevant to animal, animal products and processes under their mandate.

The VS should actively and regularly participate at the international level in the formulation, negotiation and adoption of international standards and use the standards to harmonize national legislation, regulations and sanitary measures.

The VS consult their stakeholders in participating in the preparation of national and international legislation and regulations and implementing regulations to meet national and international trade needs.

7. Test methods and validation

Table 12 illustrates that:

- 12 countries (85.72%) have a procedures for all test within its scope.
- Most countries diagnosed different infectious agents diseases using different kinds of diagnosis methods.
- 13 countries (92.86%) base their diagnostic method on the OIE international standards.
- 10 countries (71.43%) check their results with other method used by other laboratory, interlaboratory comparison, inter-laboratory proficiency test.
- 10 countries (71.43%) confirm relevant diagnosis either positive or negative with an OIE Reference Laboratory or at Pirbright Laboratory.
- 11 countries (78.57%) aware of OIE twinning programme (animal disease monitoring and control policies and practices) and interested in entering in a twinning project.
- 13 countries (92.86%) want that the OIE continue supporting its Members.

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A m ore m	Laboratory procedure		Using OIE standard		Inter-laboratory comparison test		Comparison with OIE Ref. Lab.		Twinning		Want that OIE continue support	
Answei	Number	%	Number	%	Number	%	Number	%	Number	%	Number	%
Yes	12	85.71	13	92.86	10	71.43	12	85.71	11	78.57	13	92.86
No	1	85.71	0	0.00	3	21.43	1	7.14	2	14.29	0	0.00
No comment	1	85.71	1	7.14	1	7.14	1	7.14	1	7.14	1	7.14
Total	14	100	14	100	14	100	14	100	14	100	14	100

Views and comments:

The laboratory should have appropriate method and procedures for all tests within its scope. Method published in international (e.g. OIE international standards) should be used.

Validation includes procedure for sampling, handling and transportation. The performance of method should be one of the following:

- Calibration using reference standards or reference materials.
- Comparison of results achieved with other methods used by other laboratories.
- Inter-laboratory comparison.
- Systematic assessment of the factors influencing results.
- Relevant diagnosis with an OIE Reference Laboratory by entering into a twinning project with an existing OIE Reference Laboratory.

The main objective of twinning is to assist laboratories in developing or in-transition countries to build their capacity and scientific expertise with the eventual aim that some of them could become OIE Reference Laboratories in their own right. A link between an existing OIE Reference Laboratory or Collaborating Centre and another laboratory or institute in developing or in-transition country must therefore be established for exchange of scientific expertise and capacity building, taking into consideration the current geographical spread and the actual location of OIE Reference Laboratories and Collaborating Centres.

The twinning concept could imply a transfer of knowledge, training and expertise from the North to the South or from the existing OIE Reference Laboratories or Collaborating Centers in the South to another less advanced laboratory applying for such assistance.

Conclusions

- The laboratory should have management policies, procedures and organisation structure and should maintain current job description for management, technical and key support personnel.
- The laboratory should formulate the goals with respect to the education, training and skills of the personnel.
- Training the veterinarians is of a uniform standard and is subjected to regular evaluation and updating and should have up-to-date continuing education that is implemented for all relevant personnel.
- The laboratory should have suitable physical resources at all levels (national, subnational and local levels) including building, transport telecommunications, cold chain, and other relevant equipment (e.g. computers).
- A regional coordination committee should be formed to facilitate communication and cooperation within the region through active networking.
- The regional coordination committee should conduct assessment of regional laboratories for compliance with international standards and identify the gaps taking into account the biosecurity risks.
- The regional coordination committee should propose active plan for achieving a universal adherence and effective national implementation of technical innovation and international standards (e.g. OIE).
- The regional coordination committee should promote active epidemiological surveillance for enzootic, emerging and re-emerging diseases using OIE certified surveillance programmes.
- The regional coordination committee, in coordination with governments, should encourage some of the diagnostic laboratories in the region to establish BSL-3 biosecurity facilities and to train their staff on all matters related to biosecurity and biosafety.
- The laboratory should meet the requirements of ISO 17025 or equivalent quality assurance standard in its testing activity in order to ensure accurate and quality results.
- The laboratory should have a well developed communication plan, and actively and regularly circulate information to the other laboratory on diagnostic tests and field strain isolates as well as on experience, in harmonisation of standard procedures, including the development and implementation of inter-laboratory proficiency tests and monitoring to ensure the accuracy and quality of the laboratory diagnosis.
- The regional coordination committee should encourage and facilitate the laboratories in entering into twinning with existing OIE Reference Laboratories.
- Regional harmonisation of national legislations and regulations should be promoted by national laboratories using international standards.
- Funding all aspect of laboratory activities should be provided by the government. Funding is provided under full transparency and all full technical independence.

References

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.../Appendix

Appendix I

Response to the questionnaire on "Capabilities of veterinary laboratories in the region – Needs to improve animal disease diagnostic"

	List of countries in the OIE Regional Commission for the Middle East	List of responding countries from the OIE Regional Commission for the Middle East
1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. 16. 17. 18. 19. 20.	Afghanistan Bahrain Cyprus Djibouti Egypt Iran Iraq Jordan Kuwait Lebanon Libya Oman Qatar Saudi Arabia Somalia Sudan Syria Turkey United Arab Emirates Yemen	 Bahrain Cyprus Iran Iraq Jordan Kuwait Lebanon Oman Qatar Somalia Sudan Syria Turkey United Arab Emirates