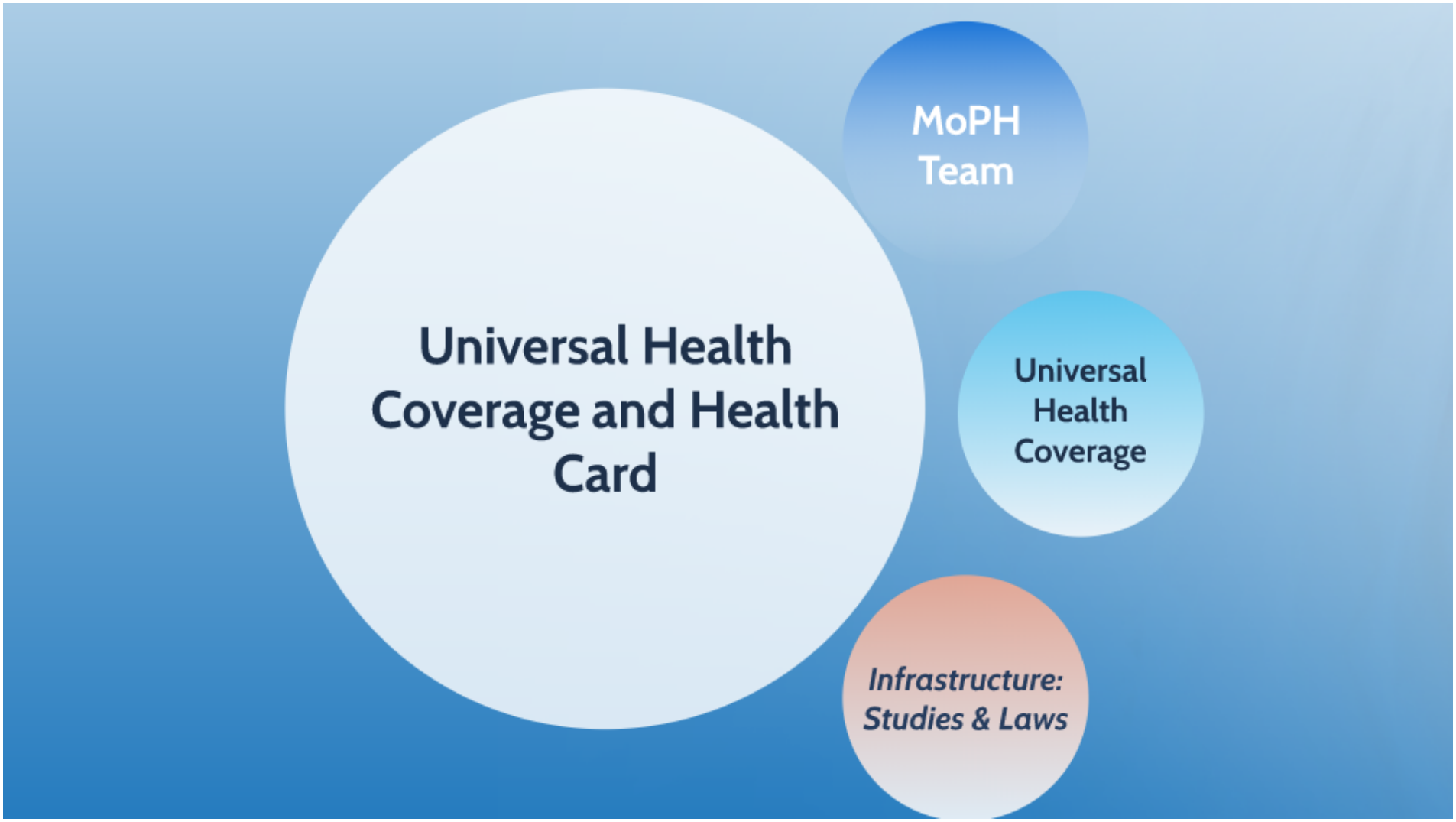
REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
500 Days Journey
Financial Burden of Drugs
Regulating Research
Universal Health Coverage
E-Health
Food Safety
Role of Media
Hospital Cost Containment
Health Security
Future HEALTH


Universal Health Coverage and Health Card
MoPH Team
Universal Health Coverage
Infrastructure: Studies & Laws

Prof. Walid Ammar MD, PhD

Director General of Ministry of Public Health

Universal Health Coverage and Health Card

Mr. Frederick Eid MS. Eng, MBA in Strategy, PhD candidate

Strategy Adviser to the Minister

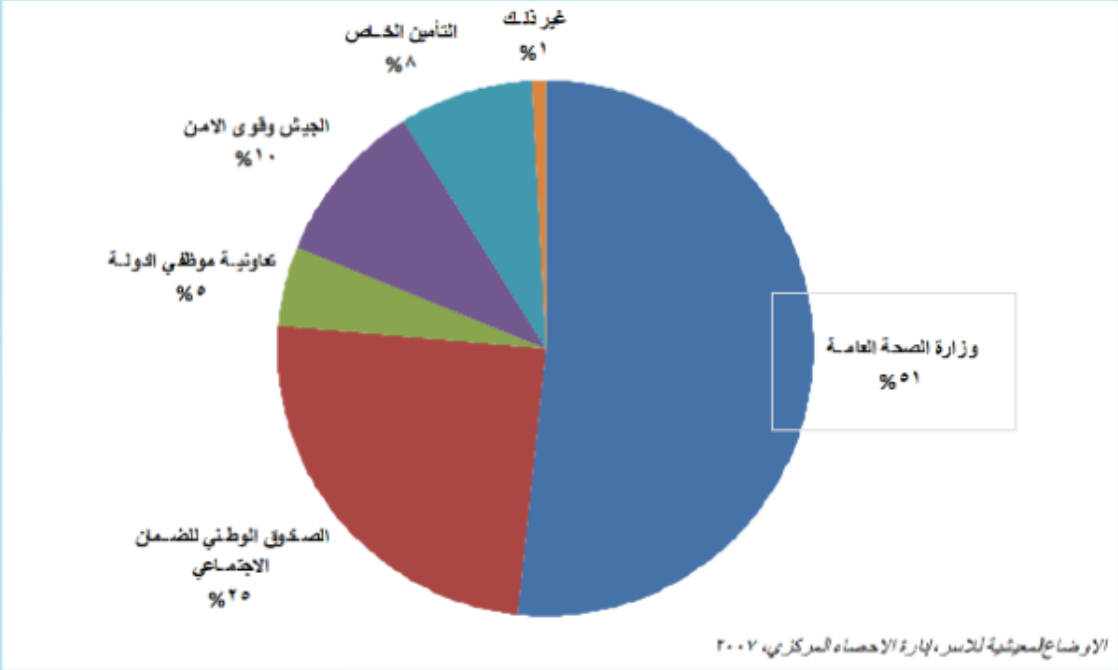
Infrastructure: Studies & Laws

الرعاية الصحية الشاملة

الرعاية الصحية الشاملة تعني ان يحصل المواطن على الخدمات الصحية الأساسية المضمونة الجودة التي يحتاجها دون ان يعاني من ضائقة مالية بسبب ذلك.

يمكن للدولة ان تمول او ان تقدم هذه الخدمات من خلال مؤسساتها كما يمكنها ان ترعى نظام ضمان اجتماعي للتمويل او ان تتعاقد مع القطاع الخاص لتقديم بعض او معظم الخدمات الصحية.

تمويل الرعاية الصحية في لبنان

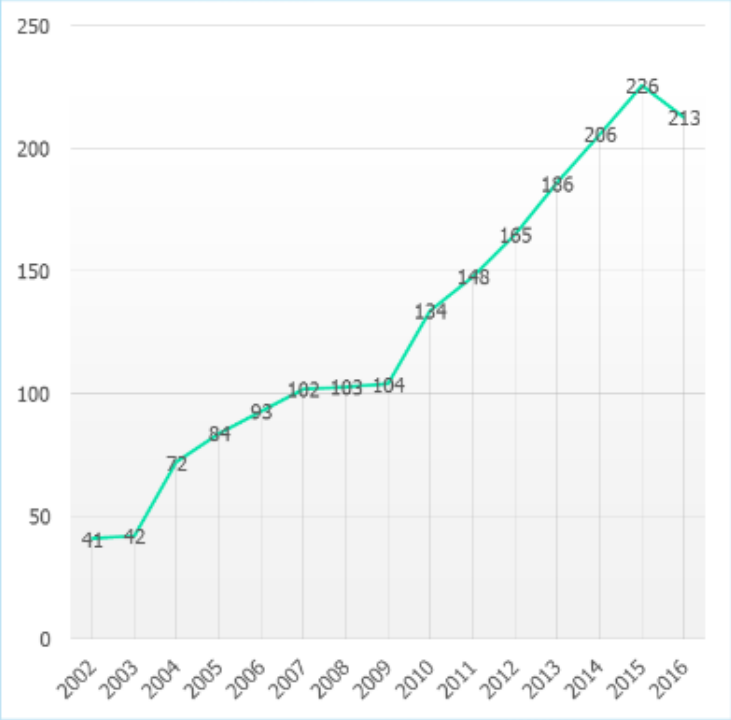


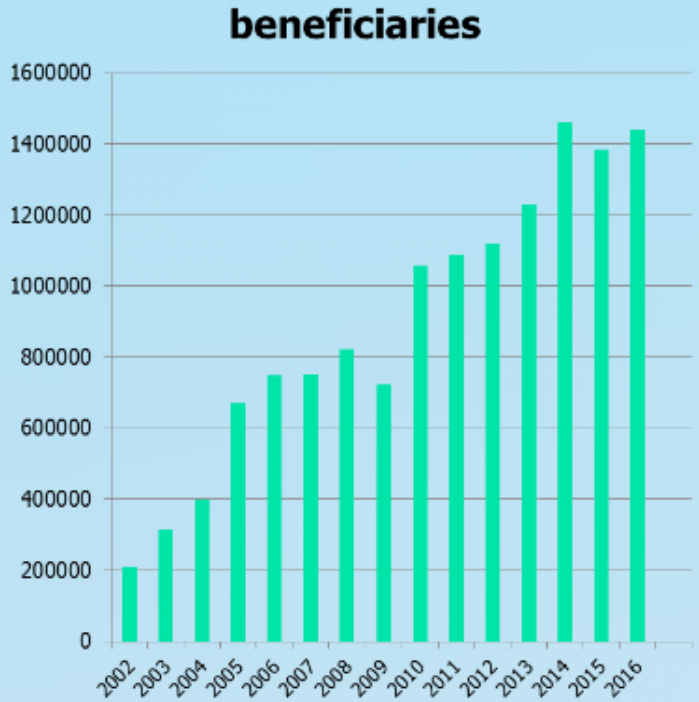
تقديم الخدمات الصحية الأساسية المضمونة الجودة

أولاً: الرعاية الصحية الأولية:

الإكتشاف المبكر للأمراض عبر فحوصات محددة وفقاً للعمر والجنس، التثقيف الصحي، التلقيح، الصحة الإنجابية، الصحة المدرسية طب العائلة، طب الأطفال، الطب النسائي، صحة الفم والأسنان، الصحة العقلية، الأدوية للأمراض المزمنة.

الشبكة الوطنية للرعاية الصحية الأولية
تطور عدد المراكز وعدد المستفيدين

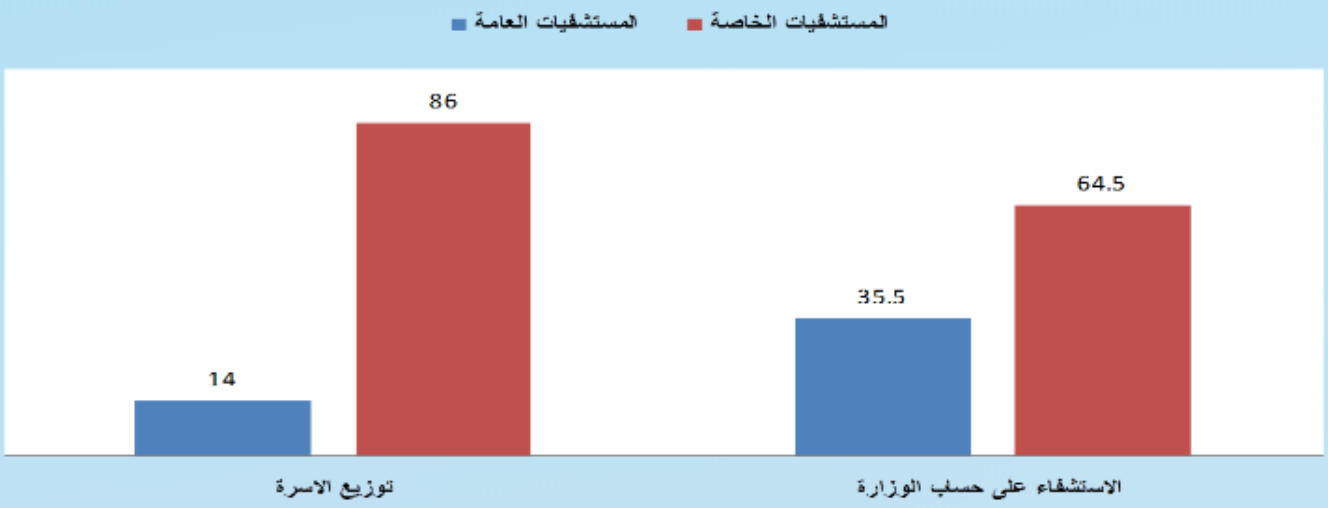




تقديم الخدمات الصحية الأساسية المضمونة الجودة

ثانياً: الإستشفاء ويشمل جميع انواع العلاجات دون استثناء سوى التجميل، وبدون لوائح انتظار.

ثالثاً: الأدوية الباهظة الثمن



مصادر تمويل الرعاية الصحية في لبنان

لحسابات الصحية الوطنية، وزارة الصحة العامة، ٢٠١٢

ما هو النقص لكي تصبح الرعاية الصحية شاملة في لبنان؟

أولاً: هناك فحوصات وعلاجات تتخطى المراكز الصحية ولا تحتاج إلى استشفاء وهي غير مشمولة بتغطية الوزارة.

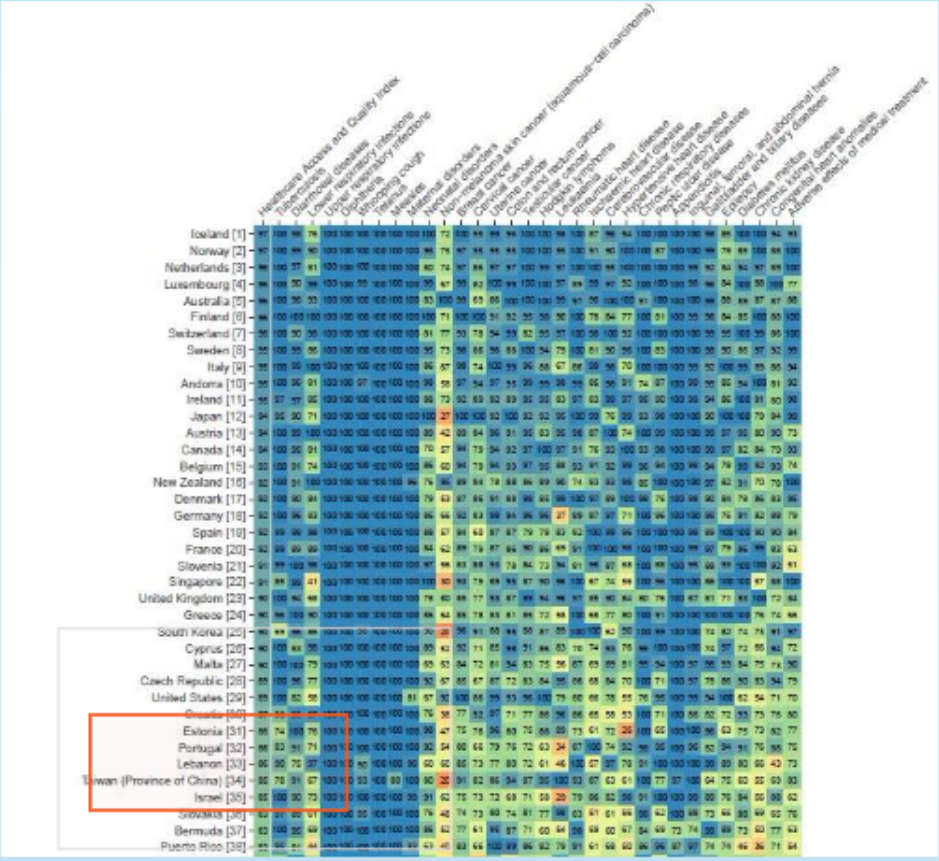
ثانياً: العبء المالي على المواطن عند الحصول على الخدمة ما زال مرتفعاً بالنسبة لمحدودي الدخل.

مبادرة الوزير غسان حاصباني لمعالجة الموضوع

أولاً: التعاقد مع المستشفيات الحكومية لتغطية الفحوصات والعلاجات الخارجية وفقاً لنظام إحالة محدد.

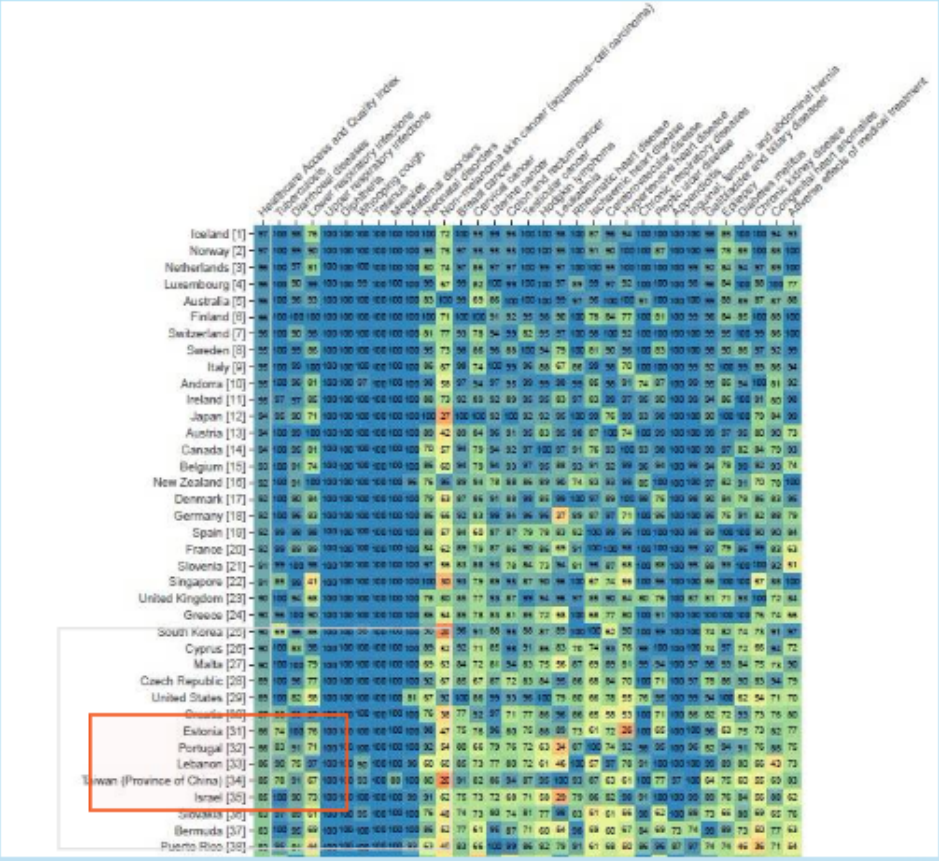
ثانياً: آلية تمويل مسبق توزع العبء المالي بشكل اكثر عدالة مرتبطة بإستعمال الهاتف الخليوي.

Healthcare access and quality index 2017



South Korea [25]	90	69	96	96	100	100	99	100	100	100	90	20
Cyprus [26]	90	100	83	98	100	100	100	100	100	100	89	52
Malta [27]	90	100	100	79	100	100	100	100	100	100	69	63
Czech Republic [28]	89	100	96	77	100	100	100	100	100	100	92	67
United States [29]	89	100	82	58	100	100	100	100	100	81	67	92
Croatia [30]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	100	100	100	100	76	38
Estonia [31]	86	74	100	76	100	100	100	100	100	100	98	47
Portugal [32]	86	83	91	71	100	100	100	100	100	100	92	54
Lebanon [33]	86	90	75	97	100	100	90	100	100	96	60	60
Taiwan (Province of China) [34]	85	78	91	67	100	100	93	100	88	100	80	20
Israel [35]	85	100	90	73	100	100	100	100	100	99	91	62
Slovakia [36]	83	97	89	61	100	100	95	100	100	100	76	48
Bermuda [37]	83	100	95	69	100	100	100	100	100	100	86	52
Puerto Rico [38]	83	95	81	44	100	100	100	100	100	93	63	40

Healthcare access and quality index 2017

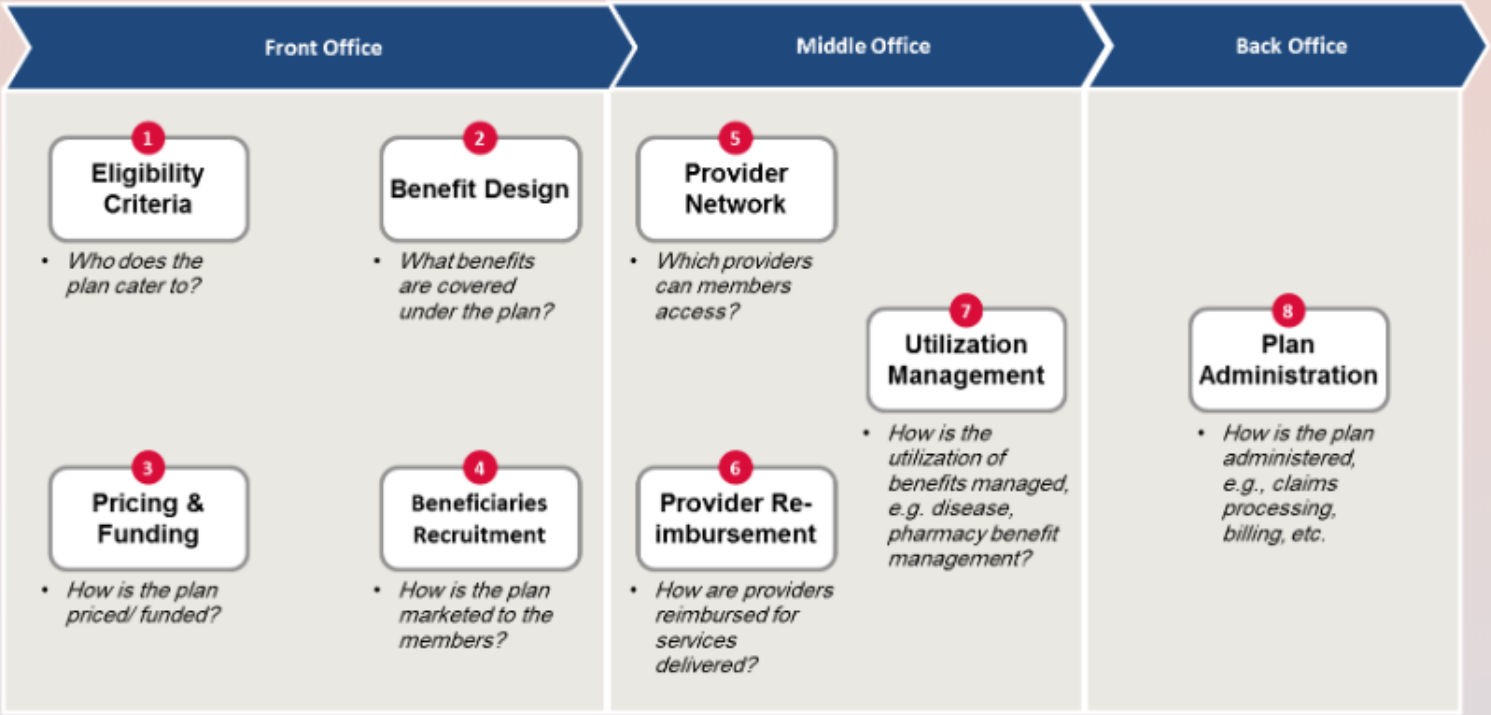


Infrastructure: Studies & Laws

Setting the infrastructure for it: Studies and Laws

Concept: Our understanding of the coverage program was built along the 8 levers of a national health insurance development framework

National Health Insurance – Development Framework



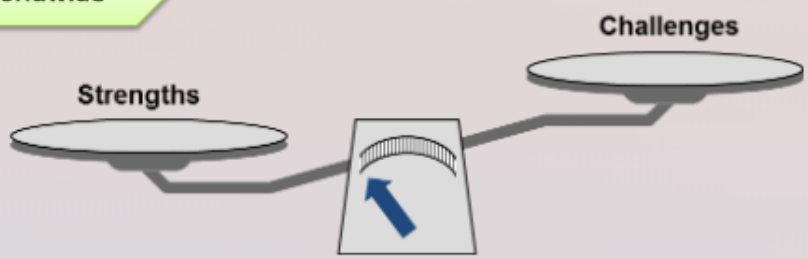
GAP Analysis: In the Lebanese and MoPH HC Systems, strengths outweigh challenges

Strengths (Leb vs. Region)

- Life Expectancy (81Y vs. 77Y)
- Hospital Beds (3.5 per 1,000 vs. 2.0)
- Physicians (3.2 per 1,000 vs. 1.3)
- Nurses (3.3 per 1,000 vs. 2.5)
- Waiting time (3d vs. 15d)
- Rank #1 in the region and #32 worldwide

Challenges

- Service Ambiguity and Unrealistic Expectations
- Absence of Solidarity
- High OOP
- Difficult Eligibility
- Uninsured Private Sector Retirees



To design a national health insurance program that follows the UHC framework, we set a number of key guiding principles

1 Access to Essential and Universal Care

- Offering **essential healthcare services** to nationals and residents
- **All residents have a right to universal/ equitable access to healthcare**
- Healthcare should not vary in coverage due to personal characteristics (e.g., SEC)

2 Solidarity in the Distribution of Costs and Risk Pooling

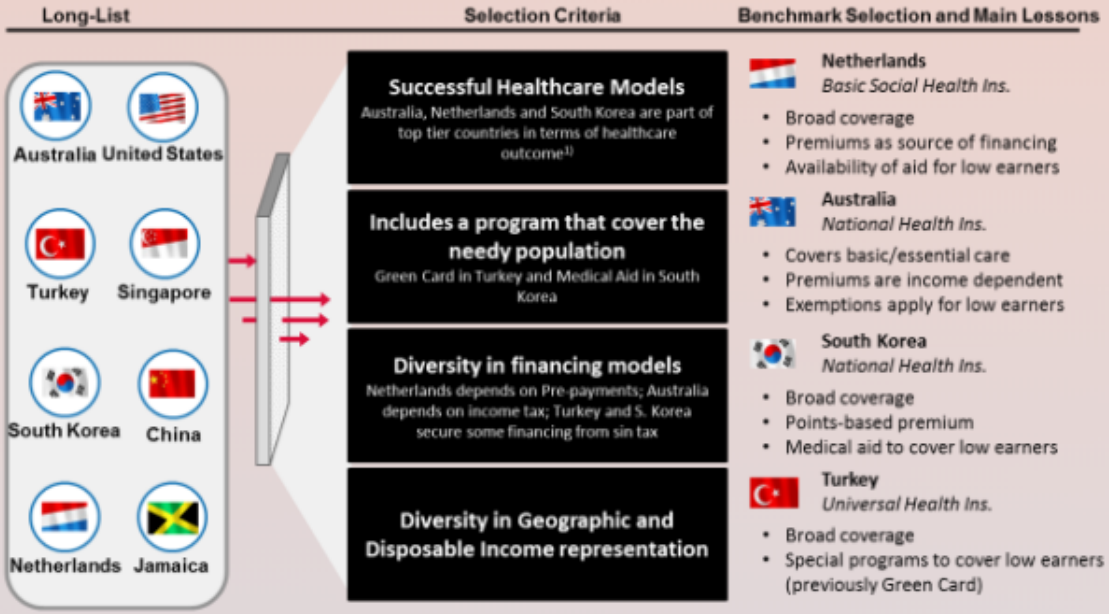
- **Each patient needs to bear some burden of health cost**
- Typically wealthier people will be paying for services used by the poor
- **Governments mandate universal membership** to prevent adverse selection
- A risk pool with a diverse population promotes equity and efficiency

3 Efficiency in Delivery of Health Care

- Strong statutory safeguards/ regulations to **monitor implementation/ performance**
- Improving coverage and access while being **mindful of costs**
- Involvement of the private sector to ensure efficiency in plan delivery

Evidence: Benchmarks aimed at providing full HC services to all citizens and fund them through various means. Utilization management and plan administration are key to ensure efficiency and sustainability of health coverage

Benchmark Selection



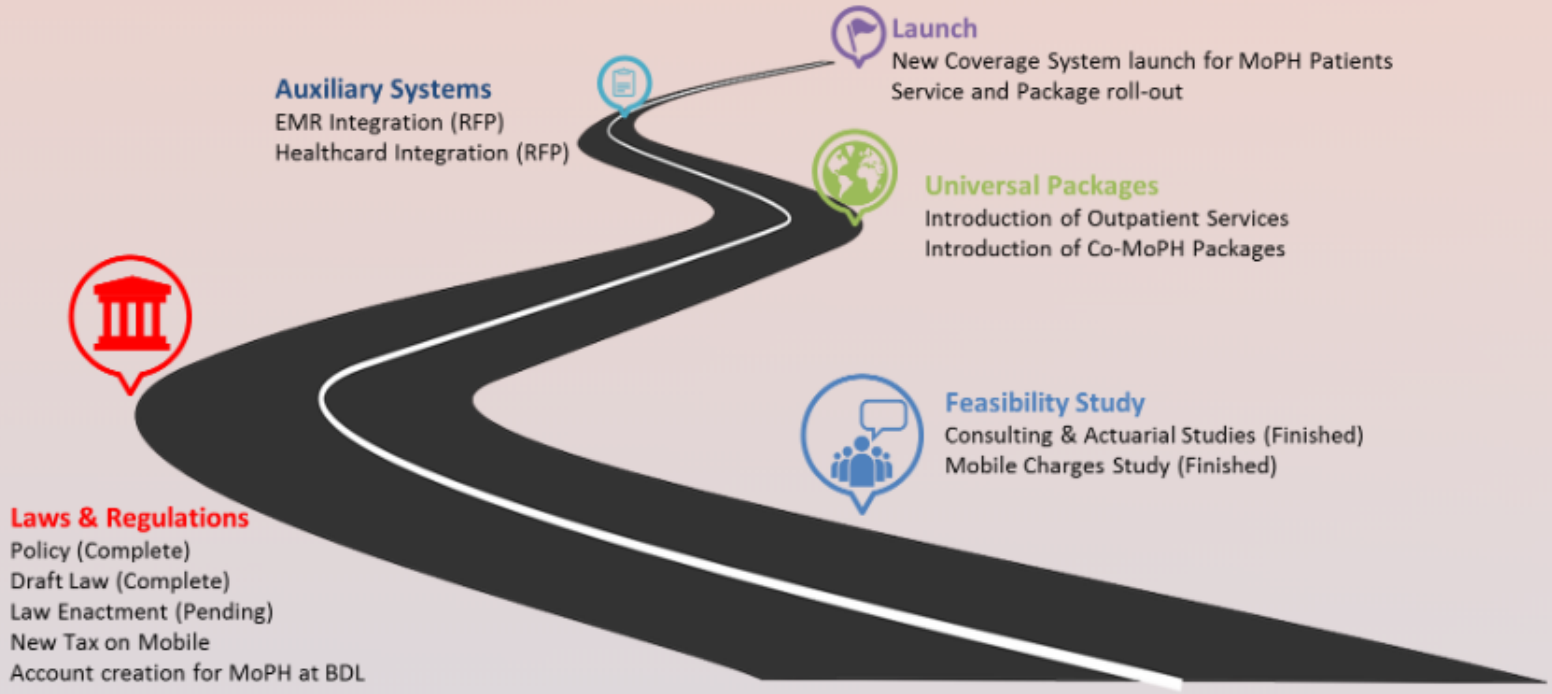
Source: Litsearch; Internal analysis; 1) Economist: Health outcomes and cost

Result: Two health coverage bundles were addressed in our National Health Insurance Policy ...

	1 Essential Bundle		2 Universal Bundle
Eligibility	• All Insured People through Public or Private Insurance Systems except MoPH		• Uninsured People (currently using MoPH as a payor of last-resort)
Benefits	• Patient File • Yearly consultation at PHC • PHC WB Packages		• **Essential Bundle** • *Inpatient + Dialysis + Essential and Expensive Drugs*
Financing		• MoPH Budget • Pre-payment • Donations	
Pricing	• Pre-payment		• Pre-payment
Subscription Collection	• Mandatory linked to Mobile Phone		• Mandatory linked to Mobile Phone
Provider Network	• PHCs		• Inpatient in public and private hospitals • Outpatient in Public and PHCs

...To enforce our policy, we developed 4 key components: (1) Consulting & Actuarial Studies, (2) the amended [Healthcard] Law, (3) New Coverage Packages for Outpatient and Co-MoPH and (4) Auxiliary ICT Systems

Universal Health Coverage Roadmap



Improving Access to Hospital Service & Cost Containment

- MoPH Team
- *Emergency Services*
- *Third Party Administrators*
- *Hospital Affiliations*

Dr. Joseph Helou
Director of Medical Care

Emergency Services

Dr. Jihad Makouk
Hospitals service department

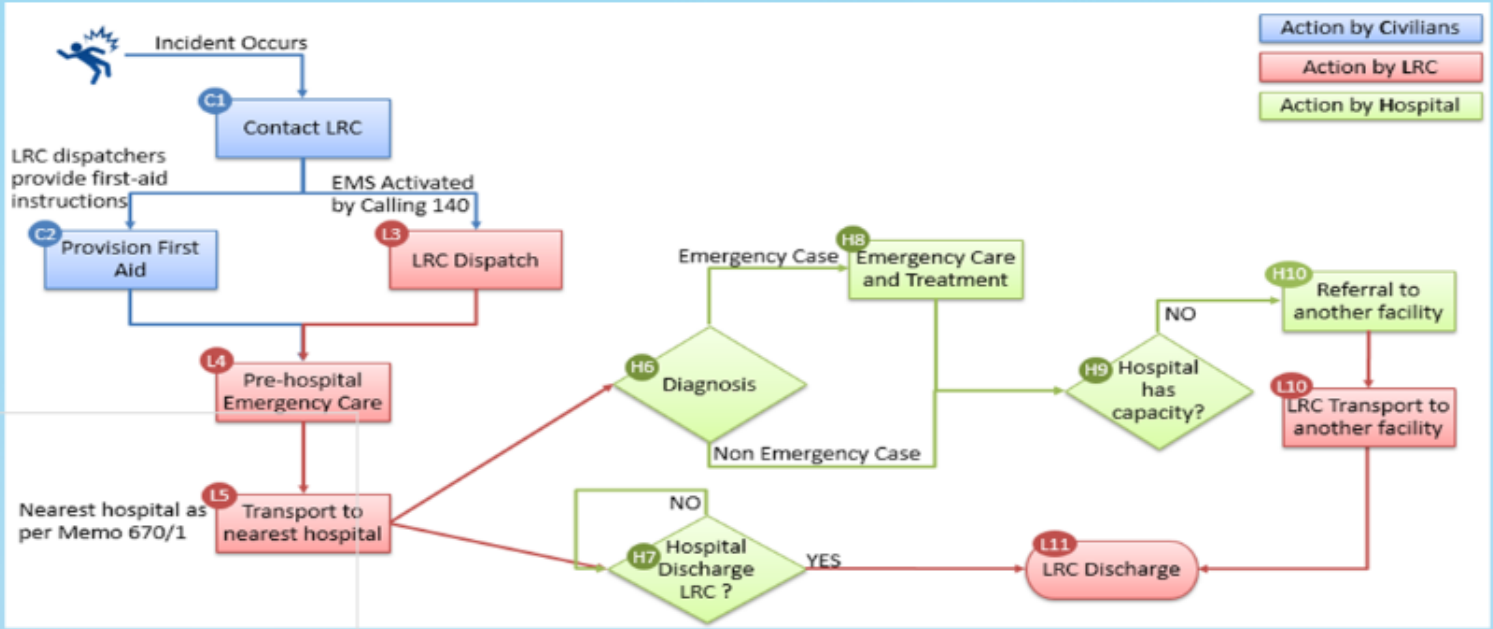
Third Party Administrators

Mr. Antoine Romanos
Head of Medical Professions Section

Hospital Affiliations

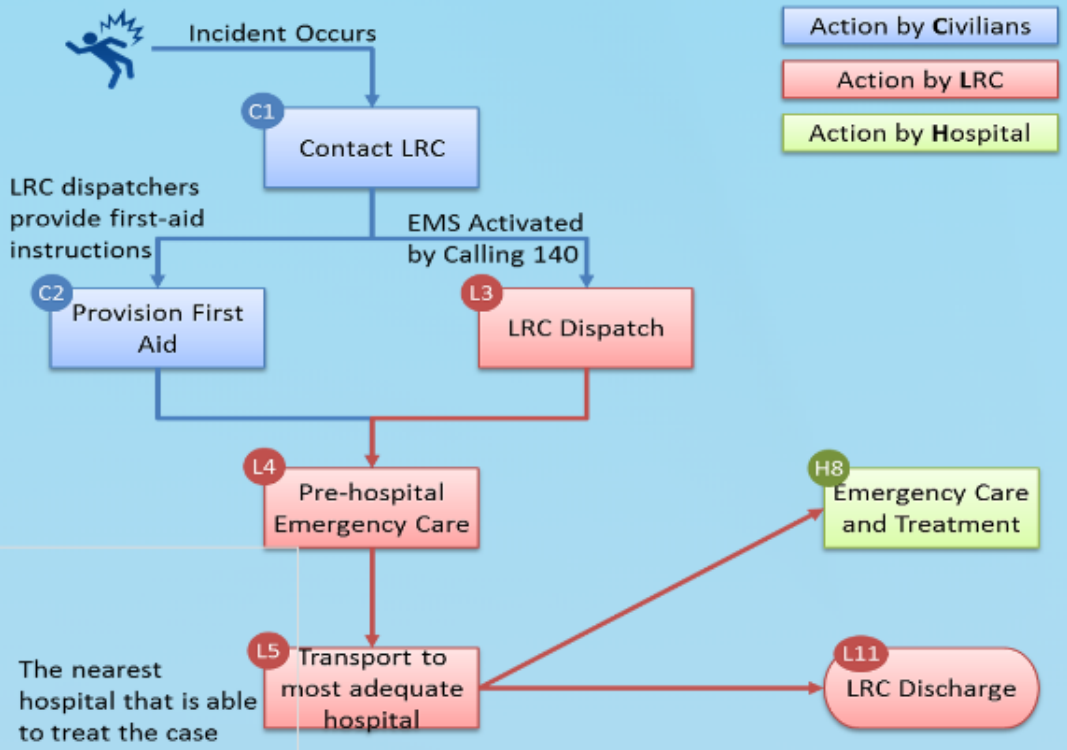
Emergency Response Current Plan

سنة ٢٠٠٦، تم اقرار المرسوم ٦٧٠/١ الذي ينص على نقل الحالة الطارئة الى اقرب مستشفى من قبل فرق الاسعاف. من اهم المشاكل التي يواجهها المواطنون و المسعفون هي عدم توفر الامكنة في غرف الطوارئ او غياب الخدمات المطلوبة لمعالجة الحالة



Emergency Response New Plan

اما الخطة الجديدة المعدة من قبلنا فهي تعتمد على تحديد اقرب و انسب مستشفى متوفر لمعالجة حالة طارئة معينة. هي تشمل ايضا عوامل عدة ستوفرها الوزارة (١) للاشراف و المتابعة، (٢) للتدخل عند الحاجة، (٣) لتلقي و معالجة صعوبات المواطنين و المسعفين و (٤) انصاف الجميع



Third Party Administrators

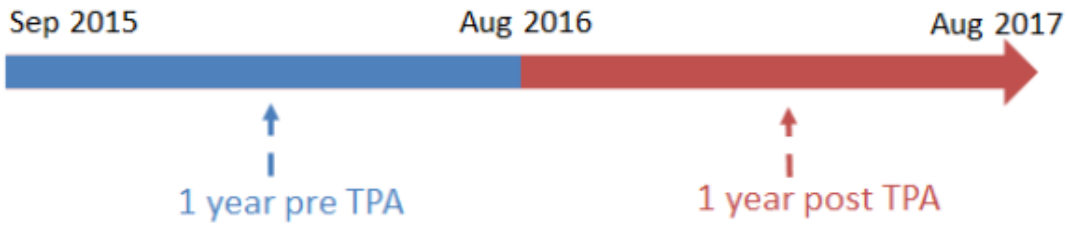
August 2016:
Contracting with 2 TPAs for private hospitals through bidding process

October 2017:
Contracting with 4 TPA companies & inclusion of public hospitals

March 2018:
Comparative study of pre and post TPA intervention

Comparative study

- Comparison of 5 indicators 1 year pre TPA and 1 year post TPA



- Indicators used

Hospitalization cost

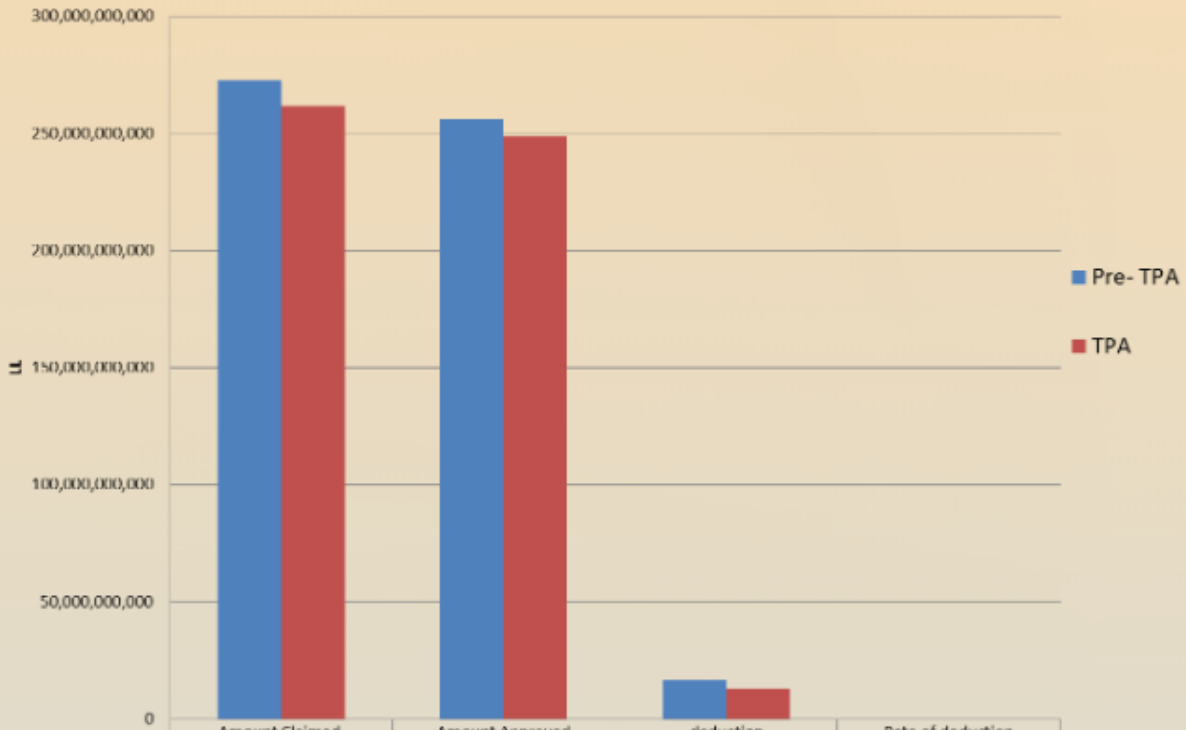
Number of admission

Deduction rate

100% coverage of patients >64 years

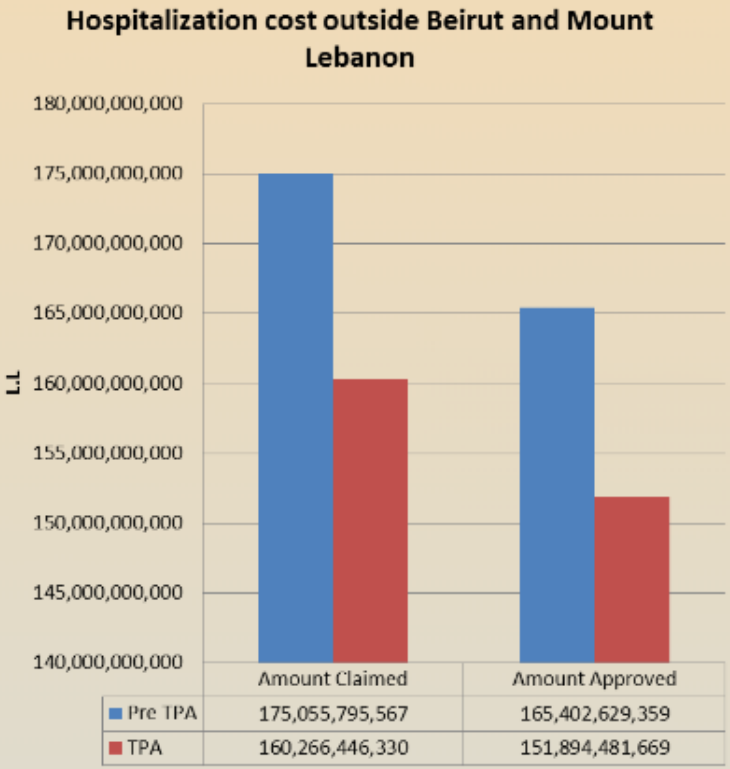
Admission criteria

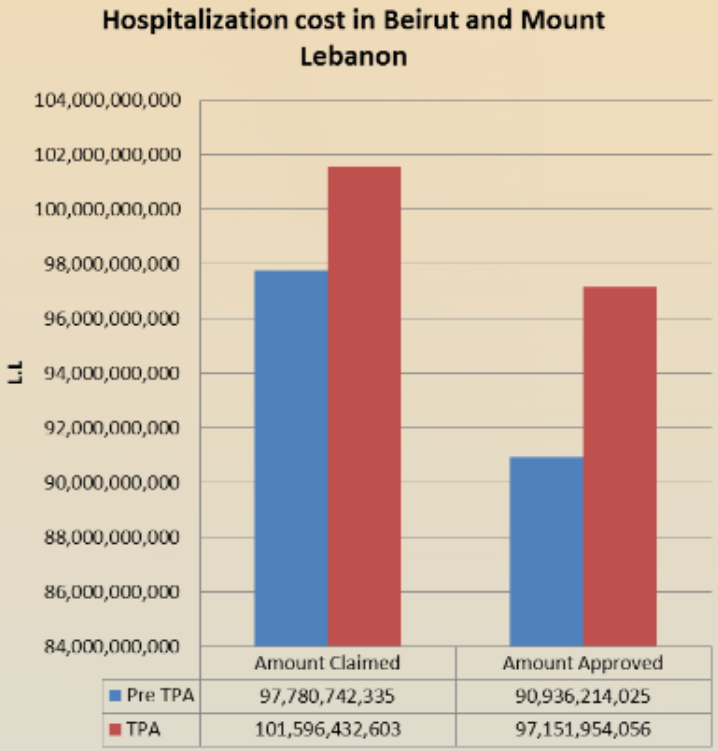
Comparision of Hospitalization cost pre and post TPA intervention



	Amount Claimed	Amount Approved	deduction	Rate of deduction
Pre- TPA	272,836,537,902	256,338,843,384	16,497,694,517	6%
TPA	261,862,878,933	249,046,435,725	12,816,443,207	5%

Comparison of hospitalization cost between regions





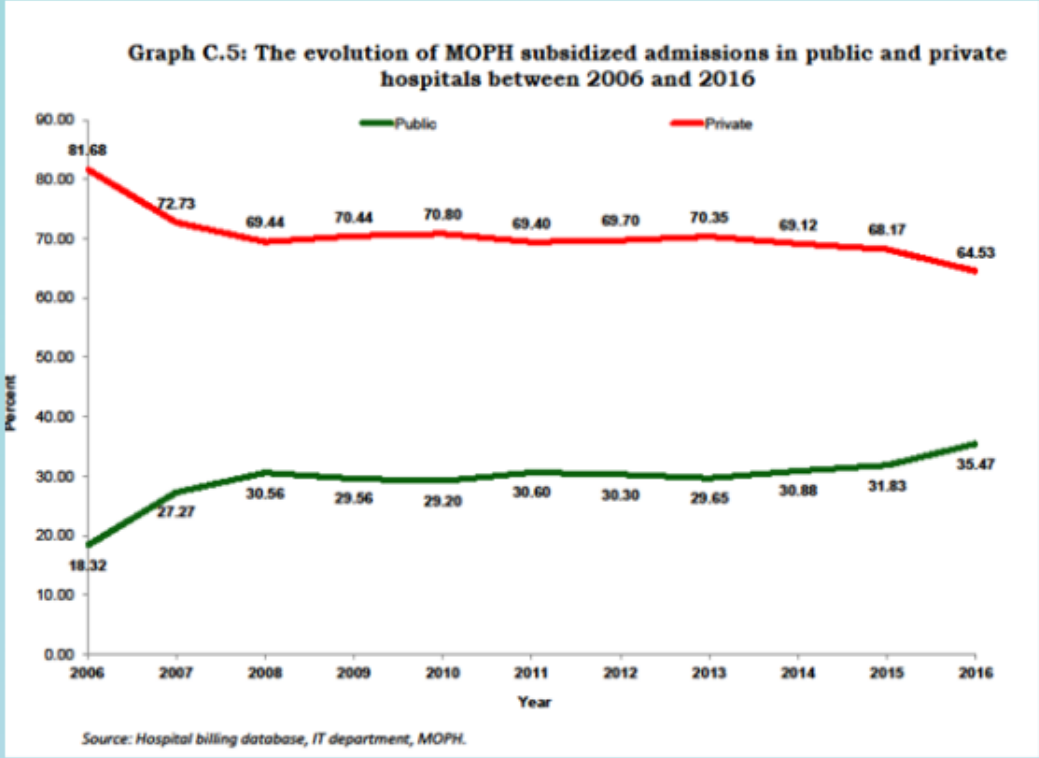
Conclusion

- Total hospitalization expenditure was reduced by 7 Billion L.L., although total elderly coverage resulted in a 17 Billion L. L. increase.
- Savings were mostly observed in governorates outside Beirut and Mount Lebanon, while expenditure increased in the latter.
- Total cost of surgical admissions increased around 1.5 Billion.
- Deduction rate for medical admissions (non- FRS) did not differ pre and post TPAs intervention.
- Total admissions decreased around 23,000 cases and number of patients >64 years increased around 200 cases which reflects appropriate implementation of admission criteria.

Hospital Affiliations

Progress Plan :(34 PH/1900 Beds)

- Administrative
- Financial
- Technical



Public /Private Partnership

- Support Public Hospitals
- Benefit from the New Technologies
- Cooperation system/Patient Transfer
- HRH Rehabilitation
- Partnership(Services IN/OUT-Equipments-Depts-HRH)

Current situation	Phase 1	Phase 2	Phase 3
3 Public Hospitals	8 Public Hospitals	Coperation Contracts	Implementation
3University Hospitals	6 university Hospitals		

Health Security
MoPH &
WHO Team
International
Health
Regulations
Epidemiological
Surveillance
Program

Dr. Rana Hajjeh

WHO EMRO Regional Director Candidate

International Health Regulations

Nada Ghosn, MD

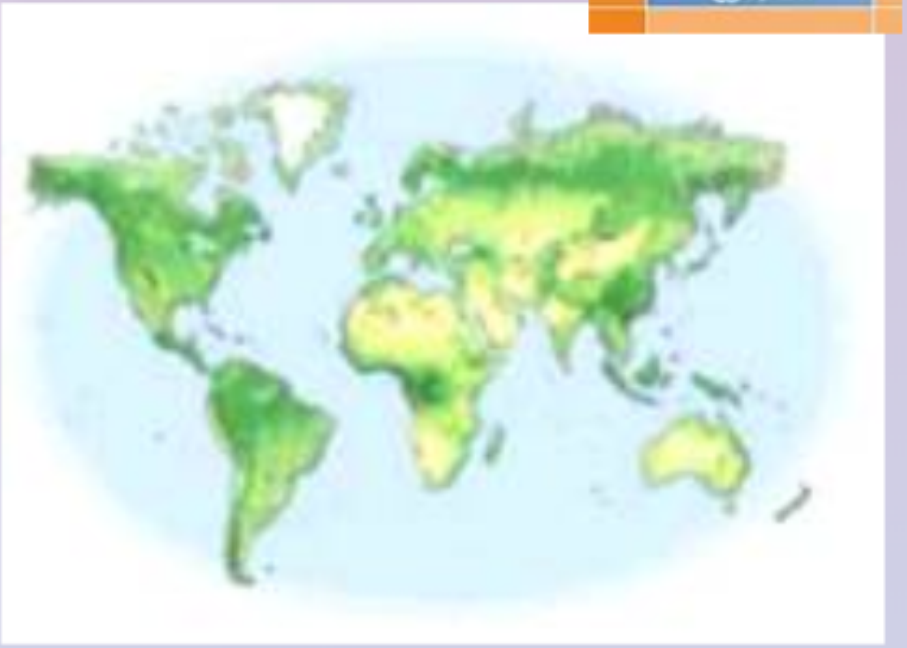
Head of Epidemiological Surveillance Program

Epidemiological Surveillance Program

International Health Regulations

The purpose and scope of IHR (original in 1969, revised in 2005)

- To prevent, protect against, control and provide a public health response to the international spread of disease (with a focus on Public Health Emergency of International Concern (PHEIC))
- To establish a single code of procedures and practices for routine public health measures



Global Health Security

Global Health Security

Key components for better Preparedness and Response/ IHR competencies

Laboratory
- Specimen referral network reaching > 80% of districts
- National reference laboratory performing 6 testing methods under IHR

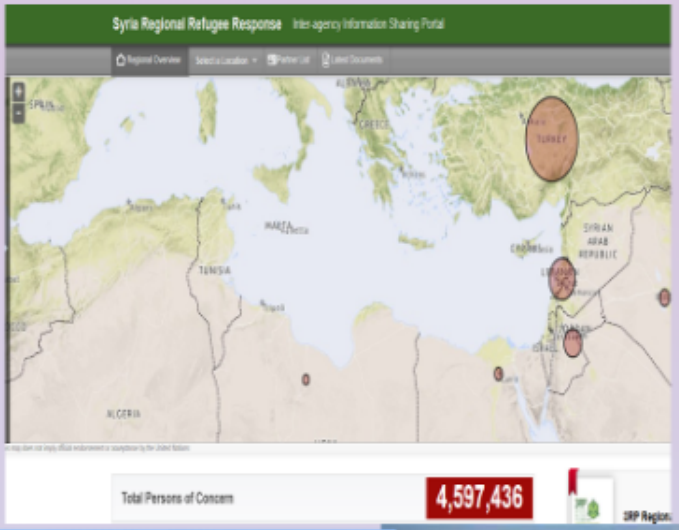
Surveillance
- Surveillance for 3 core syndromes
- Capacity to analyze and link data for functional real-time biosurveillance system

Emergency Operations
- EOC activation when needed
- Functional IMS use for preparedness and response

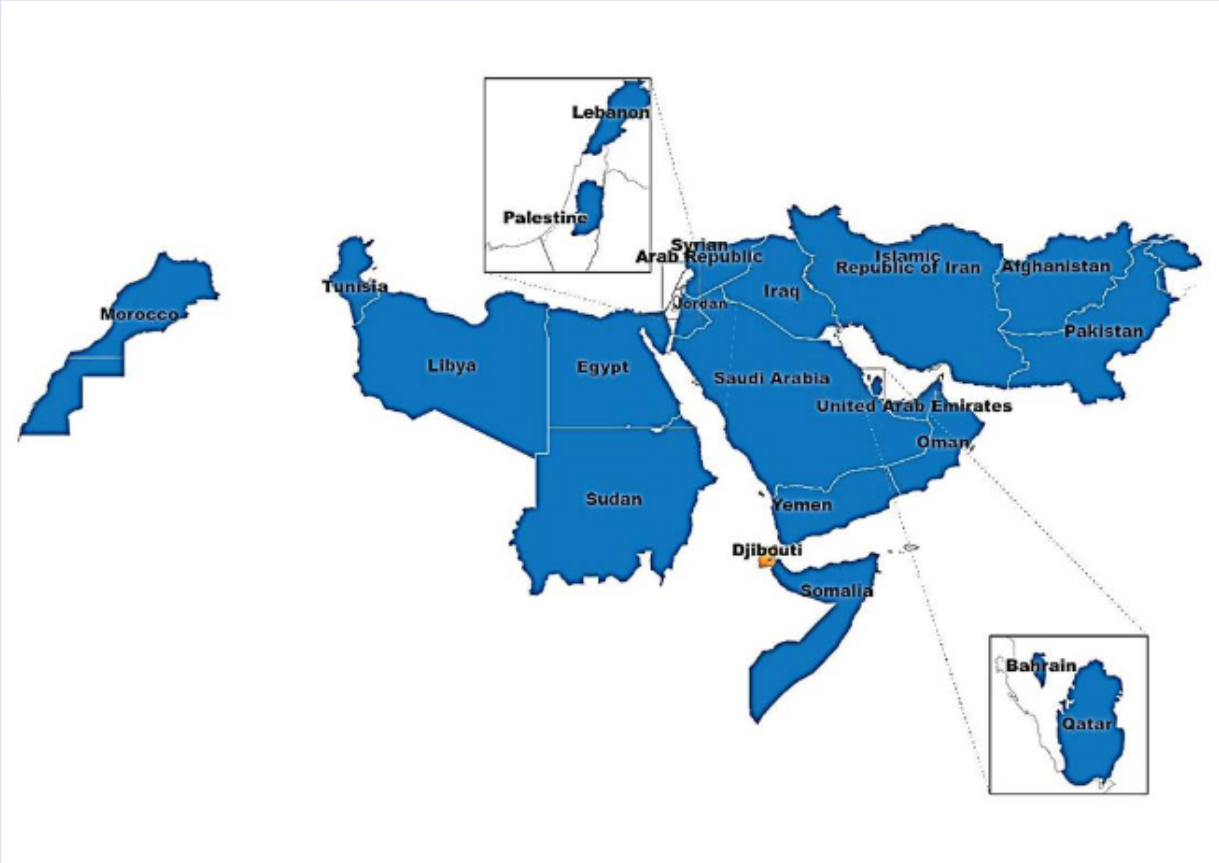
Workforce Development
- National workforce planning
- Minimum of 1 trained field epidemiologist per 200,000

- National legislation policy/ financing
- National focal point, coordination
- Surveillance
- Response
- Preparedness
- Risk Communications
  Human resources
  Laboraotories
  Points of Entry

War and Refugees



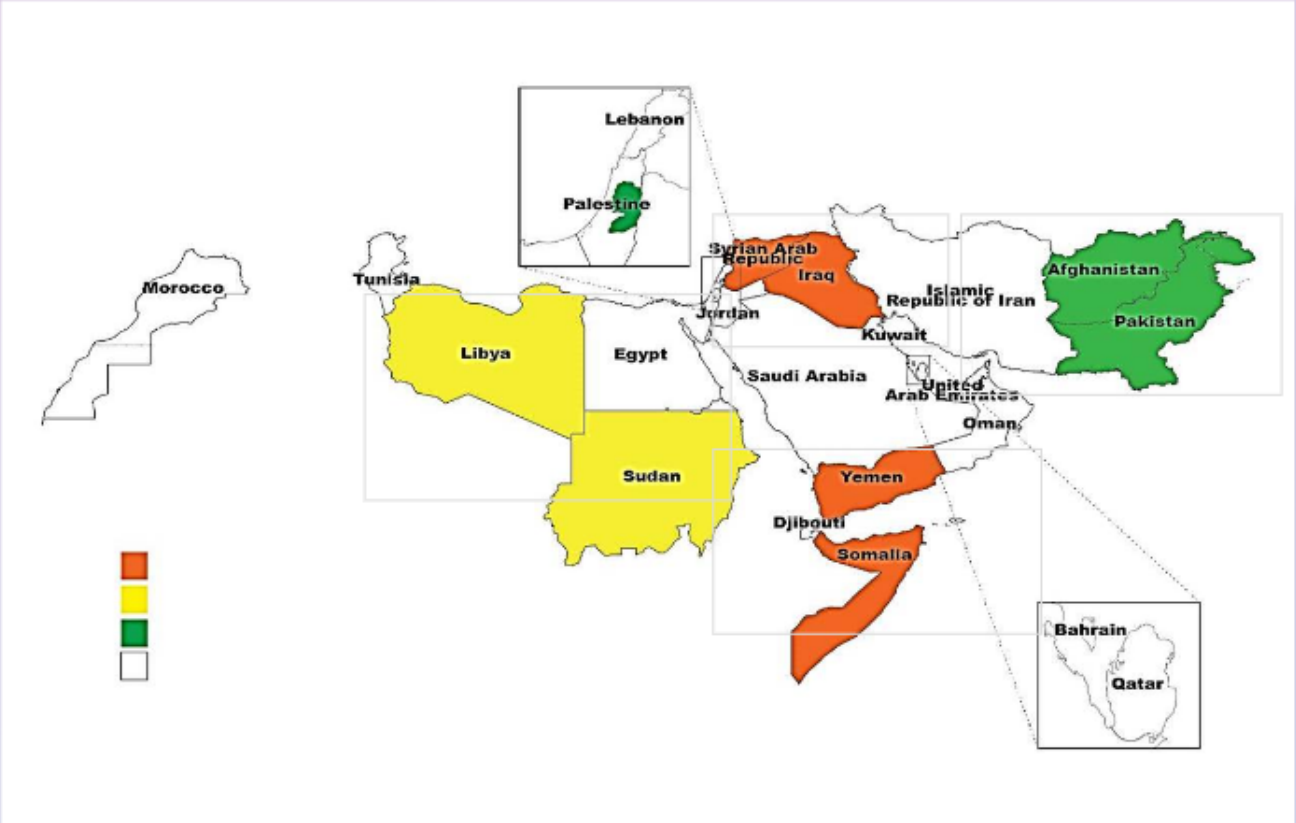
Emerging infectious diseases as of December 2017



Active disease outbreaks as of August 2017:

- Cholera in Yemen
- Cholera in Somalia
- Acute watery diarrhoea in Sudan
- Dengue fever in Pakistan
- Diphteria in Yemen

Graded emergencies as of September 2017



Epidemiological Surveillance Program

Online Communicable Diseases Reporting

Context
- International Health Regulations (2005)

Objectives
- Timely detection of alert/ outbreaks for timely response

Methods
- Selection of electronical platform: DHIS2
- Platform management: forms, accounts, dashboards
- Phase 1: aggregated-based surveillance
- Training of MOPH teams and end-users, guide

- Results
  - Online application

  - % Reports Reception

	2017 (Q1)	2018 (Q1)
Laboratory-based surveillance	71%	79%
Medical center based surveillance	42%	55%

Poliovirus Environmental Surveillance

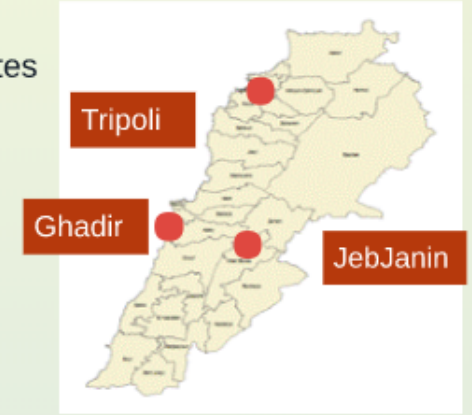
Context
- Global polio eradication initiative
- Polio outbreaks in Syria: 2013-2014, 2017

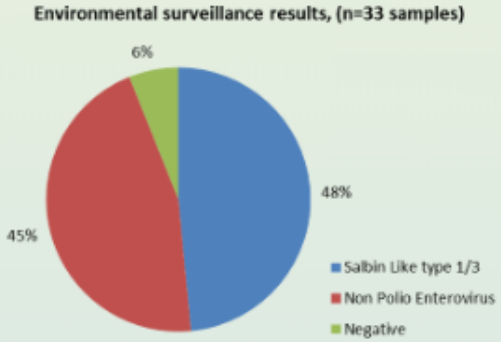
Objectives
- Timely detection of poliovirus importation for rapid containment

Methods
- Selection of sites: high risk area
- Coordination between sectors
- Monthly sampling of sewage samples and testing at WHO accredited laboratory

Results: 1st Jan 2017 – 28 Feb 2018

Selected Sites





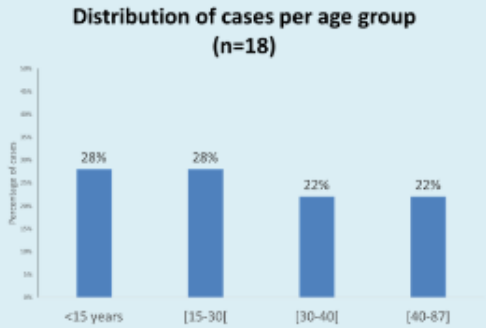
Chemical Incident Surveillance

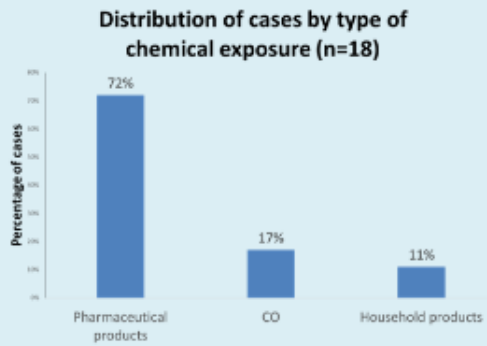
Context
- International Health Regulations (2005)

Objectives
- Acquire knowledge on chemical incidents in Lebanon to guide prevention and control programs

Methods
- National protocol
- Consensus: National workshop
- Training session
- Collaboration between sectors: governmental, academia, hospitals

- Results: 1st Jan-22nd March 2018





Measles Outbreak Surveillance

Context

- Measles elimination goal

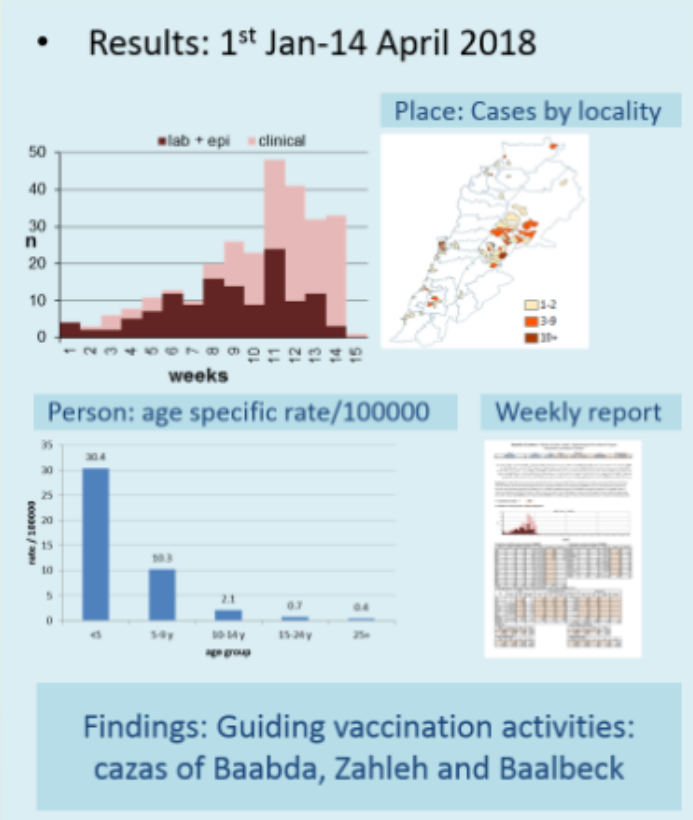
Objectives

- Detect, investigate, and monitor measles outbreak to guide immunization activities

Methods

- Case based surveillance
- Laboratory confirmation at RHUH
- Weekly coordination meeting at MOPH
- Weekly report on measles situation posted on website

- **Results: 1st Jan-14 April 2018**



Acknowledgement

- MOPH: Minister and Director General
- WHO
- Hospitals
- Laboratories
- Medical Centers
- Reference laboratories: RHUH, Jordan Lab, USJ, AUB
- Universities

Food Safety
MoPH Team
Strategy
Complaints

Engineer Joyce H. Abboud

Director of Prevention

Strategy

Complains using Mobile app. "BalleghlalSoha"

A- Strategy

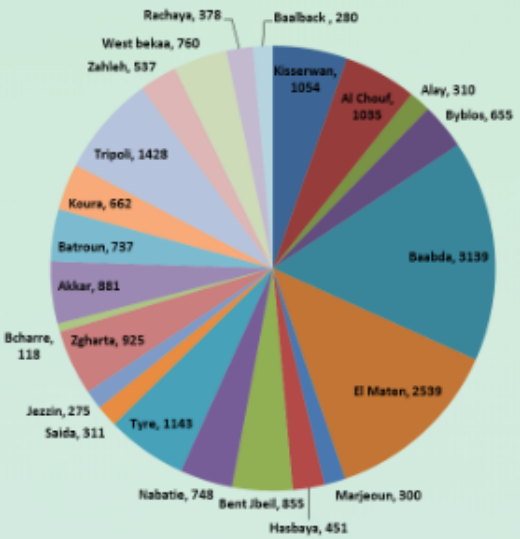
1- Studies :
- Risk assessment: pesticides, high risk food,…
- Evaluation of the efficiency of the checklist used in food safety, …

2- Partnership with the private sector:
- Collaboration with:

- The Chamber of Industry and Commerce
- Universities,…

3- Partnership with the municipalities and different Lebanese stakeholders

Number of :	
Inspections	18,378
Oral warnings	5,599
Written warnings	2,138
Fines	47
Work suspension	105
Damaged Food	38
Closures	89



B- Achievements

1- Recruitment of 75 inspectors specialized In Food Safety

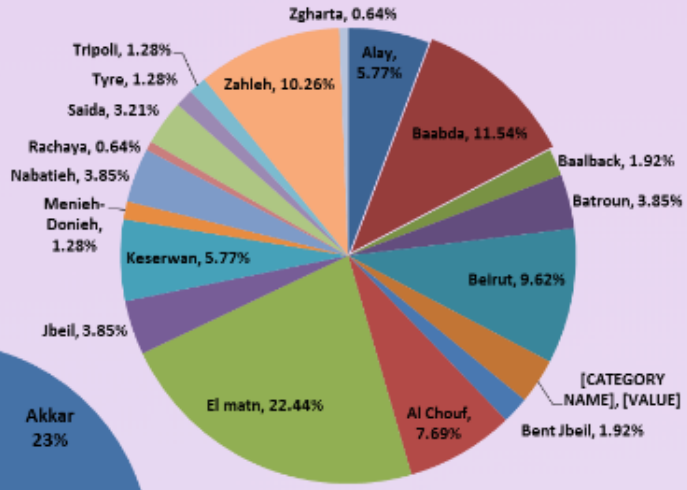
2-Elaboration of Data bases :
Statistics of food establishments
Statistics of food sampling

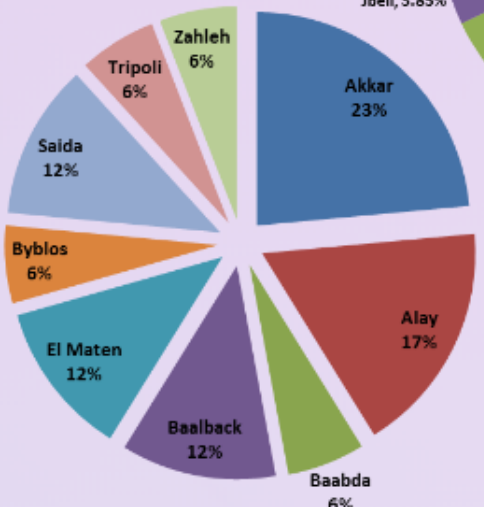
3- Participation in the Arab Initiative for Risk Assessment

4-Launching of ‘ Ballegh Lalsohha" Application

"Ballegh LaSohha" Mobile App.

Hotline (1214)





E-Health to Increase Transparency & Improve Efficiency of Health Care

- MoPH Team
- 2D barcode on pharmaceuticals products
- Electronic Customs Transactions Approval
- Administrative Services Digitization
- Emergency Response Mobile Platform
- E-Health Applications
- Electronic Medical Student File

Mrs. Lina Abou Mrad

National E-health Program Director & ICT Expert

E-Health to Increase Transparency & Improve Efficiency of Health Care

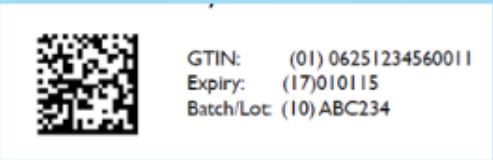
Mrs. Pamela Mansour

Head Of Dept. of Mother & Child Health & Schools

MoPH School Health Program

Implementation of GS1 2D barcode on pharmaceuticals products

- Ensuring safety and quality of pharmaceutical products in the Lebanese market
- Providing a track and trace tool
- Speed-up the Reimbursement and control fraud at the third party payers
- Fast Recall from the Lebanese market



Drivers for Traceability

Functionalities of the System

New Regulations:

- Decision No. 1817 date 2/10/2017: Drugs Barcode and Unified Prescription Committee
- Decision No. 2405 date 12/12/2017: **Barcode implementation**
- Decision No. 2428 date 14/12/2017: **Barcode Implementation Timeline**
- Decision No. 2429 ate 14/12/2017: GTIN request

Pilot Phase

Started in January 2018 → **End of 2018**

25 Pilot members:

- Manufacturers
- Importers
- Wholesalers/Distributers
- Pharmacies
- Hospitals

30 2D Products from
13 Manufacturers

Roche
Abbvie
Merck
NovoNordisk
Braun Pharma
Algorithm
APL Swift Services (Malta) Limited
Therabel Industries SAS
Leurquin Mediolanum
Aguettant, France
Hospira (Acquired by Pfizer)
SM Farmaceutici SRL, Italy
PSI, KSA

-->> Starting 2019 all pharmaceutical companies should be connected to the system

Situation in the MENA region

Lebanon
barcoding: January 2019

Jordan
1D to 2D: end June 2018
barcoding: July 2018
serialisation: 2020

Oman
purchasing requirements
barcoding: end of 2017
serialisation: end of 2018
reporting: Apr. 2017

Qatar
purchasing requirements
barcoding: Jan. 2018

Saudi-Arabia
barcoding: March 2015
serialisation: March 2017
reporting: on-going

UAE - DHA
purchasing requirements
barcoding: Jan. 2017
reporting: Jan. 2017

Bahrain
under dev.
serialisation: end March 2019 (tbc)
reporting: end April 2018 (tbc)

Egypt
serialisation: June 2018
reporting: under dev.

Electronic Customs Transactions Approval

MoPH and Customs administration are now connected through **NAJM** (Customs Clearance automated information System)

Main Objectives:

- Ensure compliance with Lebanese Laws and regulations
- Reduction of cost and time of clearance procedures
- Provision of accurate and fast int'l trade statistics

Pilot Phase:

- Started in January 12 2018
- MoPH & Customs Team to review the Tariffs & Trade Regulations related to **MoPH** to ensure that all **goods entering and exiting Lebanon are in accordance with relevant laws and regulations**

عدد البيانات الجمركية في وزارة الصحة العامة سنويا

البيانات الجمركية في مصلحة الهندسة الصحية : ١٤٤٩٣

- مبيدات الحشرات
- مستحضرات التجميل
- عطور
- مستحضرات العناية بالشعر
- معطر جو
- عصير
- مياه
- مشروب طاقة
- متممات غذائية
- أدوات طبية
- أجهزة طبية غير معقمة
- أجهزة أشعة
- أجهزة ومواد مشعة
- أدوات طب الأسنان
- محضرات غذائية للأطفال
- ملح للطعام
- بدائل سكر

البيانات الجمركية في مصلحة الصيدلة: ١٠٧٠٢

- مواد مخدرة – تخليقية
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- أدوية
- معدات ودواء

المجموع الإجمالي: ٢٥١٩٥ بيان جمركي

الجمهورية اللبنانية
وزارة الصحة العامة

مذكّرة تفاهم

بين الجمارك اللبنانية ووزارة الصحة العامة

الفريق الأول: الجمارك اللبنانية ممثّلةً بالمجلس الأعلى للجمارك

الفريق الثاني: وزارة الصحة العامة ممثّلةً بوزير الصحة العامة

مقدّمة

استناداً إلى المادة الرابعة من قانون الجمارك اللبنانية التي أكّدت على وجوب اعتماد الأساليب الحديثة والأنظمة المتقدّمة والمتطوّرة في انجاز المعاملات الجمركية،

واستناداً لجميع التشريعات ذات الصلة التي أناطت بوزارة الصحة العامة مراقبة استيراد وتصدير ومرور بعض الأصناف من خلال إصدار الإجازات والتأشيرات وغيرهما لمختلف السلع المذكورة في هذه التشريعات،

ونتيجةً لرغبة الفريقين في تسهيل عملية انسياب البضائع ورفع التقييدات المفروضة من قبل وزارة الصحة العامة على السلع أو منعها،

وبهدف تطوير علاقة التعاون بين الفريقين لتأمين الرقابة الفعّالة والموجّهة بالإضافة إلى ضمان سلامة التجارة الشرعيّة وتسهيلها، ومكافحة التجارة غير المشروعة،

وإدراكاً لأهميّة تبادل المعلومات بالوسائل الإلكترونيّة في بيئة غير ورقيّة، وضرورة اعتماد إجراءات التخليص الدولية وفقاً لما نصّت عليه اتفاقية كيوتو،

تمّ الإتفاق على منح مذكّرة التفاهم الصفة الرسميّة لتعتبر بمثابة مستند توجيهي للتعاون الثنائي،

بناءً على ما تقدّم، إتفق الفريقان على ما يلي:

المادة الأولى

تُعتبر المقدّمة جزءاً لا يتجزّأ من مذكرة التفاهم.

المادّة الثانية– نطاق التعاون

يتعاون الفريقان على اعتماد الأساليب المتقدّمة لتبادل المعلومات بالوسائل الإلكترونية وفقاً للمفاهيم التالية:

- ضمان مبدأ العلنية والشفافية؛
- تقليل الوقت الضروري لإصدار الموافقات اللازمة ووقت التخليص؛
- تبادل المعلومات بصورة إلكترونية لتعزيز التواصل وتسهيل التجارة الشرعية؛

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المجموع الإجمالي: ٢٥١٩٥ بيان جمركي

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المجموع الإجمالي: ٢٥١٩٥ بيان جمركي

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عدد البيانات الجمركية في وزارة الصحة العامة سنويا

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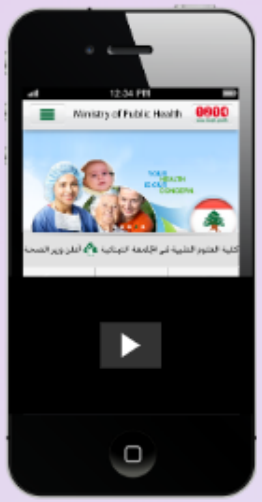
المجموع الإجمالي: ٢٥١٩٥ بيان جمركي

Administrative Services Digitization



Scope

Provision of a direct and easy multi-channel platform to access a full range of Health Services around the clock to satisfy citizens' needs

Objectives

- Increase Transparency and Fight Corruption
- Improve public services delivery
- Improve citizens' quality of life

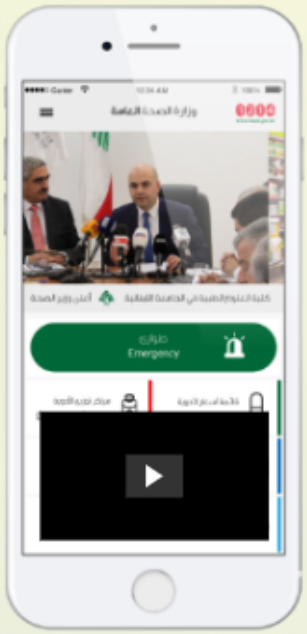
Benefits

- 24/7 hours service
- Services available anywhere
- Reduce travel and waiting time
- Less expensive
- Protect the environment

- **100 Online Services** available on **www.moph.gov.lb/Eservices** and on **EHealth Lebanon** MObile APP. (very soon)
- Application form is filled online
- Requested documents are scanned and attached to the application
- Citizen is notified whether his application was registered or failed to pass any validation.
- Tracking documents is available
- Citizen is notified when transaction is completed to pickup

Emergency Response Mobile Platform

The New Hospitals Section (Emergency)



The user will be able to check the Public/Private hospitals:

* Listed per Regions (Mohafaza) OR * Listed by nearest

Available

Not Available

On call

"Ballegh LaSohha"

تتفاوت الألون تدريجيا" كما يلي :

- نسبة الشكاوى أقل من ١٠%
- نسبة الشكاوى ما بين ١٠% و ٢٠%
- نسبة الشكاوى أكثر من ٢٠%

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"Ballegh LaSohha"

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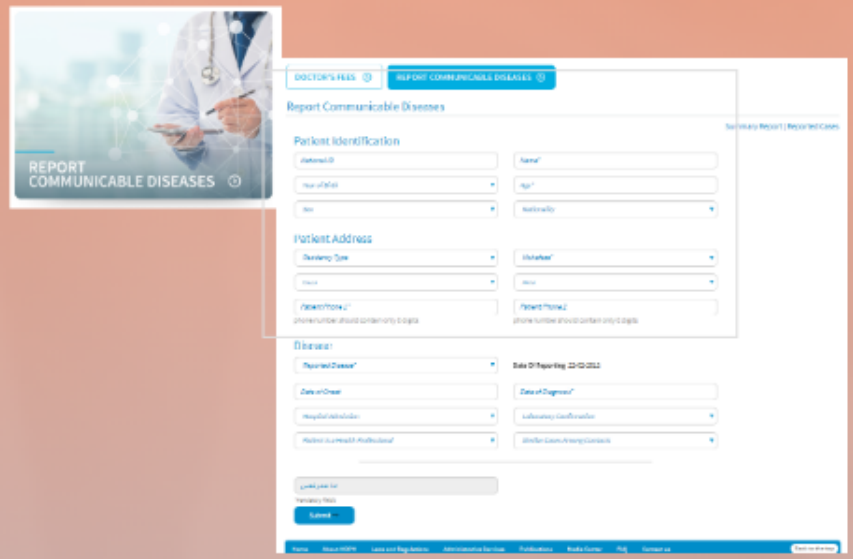
Electronic Reporting of Communicable Disease www.moph.gov.lb



DOCTOR'S FEES

REPORT COMMUNICABLE DISEASES

Report Communicable Diseases

Sur

Patient Identification

National ID

Name*

Year of Birth

Age*

Sex

Nationality

Patient Address

Residency Type

Mohafaza*

Caza

Area

Patient Phone 1*

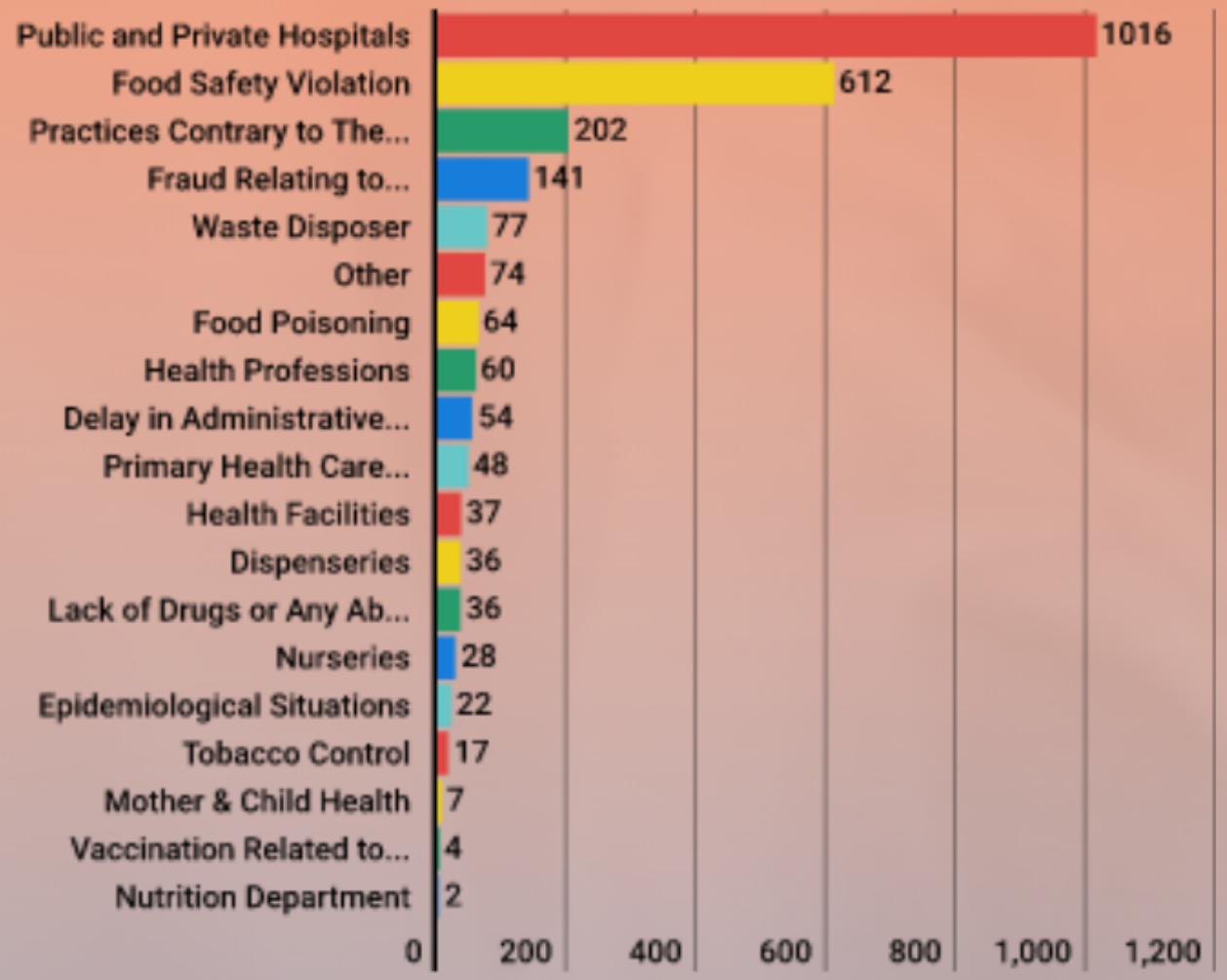
phone number should contain only 8 digits

Patient Phone 2

phone number should contain only 8 digits

1214
www.moph.gov.lb

Total 2537

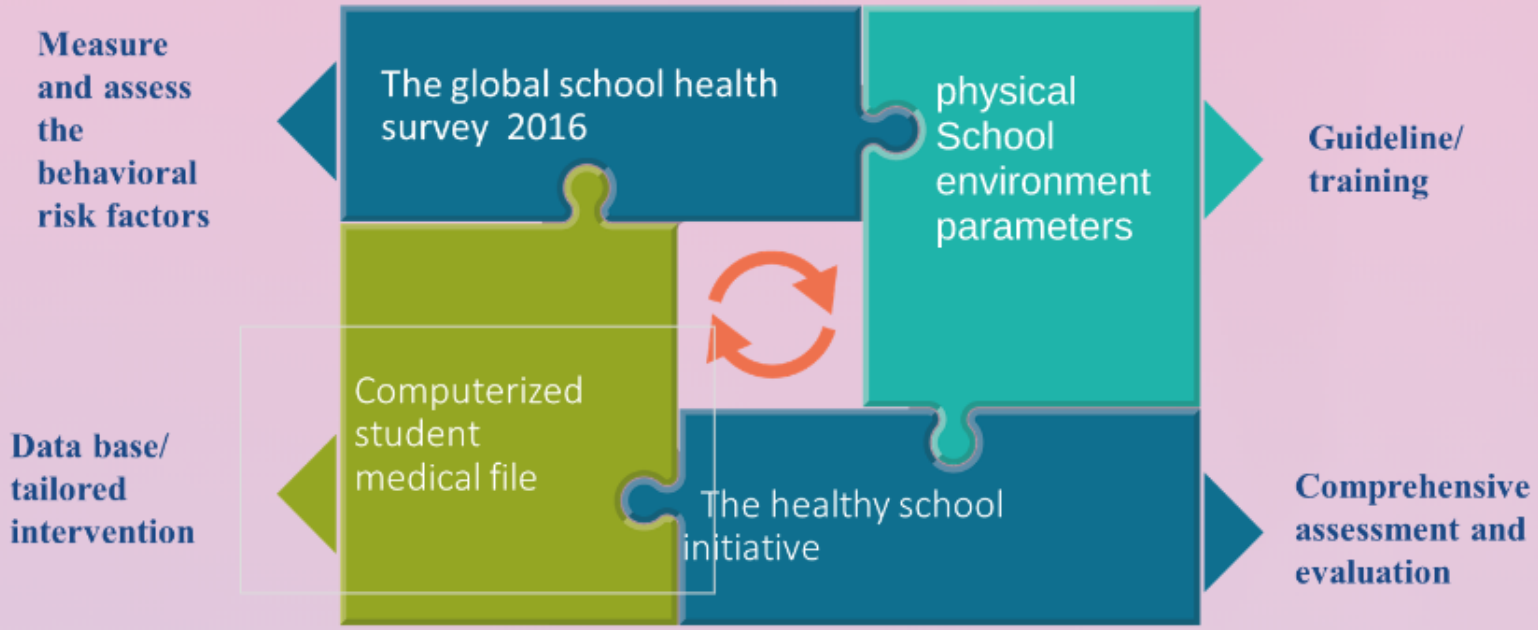


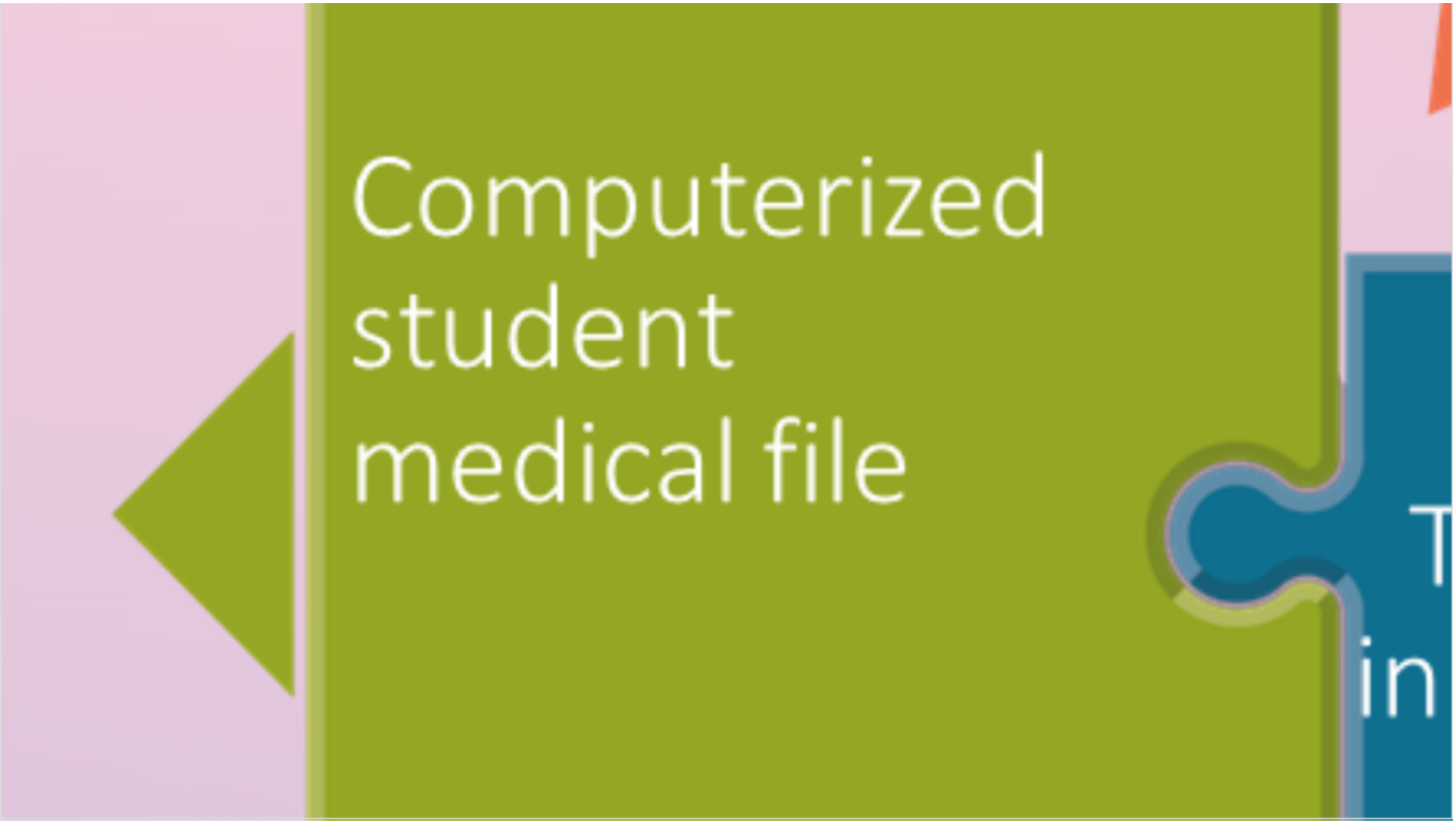
Total 2537

MoPH School Health Program

MoPH School Health Program

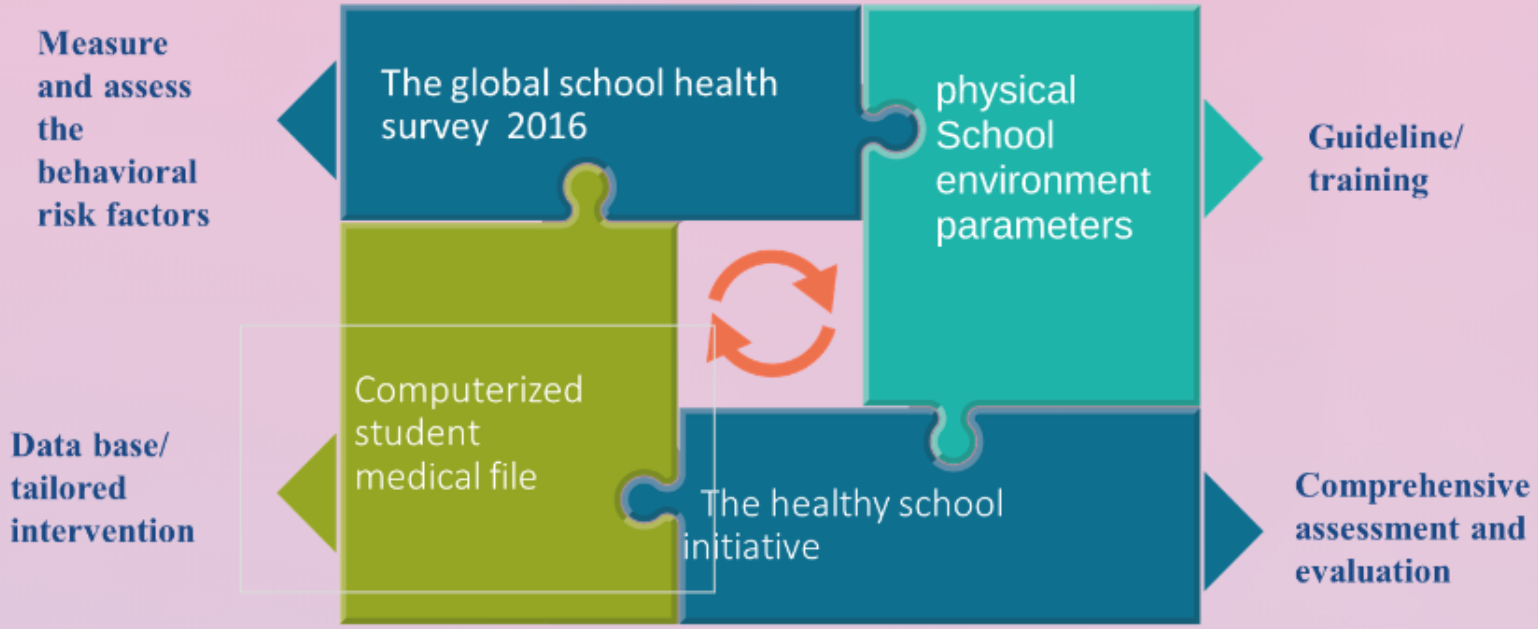
Activities




Computerized
student
medical file
T
in

MoPH School Health Program

Activities



Process of the computerized student medical file

MoPH

- Create the school account

School

- Create the students file
- Fill the medical file

MoPH

- Analyze the data and the indicators
- Tailor interventions based on the main issues

Dr. Fadia Elias

Hematologist - Oncologist
Director Cancer Control - MOPH
Head Hemato-Oncology drugs scientific committee
Approving member National Cancer Treatment Guidelines

National Treatment Protocols

National Treatment protocols

original report

Cost of Oncology Drugs in the Middle-Eastern Country of Lebanon: An Update (2014-2016)

abstract

Purpose This study aims to evaluate trends in the increasing costs of oncology drugs procured by the Lebanese Ministry of Public Health (MOPH) between 2014 and 2016 and to assess the impact of the introduction in mid-2015 of new immunotherapy drugs for the treatment of lung cancer on the overall and specific costs of that treatment.

Methods A secondary analysis of data from the MOPH Cancer Drug Scientific Committee data base was conducted using a total of 18,133 cancer files between 2014 and 2016.

Results Over the 3-year period, about $140 million (USD) was spent on cancer drugs by the MOPH free cancer drug dispensing program. The expenditures increased by 27% after immunotherapy was phased in. The average cost of drugs per patient per year measured across all cancer types increased from $7,000 in 2014 to $8,400 in 2016. Trastuzumab, approved for treating human epidermal growth factor receptor 2–positive breast cancer ranked first in total expenditures for 2014-2015. By 2016, two new immunotherapy drugs had topped the list: pembrolizumab ranked first and nivolumab ranked third, representing 64% of the total cost of lung cancer treatment and approximately 19% of the total yearly budget; beneficiaries represented only 3% of all patients.

Conclusion This update documents the increasing financial impact of newer cancer drugs on the procurement process in the middle-income country of Lebanon. The trend is aligned with the financial burden of cancer drugs worldwide, which calls for a collaborative global response to this crisis.

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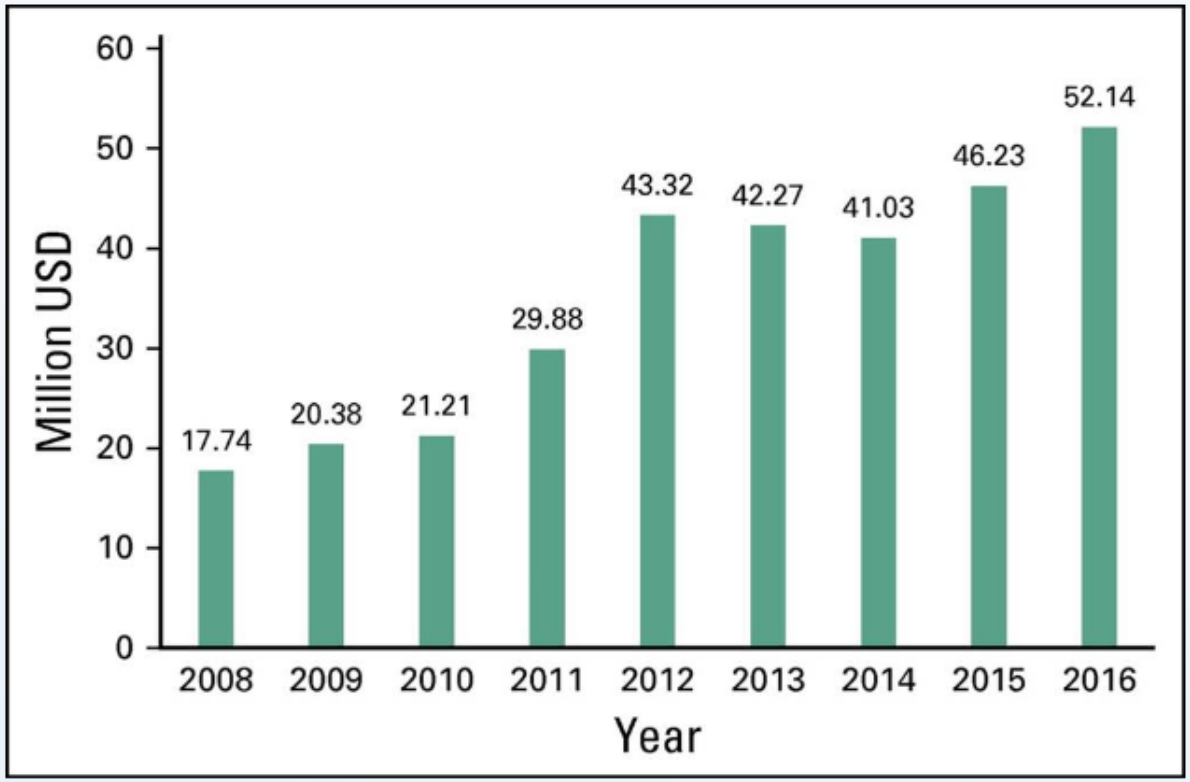
Fadia Elias [.....] Walid Ammar

Cost of cancer drugs procured by the Lebanese Ministry of Public Health from 2008 to 2016.



Elias F et al. JGO.17.00179
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Strategies to Decrease Cancer Treatment Cost

- Cancer Drug Committee (National Cancer Treatment Guideline)
- Exporting price comparison
- Drug price bargaining

Regulating Research to protect rights and to attract investments
Clinical Trials Regulations in Lebanon
MoPH & WHO Team
Clinical Trials Regulations in Lebanon
The First Clinical Trial Registry in the Arab World
The First Clinical Trial Registry in the Arab World

Quintiles IMS : Investor Survey on Pharmaceutical Sector Competitiveness of Lebanon-2017: Clinical Environment

- The hospitals possess capabilities to carry out Clinical Trials (CT)
- Compliant to global clinical standards & procedures
- Committed to participate in cutting-edge research
- Cost of conducting CT is cheaper compared to developed countries
- MoH Regulations is a must

Rasha Hamra Ambriss

PharmD, MPH, Dr. Health Candidate
Focal Point for Clinical Trials Regulations
Ministry of Public Health

Clinical Trials Regulations in Lebanon

Ghassan Karam

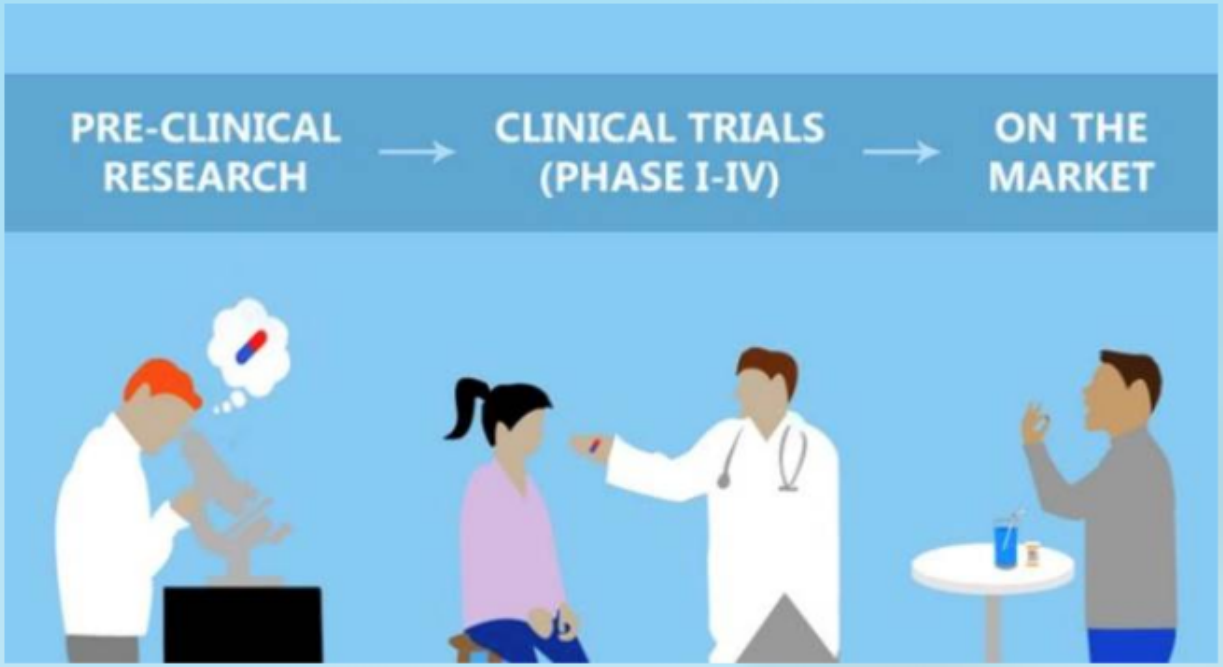
ICTRP Project Manager WHO, Geneva

Announcing the First Clinical Trial Registry in the Arab World- 2 steps away from joining international platform

Clinical Trials Regulations in Lebanon

New Regulations by Ministry of Health?

Why Do we Need to Regulate Clinical Trials?



Historical Cases of Unethical Research Contributed to how CT are Regulated Today

Why Do we Need to Regulate Clinical Trials?

- Rights, Safety, Wellbeing, & Benefits of Patients/ Participants
- Standardizing Regulatory Process
- Transparency of Information
- No Administrative Burden

Regulations in Lebanon

- Only regulation in 1996; limit clinical trials (CT) to teaching hospitals
- In 2014, set Requirements for CT requiring Importation of Investigational Drug; more than 250 CT registered
- In 2016, set Requirements to authorize IRBs; only 23 (Hospitals/ Universities) authorized
- In 2017, Joint project with WHO-EMRO office to develop CT Registry Software
- To Register ALL CT to be conducted in Lebanon; for better control
- Launching June 2018

Why Important to Lebanon?

- Shifting Research to Developing Countries; 84% of World's Population in Developing Countries
- Average cost of CT across all therapeutic areas in USA 30-40Million $
- In Lebanon: Cheaper, High Profile Professionals, Advanced Clinical Settings, etc..
- Rare Diseases: Thalassemia, Hemophilia, Sickle Cell Anemia, …

- WHO launched International CT Registry Platform in 2005
- Now it includes 17 countries, but none are from Arab World
- Since 2014, Lebanese MOH has been working with ICTRP Secretariat to create a national registry of clinical trials and to be part of ICTRP network of primary registries
- This work is almost finalized with collaboration of WHO Lebanon office and the WHO EMRO office
- More details about the work done so far and what the next steps are

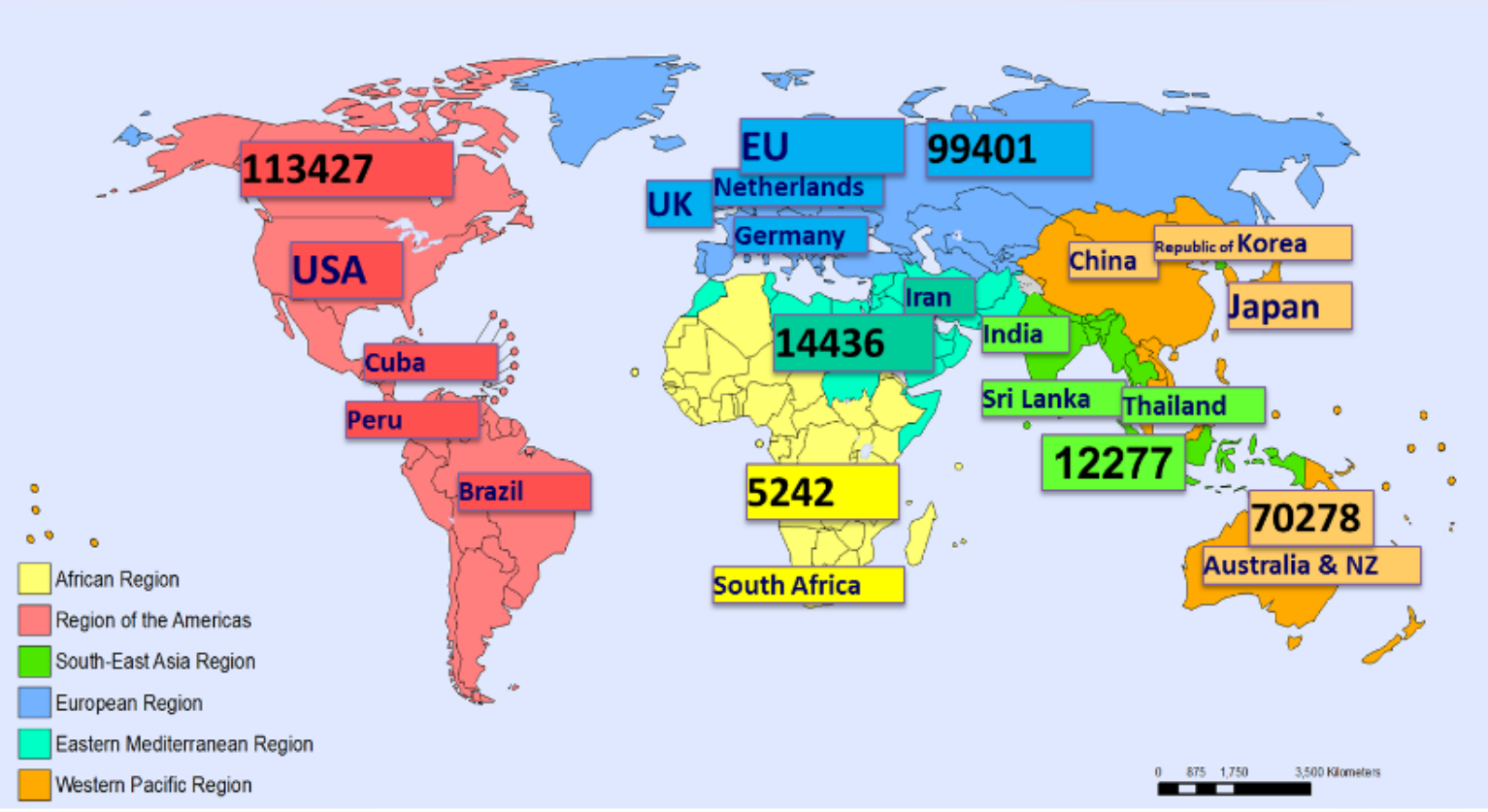
The First Clinical Trial Registry in the Arab World

2 steps away from joining international platform

The International Clinical Trials Registry Platform (ICTRP)
WHAT ? WHY? WHERE? WHO

- All clinical trials involving human beings publicly available
- Increased Research Spending + Improved Health.
- 17 countries - 485000 records of clinical trials
- Patients, Researchers and Policy makers

ICTRP Registry Network of Countries



Statistics from ICTRP – EMRO/LB

Countries: Afghanistan, Bahrain, Djibouti, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, Yemen

Country	Trials
Iran	17485
Egypt	3421
Saudi Arabia	846
Lebanon	**625**
Pakistan	610
Other	1852

Total Region 24839

Total World 485000

Lebanon 625

38% Recruiting patients
88% Interventional studies
62% Sponsored by pharma
14% Sponsored by AUB
18% Cancer related
5% Children related

Process for Lebanon to become a WHO Primary Registry

- Regulated Ethics Review & Clinical Trials √
- Establish a national registry - LBCTR √
  - Submit complete application to WHO & get reviewed by advisory panel
  - Get accredited and become the first WHO registry in the Arab countries and second in Region after Iran

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REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
500 Days Journey
Financial Burden of Drugs
Regulating Research
Universal Health Coverage
E-Health
Food Safety
Role of Media
Hospital Cost Containment
Health Security
Future HEALTH