

Study on the legal and organizational frameworks for delivery of healthcare services on distance

Country Report: **Israel**, Dr. Rachele Kaye , Assuta Medical Centers

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1

1. Context - Israel

Capital	Jerusalem
Size	20,770 square kilometers
Population	9,518,500
Population Density	431.25 inhabitants/km2
Life expectancy	83.8 years
Fertility Rate	3.01 births per woman
Age distribution	median age - 30.5 years, 65+ - 12.6%

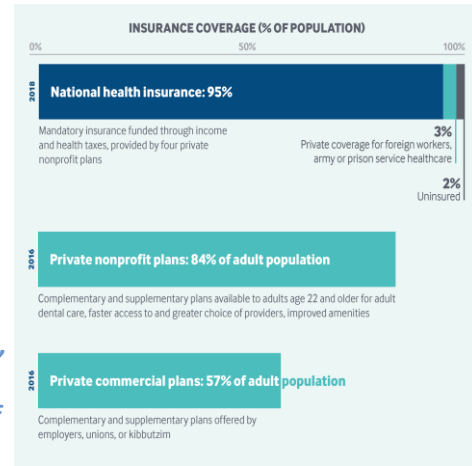
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2

1. Context – Israeli healthcare System

- *Universal compulsory statutory health insurance for all citizens*
- *Financed by earmarked and general taxation*
- *Coverage for health care services is provided by 4 competing nationwide health plans (HMOs): Clalit, Maccabi, Meuhedet and Leumit. Health Plans are Insurers, Managers and Providers*
- *Every citizen must join a health plan but is free to choose and move from one to another*
- *Public and private providers of services including physicians, hospitals, pharmacies and other health care professionals*
- *Health Plans must provide a legally defined public basket of services to all their members (which is updated annually)*
- *Voluntary supplemental insurance supplements basket*



3

Context - Israel Healthcare System

- *Both primary care doctors (GPs) and specialists work in community clinics, either solo or group practices,*
- *The majority of doctors (both GPs and specialists) are independent with contracts with the Health Plans. (except for Clalit - mostly salaried employees)*
- *The GP is not a gatekeeper, although access to some subspecialties requires a GP referral (policies differ among Health Plans)*
- *All of the Health Plans have contracts with all of the public hospitals. Payment to the hospital by the Health Plan requires Health Plan authorization (either pre for elective or post for non-elective)*



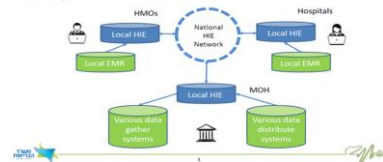
4

2. Organizational Framework for Telemedicine

- **The digital health system in Israel is decentralized**
 - Each Health Plan and Hospital has its own eHealth system
 - ePrescription is via the EMR and patient portal – including pharmacy – totally paperless
 - National Health Information Exchange for sharing EMR data across organizations
 - Patient Portals – access to medical data and “virtual visits” in the Health Plans
 - Mobile Access to EHR for both clinicians and citizens in most Health Plans
 - Telemedicine for diagnosis (e.g. tele-imaging) and treatment (e.g. tele-dermatology, videoconferencing) in all Health Plans
 - Teleconsultations with specialists in Hospitals is encouraged

The Concept – High Level Architecture

- No central repository
- Information is transmitted from the local EMR to local servers in a standard format.
- The information is collected on demand from all the local servers and displayed centralized to the staff at the point of care.



Telemedicine – Examples from a Health Plan

- **Telediagnosis**
 - Tele-radiology
 - Tele- EKG interpretation
 - Tele-dermatology– diagnosis + treatment :
 - Diabetic ulcers – video conference
 - Other skin conditions- mobile
- **Teleconsultation**
 - Virtual Consultation among doctors
 - Teleconsultation for patients
- **Call centers:**
 - Nurse Triage
 - Smoking Cessation



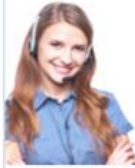
Telemedicine Services for Maccabi Members

Chat with a doctor



K app: Enter symptoms and you can continue chatting with a doctor. **Chat Hours : 7pm to**

Make a phone call



Schedule a phone call from the Maccabi app or from Maccabi online - how to make an appointment

Requests from the doctor



Contact your doctor through a digital visit service. **The service runs 24/7**

Maintaining mental health



Hot line for emotional response, professional advice from psychiatrists :

Women's medicine and pregnancy



Remote service set for pregnant women and any other female problem: call center, tracking

Call center nurses



A call center that provides information, counseling and guidance services on medical issues



7

Telemedicine Services for Maccabi Members

Maccabi app



Quick and easy access to your medical record and your children anytime, anywhere

Video visit



Video call with a doctor or therapist using a personal computer or smartphone. **During doctors' Regular hours**

Children's center Maccabi Kids



Call center for pediatrics questions, **runs from 7:00 pm until 7:00 am**

Back Maccabi - Physical Therapy



Professional telephone counseling for low back pain, without the need to refer a doctor or visit a clinic

Talk to the pediatrician



Is the child not feeling well and the clinic is closed? Consult your pediatrician over the phone,

Ordering prescription drugs



Unique service for Maccabi members at Super Pharm: ordering prescription drugs



8

3. Legislation and regulation for telemedicine

- *Telemedicine has been practiced by Israeli healthcare providers since the 1990s, through various technological means and devices*
- *The only regulation today governing Telemedicine is General Director Circular No. 6/2019 on Standards for Provision of Telemedicine Services dated June 26, 2019 that defines guidelines specifically regulating the provision of telemedicine services*
- *It has been supplemented in September 2019 by Standards for Telemedicine in Hospitals*

The Israeli Ministry of Health Digital Health Strategy- 2017, Key enactments for creating a digital health support policy

- *Regulation for the use of health data (goals, manner of use, users, transparency).*
- *Regulation for the use of remote medical care (the manner in which the service is provided and service provider obligations).*
- *Regulation for the access of personal electronic health record files by patients.*
- *Regulation for determining the minimum content of the electronic health records.*
- *Regulation applying on outcome measures of health data, which collect and monitor health data.*
- *Regulation for the development and maintenance processes of clinical information systems.*
- *Regulation for aspects of cyber protection of data.*

Regulation for Digital Health

The following general regulations apply to healthcare in general as well to digital health:

- *National Health Insurance Law, 5754-1994.*
- *Public Health Ordinance, 1940.*
- *Public Health Regulations (Clinical Trials in Human Subjects), 5741-1980.*
- *Patient's Rights Law, 5756-1996.*
- *Public Health Ordinance (Food) (New Version), 5743-1983.*
- *Protection of Privacy Law, 5741-1981*
and Protection of Privacy Regulations (Data Security), 5777-2017.
- *Class Actions Law, 5766-2006.*

Regulations for Digital health

The General Director ("GD") of the MOH has published a number of circulars referring specifically to digital health, as listed below:

- GD Circular, dated 17 January 2018, regarding secondary uses of health data.
- GD Circular, dated 17 January 2018, regarding collaborations based on secondary uses of health data.
- GD Circular, dated 11 November 2019, regarding patient access to personal health data: "Healthcare under your Control."

The health data circulars currently prescribe the extent of protection over health data.

In general, unless otherwise specified by law or approved by an explicit opt-in, any data for secondary use will be de-identified.

Furthermore, any secondary use of health data for research purposes must be pre-approved by the Helsinki Committee (Ethics Committee)

Main Directives of General Director Circular on Telemedicine

Prior to the Service, the provider (Health Plan/Hospital) shall prepare a dossier with:

- i. A description of the Service and its compatibility with technological devices;
- ii. Mapping of existing alternatives for the Service through ambulatory treatment or hospitalization, and the pros, cons and risks of the Service;
- iii. The Digital means used and the data security safeguards;
- iv. Safety rules, specifically with respect to identification of cases where the patient is in need for urgent frontal treatment;
- v. Identification of the professional manager in charge of the Service

Main Directives of General Director Circular No. 6/2019

- *The Ministry of Health may demand the dossier for review;*
- *The Manager should be a licensed professional having the same certification as the personnel employed in providing the Service;*
- *The providers shall undergo dedicated training in telemedicine;*
- *If the patient is using the service abroad, the treatment shall be conducted by personnel having Israeli certification, if such treatment is part of a broader treatment performed in Israel*
- *Enforcement of the Circular is carried out by the Ministry of Health by the existing regulation, not specific for remote services*

Eligibility of Patients to Receive Telemedicine Services

- *All Patients are eligible to receive telemedicine*
- *It is the responsibility of the healthcare professional providing the service to assure that the telemedicine encounter is sufficient and that a frontal encounter is not required*
- *The healthcare professional must follow up the teleconsultation with whatever follow up services are required such as prescriptions, referrals, etc*
- *These are all readily available remotely in the existing EMR/Patient portal systems in all of the Health Plans*

Medical Record management

- *The management of the record will be carried out according to law.*
- *The patient must be given a written summary of the session performed, referrals for further treatment, prescriptions and approvals, in accordance with the standard in the field of treatment and in accordance with the manner of transfer agreed with him.*
- *Referrals to the ER will be sent to the patient and in addition directly to the ER, to which the patient is expected to arrive, in accordance with the agreement with him. The urgency must be recorded in the record.*

Liability of Healthcare Providers in Providing Telemedicine Services

- *There is no specific legislation on digital health; hence, general tort law applies. This includes, primarily, the tort of negligence and the regime of strict (no fault) liability under the Defective Products Liability Law, 5740-1980.*
- *Professional and legal responsibility for the actions of the service providers in the framework of remote health services is identical to professional and legal responsibility in the provision of health services.*
- *Use of the service from abroad as part of the treatment of the patient in Israel will be provided by therapists with an Israeli license, who meet the requirements of this circular.*

Reimbursement for Telemedicine

- *Health Plans do not receive any financial incentive from the government to provide remote care above and beyond their regular budget*
- *Health Plans determine reimbursement for all activities of healthcare professionals.*
- *In most Health Plans, fees for providing telemedicine services is identical with fees for face- to- face visits*
- *Any encounter through the Patient portal with a professional, even if it is only an electronic prescription, is reimbursed.*

4. Ethical guidelines Patient consent to be treated with telemedicine

- *The healthcare provider shall obtain informed consent of the patient to be treated prior to commencing the tele-encounter*
- *The management of the provider is required to determine whether Services meet appropriate standards of quality and safety and in which cases a frontal treatment would be mandatory;*
- *The therapist's responsibility in telemedicine services is completely identical to that performing frontal treatment.*
- *The healthcare provider is required to have in place appropriate data security measures and ensure regular performance of oversight and control mechanisms*

Special Regulation for Telemedicine Services in Hospitals

Hospitals may offer remote health services under the following conditions:

- The waiting time for the service will not be longer than the waiting time for physical service.
- The hospital will make sure that there is a written summary of the virtual visit that will be transferred to the HMO.
- If, during the visit, the therapist concluded that a face-to-face meeting is needed, an appointment will be made for a physical visit in as short a period of time as possible such that the total waiting time (virtual visit + physical visit) will not exceed the waiting time of an average visit at the relevant clinic in the same hospital.
- Hospitals may charge the HMO – pre-authorization is required

5. Challenges to date

- *There was a significant increase in the use of teleconsultation during the first pandemic lockdown, but a significant return to face-to-face thereafter.*
- *There is no single national platform for telemedicine - every health plan and hospital has its own. The MOH plans a platform for smaller providers to use*
- *While platforms were developed specifically for Corona that doctors could use from their EMR, doctors overwhelmingly preferred to talk to their patients on the phone rather than videoconference*
- *Telemonitoring was largely focused on corona – related symptoms, but has started to expand to patients suffering from chronic disease*
- *There has been an increase in the use of instant messaging such as WhatsApp - but there is no automatic documentation in the EMR and no research has been done to assess the volume of this phenomenon*
- *The Ministry of Health is in the process of developing updated regulations for telemedicine*

THANK YOU