Norwegian Institute of Public Health | **eRegistries**
interactive information for health

Governance Guidance for eRegistries: Lessons from Palestine

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'Fundamental to any large clinical registry is its ability to function within the parameters laid out by the legal framework governing it. Issues that fall under this umbrella include data privacy and protection, ethical use of data and intellectual property right.'[1]

[1]Hickey GL, Grant SW, Cosgriff R, et al. Clinical registries: governance, management, analysis and applications. European Journal of Cardio-thoracic surgery: Official journal of the European Association for Cardio-thoracic Surgery 2013; 44(4): 605-14

BACKGROUND

- **The eRegistry for maternal and child health** is an electronic, organized system for the collection, storage, retrieval, analysis, and dissemination of information on health determinants and outcomes for individuals with the purpose to serve health care provision, public health surveillance, and research.

- Given the ***highly sensitive nature of reproductive health data***, a critical first step is to ensure that a protective legal umbrella and framework is in place. An important **balance** must be achieved that maximizes the value of registry data while protecting patients' privacy and confidentiality.

WHY IS THIS IMPORTANT?

- **Personal health information** contains highly sensitive information thus unintended or deliberate disclosure may result in **social stigma, embarrassment, discrimination** or worse.

- **Security breaches** may involve unintentional disclosures, internal privacy breaches, intentional hacking, or **medical identify theft** – currently, the fastest-growing type of identity theft.

- **Privacy breaches** involving registry data could compromise individuals' privacy and the overall integrity of the registry.

STUDY OBJECTIVES

- A primary objective of this study was to map the current **legal, regulatory, and ethical landscape** in Palestine.

- Understanding the existing legal and regulatory structures ensures that a registry is developed, governed, and used in an **ethical and lawful manner** with respect to **individual rights, privacy, research and medical ethics.**

- Ensuring that a robust governance structure is in place and that legislation is adhered to is a core pillar of the **eRegistry for maternal and child health's strategy.**

METHODS

Data collection instrument: An exploratory Situation Analysis Tool (SAT) was created and designed for the eRegistries framework to assess the legal, regulatory, and ethical landscape in Palestine

Country adaptation: The SAT was customized to fit the Palestinian legal and medical context

Data collection methods: The Palestinian National Institute of Public Health completed the SAT and conducted workshops with relevant stakeholders

Timeframe: November, 2013

Location: Ramallah, Palestine

Administrator: Palestinian National Institute of Public Health

Participants: Legal experts, Ministry of Health Legal Affairs department, PNIPH staff, stakeholders

RESULTS

FOCAL TOPIC	EXAMPLE QUESTIONS	PALESTINE RESULTS	ASSESSMENT
HEALTH REGISTRIES	Do you have registries that collect data on: • Vital statistics, i.e., births, deaths? • Public health registries? • Maternal health registries? • Reproductive health purposes?	✓ Birth, death registry ✓ Some ✓ Maternal and child health ✓ No	**Few existing public health registries**
LEGISLATION	Do you have specific legislation that applies to: • Birth registration? • Health registries? (i.e., maternal, etc.) • Data protection or privacy legislation? • Special guidelines in lieu of legislation? • Other guidelines?	✓ Birth registration law ✓ No ✓ No ✓ No ✓ WHO and UNICEF guidelines	**Virtually no legislation Limited guidelines**
GOVERNANCE	How are registries governed? • Manager, staff? • Advisory board? • Ministry of Health advisory role? • External experts? • Public engagement?	✓ Available at different levels ✓ Palestinian Health Information Center (PHIC) ✓ Thematic group consisting of several agencies ✓ Via thematic group ✓ Limited	**Some governance in place**
ACCOUNTABILITY	Is regular reporting required to: • Advisory or Management board? • Ministry of Health? • Data Protection Authority? • Available to general public?	✓ Different reporting protocols ✓ Yes ✓ No ✓ Yes, on website	**Limited accountability**
DATA SECURITY	Are the following principles of data collection legislation: • Limited to public health purpose? • Data collection for registries is mandatory? • Data privacy via security safeguards? • Access to premises, equipment, records is restricted? • Data collection policies and practices ensure confidentiality	✓ Not specified ✓ Yes ✓ No but USAID 'Privacy Manual' under consideration ✓ Yes ✓ No formal manuals, limited policies	**Weak data security**
RESEARCH OVERSIGHT	Do health registries have: • Publicly available data for researchers? • Data access protocols for researchers? • Personally identifiable data requires permission and controls? • Ethical Approval board?	✓ Partially available on the Ministry website ✓ Only available on adhoc basis ✓ Yes ✓ Yes - Helsinki Committee for Ethical Approval in Gaza	**Some oversight mechanisms**
ETHICAL IMPLICATIONS	Ethical and societal challenges may include: • General public confidence? • General attitude towards health registries? • Concern about privacy of personal health data?	✓ General confidence despite political instability ✓ Not available ✓ Not sure	**Unclear**

CONCLUSION

Findings gathered using the SAT pinpoint specific areas within Palestine's legal and regulatory framework that can be strengthened and improved, namely:

■ Currently, no laws address data privacy or health registry data. Existing governance bodies may facilitate the eRegistry and should be strengthened.

■ Data security policies and protocols should be institutionalized. Minimal reporting requirements suggest that accountability can be improved.

■ Research oversight mechanisms are currently in place. Public engagement and political instability should be carefully considered.

NEXT STEPS

- As part of the eRegistries framework, a ***Governance Guidance Toolkit*** was created that provides concrete steps to ensure robust governance structures that safeguard data privacy and confidentiality.

- The ***Toolkit*** includes protocols, policies, and best practices that emulate principles found in data privacy and security legislation (www.fhi.no/hrhr).