

Legal, Privacy and Security Framework for eHealth Record (eHR)



**eHealth Record Office
Food and Health Bureau**



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Background

- First Stage Public Consultation on Healthcare Reform (2008):
General public support for developing eHR Sharing
- Funding approved by Finance Committee (2009):
HK\$ 702M for implementing 1st stage of eHR Programme
- Working Group on Legal Privacy and Security Issues:
To engage stakeholders and relevant parties, including the Office of the Privacy Commissioner for Personal Data (PCPD), patients' groups, healthcare providers, etc. in formulating the Framework

Benefits of eHR sharing

- **For Clinicians**
 - ✓ Improved availability and transparency of information shared between the public and private sectors
 - ✓ Efficient clinical practice
 - ✓ Efficiency gains by avoiding the need to store, collate and transfer paper records
- **For Patients**
 - ✓ Reduced medication errors
 - ✓ More efficient and effective use of diagnostic tests
 - ✓ Timely treatment
 - ✓ Improved accuracy of diagnosis and disease management
- **For Healthcare System**
 - ✓ More efficient and better quality healthcare
 - ✓ Better disease surveillance
 - ✓ Support public health policy making

Development Progress

- Pilot projects to allow patients and healthcare providers to experience eHR sharing
- Formulation of the blueprint for the eHR Core Sharing Infrastructure and the Clinical Management System Extension Components
- eHR Standardisation
- eHR Engagement Initiative and Partnership Projects with Professional Bodies
- Promotion and publicity

Need for an eHR-specific legislation

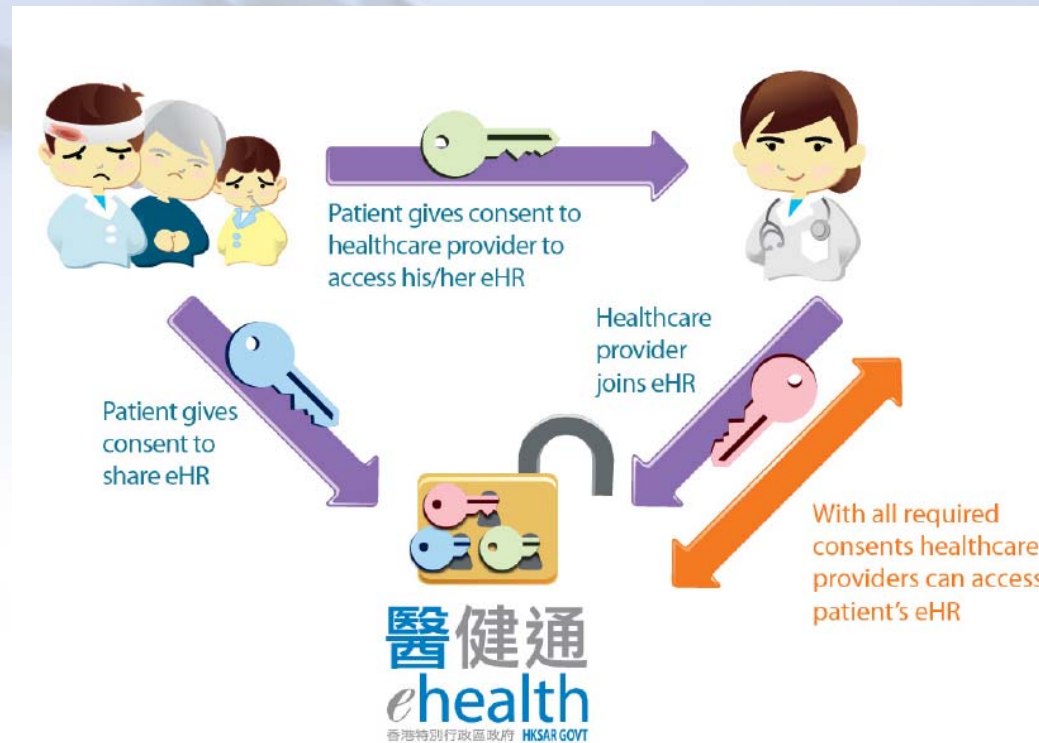
- Personal Data (Privacy) Ordinance (PDPO) (Cap. 486) - general safeguards for personal data privacy
- Overseas -
 - Canada and Denmark have health information specific legislation
 - Australia introduced a new eHR-specific Bill in late 2011 after public consultation
- eHR Sharing – unique functions of the System, speedy transmission of sensitive health data

Key Concepts and Principles

- Voluntary participation
- “Patient-under-care” and “need-to-know”
- Pre-defined scope
- Identification and authentication of patients, healthcare providers and professionals
- Government-led
- Patient privacy and needs of healthcare providers
- Versatile and technology neutral

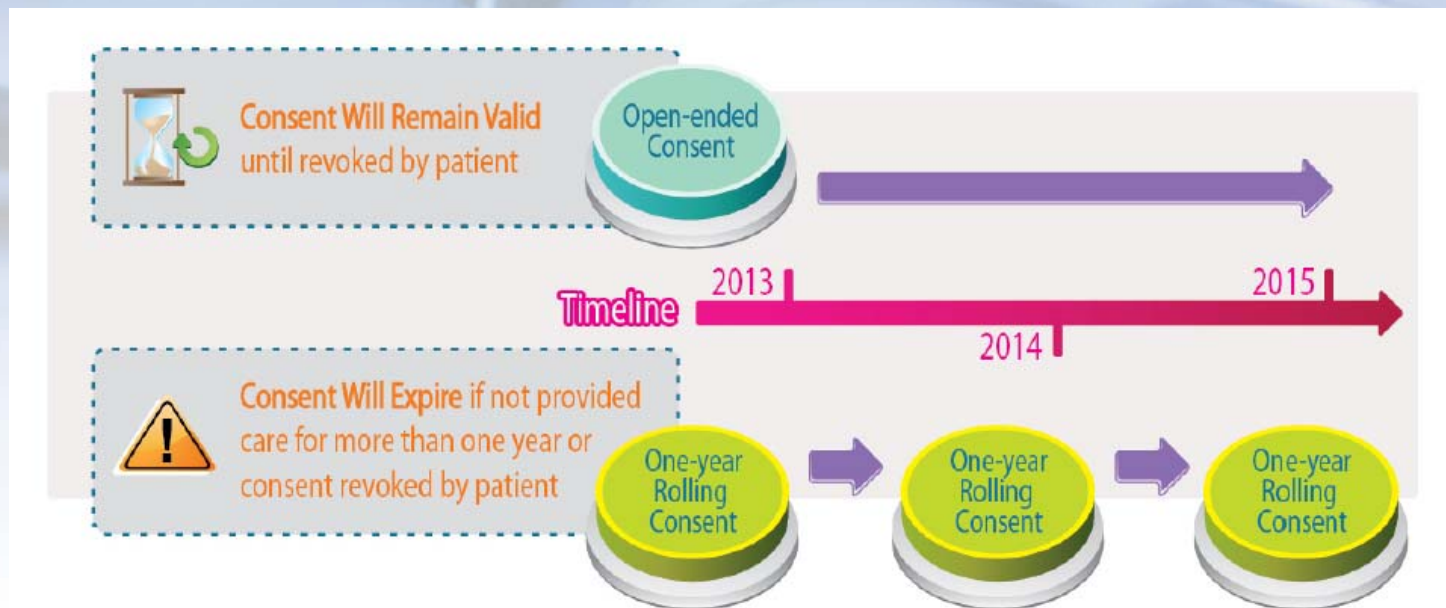
Basic model of eHR Sharing

- Patient
 - Express and informed consent
 - Patient information notice, consent form
- Healthcare provider
 - Patient-under-care and need-to-know
 - User agreement



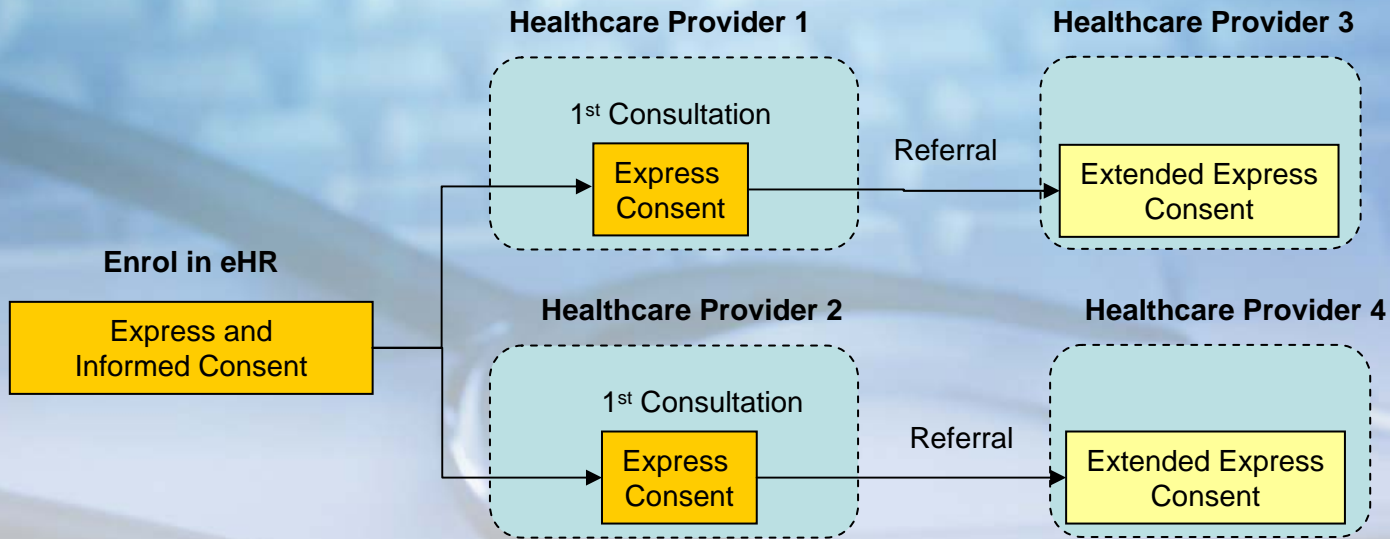
Patient's consent

- eHR Sharing System Operating Body (eHR-OB)
 - Consent to Hospital Authority and Department of Health is part and parcel of patient's participation
- Individual healthcare providers
 - Open-ended until revocation or 1-year rolling

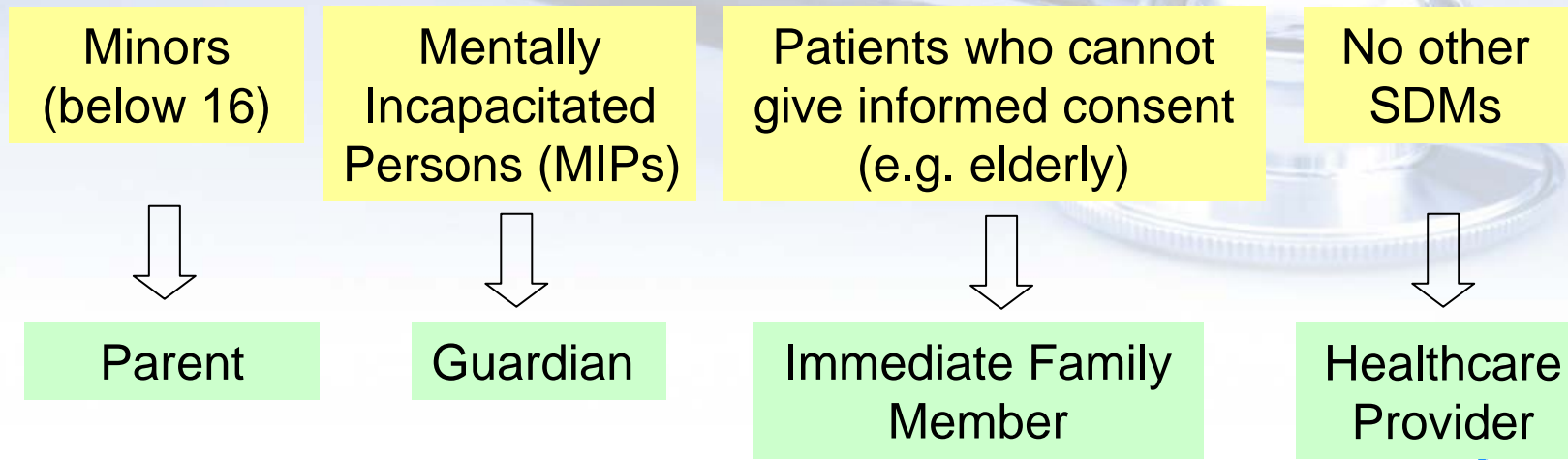


- Referral
 - In line with existing practice

Patient's consent



- Substitute decision makers (SDMs)



Minors

- **Interpretation and General Clauses Ordinance (Cap.1):** A person who has not attained the age of **18**
- **Parent and Child Ordinance (Cap.429):** The consent of a minor who has attained the age of **16** years to the taking from himself of a bodily sample shall be as effective as it would be if he were of full age
- **Overseas Reference:** The age for granting effective consent in Australia, Ontario (Canada) and the United Kingdom ranges from **14** to **16**
- **Gillick Test:** Applied in cases where a minor intends to give consent in the absence of an SDM, or is in dispute with his/her SDM on sharing of his/her eHR

Exemptions

- for emergency access in line with S.59 of PDPO

Withdrawal/Expiry of Consent

“Frozen” eHR

- not be available for access
- remain in the System for a specified period before de-identification
 - **Withdrawn Patients’ eHR:** three years
 - **Deceased Patients’ eHR:** 10 years

eHR Sharable Scope

- (i) Only data necessary and beneficial for the continuity of healthcare
- (ii) No safe deposit box / exclusion

<i>Phase 1</i>		<i>Later phases</i>
Person demographics	Procedures	Assessment / physical exam
Referrals	Medication	Social history
Episode summary	Immunisation	Past medical history
Adverse reactions / allergies	Encounters	Family history
Problems	Radiology results	Clinical request
Laboratory results		Care and treatment plan

Use of eHR data

- **Primary use**
Enhance the continuity of care for patient
- **Secondary use**
Public health research and disease surveillance
 - non-patient identifiable data:
approved by eHR-OB
 - patient-identifiable data :
approved by the Secretary of Food and Health
on recommendation by a research board

Data Access and Correction

- eHR-OB will comply with Data Access Request / Correction Request by
 - subject patients
 - parents of minors, and
 - guardians of MIPs
- Data Correction
 - either by healthcare provider on his own initiative or on request (with track and trace)
- Editing Person Master Index
 - patient's consent is required

Complaint and review

- With reference to PDPO and overseas experience, we will formulate a mechanism to initiate review and resolve complaints arising from eHR sharing under the Framework

Sanctions

- Existing legislation which criminalises unauthorised access to, and dishonest use of computer systems includes:
 - Telecommunications Ordinance (Cap.106, S.27) (\$20,000 fine)
 - Crimes Ordinance (Cap.200, S.161) (5-year imprisonment)
- New criminal offences
- Innocent errors in inputting eHR data or other unintentional contraventions in the delivery of healthcare will not be criminalised
- Civil remedies under PDPO

Security, Certification and Audit

- Code of Practice and guidelines
- Security audits on
 - (a) electronic medical/patient record systems;
 - (b) eHR Sharing System
- Authentication and role-based access control
- Network security mechanisms
- Non-repudiation
- Data validation
- Data encryption
- Restricted downloading
- Access notification
- Access logging
- Privacy and security breaches

Key Milestones

- Public Consultation
(Dec 2011 – Feb 2012)
- Preparation of draft eHR Bill
(2Q 2012 – 3Q 2013)
- Tabling of eHR Bill at LegCo
(4Q 2013)
- Enactment of eHR Bill
(Mid 2014)
- Commencement of eHR Sharing System
(Mid-End 2014)



Thank You