Bills Committee on
Electronic Health Record Sharing System Bill

The Administration's Response to the issues arising from the discussion at the meeting on 14 October 2014

This paper sets out the Administration's response to the issues arising from the discussion of the Bills Committee on the Electronic Health Record Sharing System (eHRSS) Bill on 14 October 2014.

(a) Steering Committee on Electronic Health Record (eHR) Sharing

2. The Steering Committee on eHR Sharing (eHRSC) was set up in July 2007 to provide advice to the Food and Health Bureau on the strategies and work programmes of the development of the eHRSS. The eHRSC is chaired by the Permanent Secretary for Food and Health (Health) and representatives of key stakeholders in the public and private sectors (including Hospital Authority (HA), Department of Health, patient groups, healthcare related professional bodies, and the Office of the Government Chief Information Officer) have been serving on it as members. The eHRSC is underpinned by four specialised working groups and these working groups have further engaged experts in particular sectors or representatives of relevant organizations (such as the Privacy Commissioner for Personal Data and the Consumer Council) as members. The terms of reference and membership list of the eHRSC are at **Annexes A1 and A2** respectively. A chart showing the structure of eHRSC and its working groups is at **Annex A3**.

3. As regards the issue of representation of patient groups, Dr Hon Elizabeth Quat mentioned at the meeting of the Bills Committee on 14 October 2014 some comments from a letter received from the Alliance for Patients Mutual Help Organisations dated 20 May 2014. We subsequently gathered that the letter was a submission to the Legislative Council on the Pharmacy and Poisons (Amendment) Bill 2014. The context is therefore different. In our case of eHR programme, the Alliance (and in fact two other patient groups) is already represented on

the eHRSC to offer their valuable advice and suggestions.

4. We intend to retain essentially the same advisory structure for the eHR programme upon commencement of operation of the eHRSS. We are prepared to review the terms of reference and membership composition of the eHRSC from time to time, having regard to the progress of development of the eHRSS and the changing needs for expertise in taking forward the development of the eHRSS.

(b) Sharable scope of eHRSS

Sharable scope in Stage 1

5. Most healthcare providers (HCPs) will continue to maintain their own medical record systems after the launch of the eHRSS. Not all the health information contained in the HCP's own medical records will be uploaded and shared under the eHRSS. The design of the Stage 1 eHRSS is to only capture those essential data within a pre-defined scope for sharing. We have set out in the public consultation document the proposed scope of data for sharing in Stage 1 eHRSS.

- Personal identification and demographic data
- Adverse reactions and allergies
- Summary of episodes and encounters with HCPs
- Diagnosis, procedures and medication
- Laboratory and radiology results
- Other investigation results
- Clinical note summary
- Birth and immunization records
- Referral between providers

6. In drawing up the sharable scope proposal, we need to not only identify and define the types of health data to be shared, but also determine the formats and standards of such data. The process requires expert advice from the clinical need perspective and has to take into consideration information technology (IT) and data security concerns. Since the inception of the eHR programme, we have been working with

relevant professionals in formulating the sharable scope. We have been mindful not to collect or share patients' data excessively. We have therefore consulted the eHRSC, its working groups and also expert domain groups and made refinements before finalising the scope for Stage 1 sharing. These working groups and domain groups comprise healthcare professionals, representatives of patients groups, IT experts, specialists in particular streams (e.g. Hong Kong Academy of Medicine, Hong Kong College of Pathologists, Hong Kong College of Radiologists, Hong Kong Society of Medical Informatics) and standards bodies (e.g. GS1, HL7 Hong Kong). Reference has also been made to the sharable scope of data used in the pilot Public Private Interface-Electronic Patient Record (PPI-ePR) project[1]. According to the findings of two surveys, the scope in the pilot was found acceptable to both the public and healthcare professionals and not considered excessive. During our public consultation in late 2011 to early 2012, no adverse comment on the proposed sharable scope was received.

7. The information to be included under each type of data within the sharable scope of Stage 1 eHRSS is set out in **Annex B**.

Future expansion of sharable scope

8. The design of the eHRSS has catered for the potential expansion of the sharable scope in future. The sharable scope will be reviewed from time to time. Any proposed change will need to go through the due process of discussion and consultation as mentioned above.

9. The Stage 2 development of eHRSS will be a 5-year programme. Review of the sharable scope will be an on-going process. Depending on the complexity of work involved, expansion or modification of the sharable scope could be pursued at different times during the Stage 2 eHR programme.

[1] PPI-ePR was a pilot project to test the concept of eHR sharing, which started in 2006, for healthcare professionals working in the private sector to access a defined scope of patients' data from the HA's electronic patient records.

(c) Collaboration with the private sector in the future development of Stage 2 eHRSS

10. There are various possible modes of delivery in developing a new eHRSS. The Clinical Management System (CMS) of HA, being the largest scale integrated electronic medical record/electronic patient record (eMR/ePR) system in Hong Kong and probably one of the most successful of its kind in terms of coverage, functionalities and complexity, could well serve as one of the main supporting pillars to the eHRSS. Moreover, the eHRSS is a very special IT system. Its development requires heavy input of clinical expertise not readily possessed by IT vendors in the private sector. Fine technical details, which may appear to be trivial from the IT perspective, may well have material implication on the clinical usability of the eHRSS and impact on patient safety.

11. The HA is largest HCP in Hong Kong and possesses rich experience and expertise in the development and operation of its CMS. The HA is in the best position to serve as the technical agency for the technical development of the eHRSS. The future eHR Commissioner (eHRC) will be responsible for overseeing the operation, security and integrity of the eHRSS as well as to regulate the use and sharing of data contained in the eHRSS. Given the complexity of the project and the large amount of patient data involved, it is prudent for the eHRC to engage a statutory body (HA) to perform the most critical development tasks of the programme.

12. That said, while HA serves as the technical agency in the Stage 1 eHRSS development, a substantial portion of the work, apart from hardware and supplies, has been sourced from the private sector. The implementation of the project has been providing business opportunities for the private sector including small and medium enterprises. As at today, more than half of the eHR Development Programme capital expenditure has been incurred in the areas of purchasing hardware and software, procuring IT operational services (such as network services), hiring contractors and supplementary IT contract staff, and outsourcing certain work assignments to the private IT sector. Moreover, much of the expenditure by the private sector was awarded locally, presenting

opportunities for small and medium enterprises.

13. As regards the clinical management systems used by individual HCPs, the Government's policy is to maintain a level playing field and provide facilitation for all these systems to connect to the eHRSS. In this regard, the Government has developed "CMS Adaptation Modules" and "CMS On-ramp" as low investment options for private HCPs to adopt. An eHR Service Provider Training Scheme is organised to provide training for IT vendors to provide end-user support services to those HCPs for deploying CMS On-ramp. To meet the specific customer needs of individual HCPs, IT vendors may assist them to further enhance and customise "CMS on-ramp". Furthermore, we also provide information on data sharing standards, interface specifications and interoperability requirements for eHRSS connection. IT vendors / HCPs are welcome to approach us to discuss the connectivity of their systems to the eHRSS.

14. When taking forward the development of the Stage 2 eHRSS, we will continue to adopt a prudent approach to ensure security and reliability of the system. On the other hand, we will ensure that the private IT sector would also benefit from new business opportunities.

(d) Locations where the provider could access the eHRSS

15. The "service location" in clause 17 of the eHRSS Bill is concerned with the information required for registration of HCPs. The Bill has not stipulated that HCPs could only access the eHRSS at those particular locations.

16. The connection between individual eMR system or user workstation of HCPs with the eHRSS is restricted through registered and pre-defined connection modes. The HCPs can connect their own eMR system or workstation (which could be notebook) with the eHRSS through Virtual Private Network or fixed Internet Protocol address or with registered security module.

17. Connection from certain mobile device (such as smart phone) with the eHRSS direct is currently not supported. However, it is possible for HCPs to access the eHRSS using mobile devices through their eMR systems subject to compliance with security requirements defined by the eHRC such as appropriate security policy and measures.

(e) Response to Dr Hon Elizabeth Quat's letter dated 28 July 2014

18. We have not been previously requested to provide written response to Dr Hon Elizabeth Quat's letter dated 28 July 2014. Following a specific request at the meeting of the Bills Committee on 14 October 2014, we set out below our replies to the questions and comments raised in the letter.

Comments / Enquiries No. 1-3

19. In our previous written and verbal responses, we have repeatedly reiterated that there are diverse views over the "safe deposit box" issue. We have reported the views of **BOTH** the supporting and the objecting parties. The responses received in the public consultation conducted in December 2011, as well as the views expressed by the deputations at the meeting of the Bills Committee on 26 May 2014, are clearly reflecting that no consensus has been reached.

20. As explained previously, "safe deposit box" is a broad general concept. There is no commonly accepted definition nor standard technical design, and different countries have different extents of control to access imposed. We have only limited information available based on desktop research. For example, the review on the Personally Controlled Electronic Health Record System in Australia is a complex subject. The review panel has identified some possible areas of improvements and come up with 38 recommendations. In the absence of an in-depth study, it is not possible to fully understand the justifications for the proposed subtle changes or to analyse the implications.

21. "Safe deposit box" is not an item within the project scope of the 2009-2014 Stage 1 eHR programme. In line with our previous

undertaking, we will conduct a study on additional access control for sensitive data as a priority for the Stage 2 eHR Programme after passage of the eHRSS Bill. The study will provide important background information and analysis on various options to facilitate the decision on possible new features to be added. Pending the outcome of the study, the Administration has no predetermined stance at this stage.

Comment / Enquiry No. 4

22. For cases where emergency access to a healthcare recipient (HCR)'s eHR in the eHRSS is necessary in tandem with the carrying out of emergency treatments on that HCR, the HCP concerned could make a request for such access on a temporary basis without the data subject's consent by virtue of an exemption under the Personal Data (Privacy) Ordinance (Cap. 486). When making such an access request, the HCP concerned would need to provide justifications for the access on the spot, which would be logged in the eHRSS and subject to audit.

23. As mentioned in our previous response, there may be different possible arrangements in overseas to allow exemption for accessing restricted data in special circumstances. Notwithstanding, the considerations for allowing access to the entire record vis-a-vis access to particular piece of data may be different. In studying the possible forms of system enhancement feature for the next stage of the eHR Programme, the means and circumstances to break relevant access restriction will also be looked into.

Comment / Enquiry No. 5

24. Clause 25 of the eHRSS Bill includes a *general prohibition* of use of data and information contained in an eHR, while Clause 26 provides that the data and information of a registered HCR may be used for improving the efficiency, quality, continuity or integration of the healthcare provided (or to be provided) to the HCR. These clauses would guard against the use of data and information by any person who has nothing to do with the healthcare provided to the HCR.

25. The future operation/workflows of the eHRSS have also been designed to incorporate access control features, similar to many other major computer systems. Authorisation of access to the health data in eHR by healthcare professionals would only be granted to those who have valid registration status contained in the statutory professional registers. Administrative staff in an HCP who has to handle registration or sharing consent of an HCR will only be given access to the HCR's index data (such as name, address, mobile phone number). All accesses to eHR will be logged and traceable. Access of an HCR's eHR will trigger the issue of a notification (such as Short Message Service) to the relevant HCR. If an HCR has doubts upon receiving a notification, the HCR could approach us to file complaints and enquiries. We will assist in ascertaining whether the concerned access is in order. In addition, we will conduct audits of accesses to eHR from time to time. In case any irregularities are identified, they will be subject to investigations and follow-ups such as disciplinary actions as appropriate.

Food and Health Bureau
November 2014

Annex A1

Steering Committee on Electronic Health Record Sharing – Terms of Reference

- To formulate strategies to facilitate the development of electronic health record (eHR) infrastructure and sharing of patients' records in both the public and private sectors.

- To propose the institutional framework and structure that support and sustain the governance, management, operation and maintenance of the eHR sharing infrastructure.

- To develop viable business models for the eHR sharing infrastructure with a view to ensuring the sustainability of the infrastructure, both financially and institutionally.

- To study various legal and related issues relating to the eHR sharing infrastructure including ownership, privacy, confidentiality, security and liability and recommend appropriate legal and other solutions.

- To address technical issues relating to the eHR sharing infrastructure, including definitions, data security, data structures, data quality, standards and protocols of health record and information, and any other relevant technical and security issues.

- To draw up and take forward work programmes, in stages as necessary, for implementation of various components of eHR sharing infrastructure including pilot projects in both the public and private sectors.

- To promote the concepts of eHR, eHR technology, and patient record sharing among healthcare providers and the public.

- To examine any other issues that are relevant to the development of the eHR sharing infrastructure.

Annex A2

Steering Committee on Electronic Health Record Sharing
Membership List

Chairman:
Permanent Secretary for Food and Health (Health)

Members:

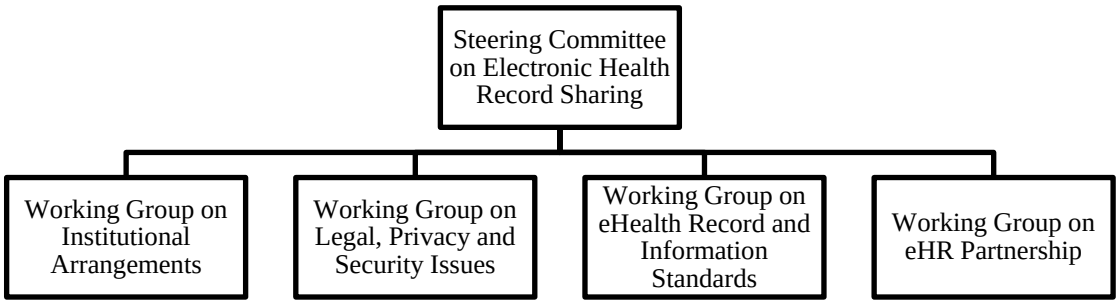
Representatives of:
Hong Kong Academy of Medicine
Hong Kong Private Hospitals Association
Hong Kong Medical Association
Hong Kong Public Doctors' Association
Alliance for Renal Patients Mutual Help Association
Care For Your Heart
Alliance for Patients Mutual Help Organisations

Dr Eric CHAN
Dr Roy CHO Kwai-chee
Mr Lawrence FUNG
Dr LAU Ho-lim
Dr Sigmund LEUNG
Mr Paul LI
Prof. Helen MENG Mei-ling

Representatives of:
Food and Health Bureau
Department of Health
Hospital Authority
Office of the Government Chief Information Officer

Annex A3

Structure of Steering Committee on Electronic Health Record Sharing and its working groups



Annex B

Information to be included for sharing in Stage 1 eHRSS

Data Type	Information to be included
Personal identification and demographic data	Information that is required to accurately and uniquely identify a healthcare recipient (e.g. identity data, demographic data, eHR personal identifier)
Adverse reactions and allergies	Information on the type of biological, physical or chemical agents that were noted to have given rise to adverse health effects and/or allergies in the healthcare recipient
Summary of episode and encounters with healthcare providers	A list of booked appointments and attended healthcare visits
Diagnosis, procedures and medication	Significant health and social problems identified; significant procedures done for diagnosis, exploratory or treatment purposes; and medication ordered and/or dispensed
Laboratory and radiology results	Reports of laboratory investigations (e.g. biochemistry, haematology, microbiology) and reports of radiology investigations (e.g. x-ray, ultrasound, computer tomography, magnetic resonance imaging)
Other investigation results	Results of other diagnostic tests (e.g. pulmonary function test, echocardiography)
Clinical note summary	Information that summarize the important clinical findings, diagnosis, problems, management and treatment received and follow-up arrangement of the healthcare recipient in a clinical visit / episode
Birth and immunization records	Information about the healthcare recipient's birth (e.g. place of birth, birth weight, maturity) and vaccines administered to the person
Referral between providers	Information that is required when a healthcare provider refers a healthcare recipient to another healthcare provider for care