Report of
the Investigation Panel
on the Dental Unit Incident

November 2012

EXECUTIVE SUMMARY

1. The Investigation Panel was set up by the University Health Services Committee to investigate into the incident of dental instruments in the Dental Unit of the University Health Service (UHS) not having gone through the full process of sterilization and being used in the treatment of patients between the afternoon of October 30, 2012 and the morning of November 2, 2012. The Panel was to make recommendations on the management of the patients affected by the incident and how to prevent similar incident from happening in future.

2. No such incident was previously reported at the Dental Unit of UHS which has been generally complying with "The Basic Protocol – Infection Control Guidelines for the Dental Service" from the Department of Health of HKSAR since its inception. Its overall standard of infection control practices is high. This incident was found to be a very rare lapse of the monitoring role by the on-duty dental surgery assistants who executed 3 to 4 rounds of autoclave process per day.

3. Based on the schedule of dental surgeries and sterilization sessions, the Panel believed that the dental staff did not check the completion of autoclaving cycle at around 15:30 on October 30, 2012. This lot of unsterilized dental instruments might have been used on patients attending the Dental Unit between the afternoon session of October 30, 2012 and the morning session of November 2, 2012, when the incident was discovered and immediately reported at 12:45 on November 2, 2012.

4. Risk assessment based on the literature review, the seroprevalence of HIV and HCV in the general population and the available serostatus of the "possible source" patients treated between the morning of October 29, 2012 and the morning of October 30, 2012 suggested an extremely low risk from these two infections, but the risk of HBV and tetanus were considered significant. "Possibly exposed" and susceptible patients were counselled and monitored for their serostatus of HBV, HCV, and HIV at baseline, and seroconversion will be monitored at 3 and 6 months after exposure. Immunization against HBV and tetanus were offered to all susceptible exposed patients.

5. The Panel recommended that dating of instrument packages and signed documentation of each autoclave printout, colour change of chemical indicators of each load and the daily autoclave performance should be recorded and audited to prevent similar incidents in accordance with the British Dental Association advice sheet - Infection Control in Dentistry and the Australian Dental Association Guidelines for Infection Control.

DECLARATION:

Members of the Investigation Panel declared the following potential conflict of interests:

Professor K.Y. Yuen: Alumnus of the University of Hong Kong (HKU), now Chair of Infectious Diseases in the Department of Microbiology, HKU

Professor Edward C.M. Lo: Alumnus of HKU, now Professor in Dental Public Health in the Faculty of Dentistry, HKU and a member of the University Health Services Committee

Dr. Vincent C.C. Cheng: Alumnus of HKU, now Honorary Associate Professor in the Department of Microbiology, HKU

Dr. K.H. Wong: Alumnus of HKU, now Honorary Associate Professor in the Department of Microbiology, HKU

The Investigation Panel declared that it had conducted an independent, open, fair and impartial investigation of the said incident.

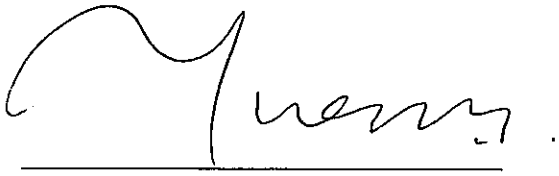
The report of this investigation was a factual account of the incident and the recommendations were given in the hope to prevent similar incident and to protect patients from such exposure.

The Panel would like to thank the hardworking and conscientious frontline health care staff in the UHS, source and exposed patients who have been highly cooperative in this investigation.

We are also grateful to the external expert observer Dr. Ka-Hing Wong from the Department of Health of HKSAR, and resource persons who had provided information or had given expert opinion in this investigation, namely: Professor Patrick Woo, Dr. Susanna Lau in the Department of Microbiology, HKU and Professor Man-Fung Yuen, Department of Medicine, HKU.

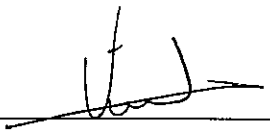
The Panel would also take this opportunity to express their sincere concern to the exposed patients in this incident.

Signed by



Professor Kwok-Yung Yuen

Professor Edward C.M. Lo



Dr. Vincent C.C. Cheng

November 26, 2012

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Appendix 14	Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis, Centre for Disease Control and Prevention (CDC), Atlanta, Department of Health and Human Services, U.S., June 29, 2001
Appendix 15	A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, Centre for Disease Control and Prevention (CDC), Atlanta, Department of Health and Human Services, U.S., December 23, 2005

I. TERMS OF REFERENCE

1.1 The Investigation Panel was set up by the University Health Services Committee (UHSC) with the following terms of reference:

(a) To investigate into the incident of dental instruments in the Dental Unit of the University Health Service (UHS) not having gone through the full process of sterilization and being used in the treatment of patients between the afternoon of October 30, 2012 and the morning of November 2, 2012 (the 'Incident');

(b) To recommend actions and arrangements needed for patients being affected by the Incident;

(c) To recommend safety measures and actions needed to prevent similar incidents from happening in future;

(d) To make recommendations on any other issues relating to, or arising from, the Incident as appropriate; and

(e) To submit a report on the outcome of the investigation of the Incident and the recommendations to the University Health Services Committee.

II. MEMBERSHIP OF THE INVESTIGATION PANEL

A medical specialist of the University (Chairman):
Professor Kwok-Yung Yuen, Li Ka Shing Faculty of Medicine, HKU

A member of University Health Services Committee:
Professor Edward C.M. Lo, Faculty of Dentistry, HKU

A medical professional from the community:
Dr Vincent C.C. Cheng, Queen Mary Hospital

External Expert Observer:

Dr Ka-Hing Wong, Consultant (Special Preventive Programme), Centre for Health Protection, Department of Health, HKSAR

Resource Persons who were invited as deemed necessary.
The following are non-member experts who have assisted in the initial phase of the investigation:

Professor Man-Fung Yuen, Professor, Division of Gastroenterology and Hepatology, Department of Medicine, HKU

Professor Patrick C.Y. Woo, Professor, Department of Microbiology, HKU

Dr. Susanna Lau, Associate Professor, Department of Microbiology, HKU

Dr Kitty Chan, Director of University Health Service, HKU

Miss Kamela K.M. Ma, Health Education Officer, University Health Service, HKU

Dr Sally Wong, Honorary Assistant Professor, Department of Microbiology, HKU

Dr Siddharth Sridhar, Resident, Department of Microbiology, Queen Mary Hospital

Dr Cheuk-Kwong Lee, Consultant, Blood Transfusion Service, Hospital Authority

Miss Modissa Ng, Advanced Practice Nurse, Infection Control Team, Queen Mary Hospital

III. PROCEDURE AND METHODOLOGY OF INVESTIGATION

3.1 Members of the Panel ascertained the sequence of events by interviewing all involved Dental Unit staff on November 5, 2012 and November 15, 2012 to make recommendations for the management of the exposed patients.

3.2 Members of the Panel walked through the Dental Unit on November 5, 2012 and November 15, 2012 to examine the overall standard of infection control (Floor plan of the cleansing and sterilization area in Appendix 1) and specifically to ascertain:

(a) How the dental instruments were placed and used at the chair-side;

(b) How the used dental instruments were transported from the chair-side to the dirty zone of the instrument processing room;

(c) How the used dental instruments underwent pre-sterilization cleansing;

(d) How the cleansed instruments were packed;

(e) How the packed instruments were autoclaved;

(f) How the autoclaved instruments were unloaded; and

(g) How the autoclaved instruments were stored on the shelf and later distributed to the chair-side.

3.3 Risk assessment for “possible source patients” (referred as source patients) was conducted (Table of HIV, HBV and HCV serostatus of source patients in Appendix 2).

3.4 Risk assessment of the dental procedures in terms of the invasiveness of the dental procedure, the microbial inoculum and the susceptibility of the “possibly exposed patients” (referred as exposed patients) was conducted (Table of dental procedure risk, serostatus and susceptibility status of exposed patients in Appendix 3).

3.5 Immediate recommendations were made and counselling for exposed patients to decrease the risk from common infections was provided (Post-exposure prophylaxis for HIV, HBV and HCV in Appendix 4).

3.6 Literature review on microbes which may pose risks to exposed patients was carried out (Dental transmission of HIV, HBV, HCV and tetanus in Appendix 5).

3.7 Recommendations to prevent similar happenings according to the British Dental Association Advice Sheet – Infection Control in Dentistry (Appendix 6), the Australian Dental Association Guidelines for Infection Control (Appendix 7), Guidelines for Infection Control in Dental Health-Care Settings – 2003, Centre for Disease Control and Prevention, U.S. (Appendix 8), and The Basic Protocol from Government Dental Service, Department of Health of HKSAR (Appendix 9) were made.

IV. SEQUENCE OF EVENTS

4.1 The Director of UHS was informed at 16:45 on November 2, 2012 (Friday) by the acting dental surgeon in-charge ("X") that some dental instruments were not sterilized but used on dental patients.

4.2 The Director immediately convened a meeting with three dental surgeons (i.e. acting dental surgeon in-charge X, dental surgeon Y and dental surgeon Z), the physician responsible for occupational health, the extended duty dental surgery assistant and the departmental safety representative.

4.3 The sequence of events, as reported by the extended duty dental surgery assistant, was as follows:

(a) Dental surgery assistant B while searching for a surgical pack as urgently required by her dentist at around 12:45 on November 2, 2012 found that one of the surgical packs in the autoclave room had no colour change on the autoclave tape indicative of achieving the autoclave temperature of 121°C. She then found another surgical pack with no colour change on the autoclave tape as well. She then informed dental surgery assistant A and dental surgery assistant C who discovered that two out of the three surgical packs on the shelf had no colour change (Incident Report by the extended duty dental surgery assistant in Appendix 10).

(b) They then examined other non-surgical instrument packs and found that five to six non-surgical instrument packs (the dental surgery assistants could not remember exactly whether there were five or six non-surgical instrument packs), out of 160 packs, had no colour change.

(c) They then reported the incident to the extended duty dental surgery assistant and the acting dental surgeon in-charge X.

4.4 The dental surgeons (X, Y and Z) decided on the following immediate remedial action. Two dental surgeons (Y and Z) recalled all dental instruments which had been distributed into the dental surgery rooms and replaced them with freshly autoclaved dental instruments. The acting dental surgeon in-charge X informed the Director of UHS of the incident.

4.5 The Director collected, confirmed and analyzed all the information regarding sequence of events from the extended duty dental surgery assistant. The earliest possible affected lot of instruments was assumed to be the lot autoclaved at 14:15 on October 30, 2012.

4.6 The meeting lasted from 16:45 of November 2, 2012 to 00:40 of November 3, 2012 and Professor Patrick Woo and Dr Susanna Lau from the Department of Microbiology joined the meeting at 23:00.

4.7 The meeting concluded that the at-risk exposure time period was from the afternoon of October 30, 2012 to the morning of November 2, 2012 as deduced from the probable sequence of events according to the report of the involved dental personnel.

4.8 **Facts** – Only four surgical packs were available in the Dental Unit. They were placed in the thermal disinfector before putting into the autoclave for sterilization. Used surgical packs were autoclaved either on the same day or in the morning of the next day. The routine schedule for thermal disinfector and autoclave cycle is shown below.

Routine schedule of the time to start the cycle of disinfector and sterilization

Starting Time for disinfector (Mon-Fri): 11:00am, 1:00pm, 5:00pm

Starting Time for autoclave (Mon-Fri): 8:45am, 12:00 pm, 2:15pm

(3:30pm cycle will only start if additional instruments are needed to start a separate cycle but it is not common, probably 2 – 3 times per month)

Routine disinfection and sterilization cycle typically in the afternoon:

1:00 ~ 2:00pm	Thermal Disinfector Cycle
2:15 ~ 3:30pm	Autoclave Cycle
3:30 ~ 4:00pm	Take out the ‘autoclaved’ instruments to cool down
4:00 ~4:30pm	Return instruments back to storage rack and distribute back to individual rooms

4.9 **Facts** – Based on the electronic dental patient appointment record and the autoclave timetable:

(a) Three surgical packs were used in the morning session of October 30, 2012. Only one surgical pack was used at 09:00 which was autoclaved at 12:00 on October 30, 2012.

(b) The other two surgical packs were used at 11:00 and 11:30 respectively on October 30, 2012 and autoclaved at 14:15 on October 30, 2012 (i.e. in the afternoon on the same day).

(c) Two failed autoclaved surgical packs were discovered at 12:45 on November 2, 2012.

4.10 **Assumptions** – The Panel believed that:

(a) There was only one failed autoclave cycle.

(b) The dental surgery assistants always checked the autoclave indicator before a surgical pack was used in surgery.

(c) Surgical packs were put into the same autoclave in the same cycle, as their usual practice.

4.11 **Deduction** – The most likely scenario was that there was a failure of autoclaving procedure in the afternoon session on October 30, 2012.

It was likely that the dental staff on duty during the afternoon session on October 30, 2012 in the 14:15 autoclaving cycle:

(i) did not press the 'Start' button of the autoclave;

(ii) and when taking the instruments out from the autoclave at 15:30, did not check if the autoclave signalled 'Ready', an indicator for the completion of the autoclaving cycle;

(iii) did not check the printout from the autoclave;

(iv) unloaded the unsterilized instrument packages from the autoclave and put them on the storage shelf.

4.12 This hypothesis was based on the testimonies of the Dental Unit personnel regarding their usual practice. The last spore tests of the autoclave were performed on October 27, 2012. There was otherwise a complete lack of written documentation on the dates of each autoclave package and each autoclave cycle. As such, the traceability of the whole procedure of sterilization was lacking. The quality of pre-sterilization cleansing and disinfection could not be ascertained. The colour change of chemical indicators on surgical packs was the ONLY available marker in the quality control.

4.13 Based on the above analysis, the source patients were those patients who attended the Dental Unit on October 29, 2012 and in the morning session of October 30, 2012, whereas the exposed patients were those who attended the Dental Unit between the afternoon of October 30, 2012 and the morning of November 2, 2012.

V. IMPORTANT OBSERVATIONS MADE DURING THE INTERVIEW OF THE DENTAL PERSONNEL AND THE WALK THROUGH OF THE DENTAL UNIT

5.1 The overall standard of infection control at the Dental Unit was high as evidenced by the very clean environment and the proper use of personal protective equipments with another new set between patients. The staff were conversant with the infection control practices and the equipment appeared clean, tidy and well maintained. However as in other places in HKU or HKSAR in general, there was an obvious lack of space and therefore overcrowding which accounted for the lack of adequate spatial separation between clean and dirty instruments.

5.2 The Dental Unit has been generally following "The Basic Protocol – Infection Control Guidelines for the Dental Service" from the Department of Health of HKSAR which was adopted from the U.S. CDC Guidelines. Unlike the dental infection control guidelines of the British or the Australian dental associations which clearly specified the importance of documentation of the autoclave printout and chemical indicator results, the HKSAR guidelines did not clearly specify these points but suggested the necessity of documentation and that "All packages should be dated to facilitate recall when ineffective sterilization is presumed in the event of consecutive spore test failure." (p. 19, Appendix 9) Indeed the dental surgery assistants made documentation on the weekly spore strip test results with date and signature. However, no such documentation was made for each autoclave printout or the results of the chemical indicators. If they had followed the requirement for documentation of each run of autoclave as stipulated in the British Dental Association advice sheet - Infection Control in Dentistry and Australian Dental Association Guidelines for Infection Control, this incident should have been avoided.

5.3 Chair-side:

(a) Personal Protection Equipment (PPE) including disposable gown, head cap, goggle, face mask, face shield, and gloves) were used during dental procedures and treatments:

(b) All equipment/surface were covered with plastic wrap/tubing and changed between patients;

(c) Individual sterilized package for surgical instruments were used.

5.4 Wrapping of dirty surgical packs was carried out in clean area.

5.5 Some dental equipments/instruments (12 types of items listed in Appendix 11) did not normally undergo hot water and detergent cleansing in the thermal disinfector before autoclaving (these were instruments not suitable for cleaning in the thermal disinfector and they normally rely solely on autoclaving besides the usual cleansing and brushing). The inventory list of equipments and instruments of the Dental Unit is set out in Appendix 12.

5.6 Endodontic files after autoclaving were put into a non-sterile clean box using bare hands. This was an acceptable practice because such files were put into hypochlorite disinfectant sponge before use on patients. However, a better approach would be to keep the autoclaved endodontic files in a sterile condition.

5.7 There was a lack of signed documentation leading to failed traceability of dental instruments undergoing sterilization before this incident.

5.8 All dental surgery assistants were qualified to use the medium size autoclaves while dental hygienists were not and only occasionally used the small size autoclaves with no printout of cycles.

5.9 As the workload for autoclaving was quite heavy which amounted to 3 to 4 autoclave loading per day, all the dental surgery assistants on duty on October 30, 2012 could not recall if they had performed the autoclave duty in the afternoon of the failed autoclaving. All dental hygienists declared that they had not unloaded instruments from the medium size autoclaves on October 30, 2012 (declaration of the dental surgery assistants and dental hygienists is in Appendix 13).

5.10 The dental surgery assistants had an impression that it was not necessary to date and to label the autoclaved packages because of the rapid turnover of the surgical packs which were always used well before the expiry of the sterile condition.

5.11 There was no single dentist who headed the Dental Unit. The one in charge was rotated once every three months.

VI. MICROBES POSING RISKS TO EXPOSED PATIENTS

6.1 After literature review by the members of the Panel (Appendices 14 & 15), the following were considered common microbes that may pose risk to exposed patients in the present clinical setting:

(a) Blood borne viruses with high morbidity and mortality:
  (i) HIV (HK seroprevalence: 0.004% blood donors)
  (ii) HCV (HK seroprevalence: 0.099% blood donors)
  (iii) HBV (HK HBsAg seroprevalence in blood donors: 1.09%; up to 8% in those aged over 50, unpublished data from Dr Cheuk-Kwong Lee, Consultant, Blood Transfusion Service, Hong Kong Hospital Authority, 2011)

(b) Spore forming microbes
  (i) *Clostridium tetani* (cause the highly fatal tetanus)
  (ii) *Bacillius* spp
  (iii) Mold

(c) Non-tuberculous mycobacterium or Legionella which are selectively heat- or detergent-resistant

(d) *Mycobacterium tuberculosis* infecting salivary glands or lung may produce a high oral salivary mycobacterial load. Any pathogenic virus actively shedded by source patients such as herpes simplex, varicella zoster virus or respiratory viruses may be inoculated into exposed patients.

(e) Oral flora

(f) Environmental flora

(g) nvCJD or prions were not reported after dental procedures

6.2 Only Blood borne viruses and spore-forming *Clostridium tetani* are considered to have significant risk to patients with mucosal break while undergoing dental procedures. The other agents are generally self limiting or highly treatable if symptoms appear.

VII. RISK ASSESSMENT AND IMMUNIZATION

Risk assessment

7.1 A total of 127 source patients[1] among whom 15 patients were also exposed were traced. Four source patients either refused blood taking or could not be contacted for establishing their HIV, HBV and HCV serostatus.

7.2 Risk assessment for blood borne virus infection was performed by asking the source patients to complete a questionnaire on relevant medical history including high risk behaviour.

7.3 The blood test result showed that none of the 122 patients (One patient had no dental procedure done) was positive for HIV or HCV antibody while three source patients were positive for HBsAg and one was an hepatitis B occult carrier. Their HBV DNA viral load was up to 10^3 per ml (Appendix 2).

7.4 In view of the very low seroprevalence of HIV (0.004%) and HCV (0.1%) in the general population and the significant side effects of antiretroviral post-exposure prophylaxis, antiviral prophylaxis against HIV was not recommended despite the unknown serostatus of four source patients. There was no recommendation for HCV prophylaxis in the medical literature at this stage.

7.5 The risk from HBV infection is significant as the carrier rate in the population ranges from 1% to 8% with age and at least three source patients were HBsAg positive with detectable HBV DNA viral load. Moreover, some of the dental instruments had not undergone thermal disinfection during the washing steps.

7.6 Besides HBV, *Clostridium tetani* spores can be present in inanimate environment. Though this disease is rare, this has been reported after dental procedures and the disease is highly fatal. Thus all susceptible patients should be advised to receive immunization against HBV and tetanus.

Immunization

7.7 A total of 250 exposed patients[2] attended the Dental Unit during the at-risk period among whom only 248 had received dental procedures. One patient could not be contacted and the serostatus was unknown.

7.8 The baseline HIV and HCV serostatus of these 247 exposed patients were negative (although two were tested positive and indeterminate for HCV antibody, the HCV RNA were negative).

7.9 One-hundred and forty-nine of the 247 patients were HBsAb positive and therefore were immune against HBV. Three of the remaining 98 patients had a complete course of immunization and >6 mIU/mL HBsAb in the present serological testing. Ten of the 98 patients were HBsAg positive and therefore were chronic carriers. One of these 98 patients was HBcAb positive and therefore was an occult carrier.

7.10 Only 78 of the 84 susceptible patients received immunization with hepatitis B vaccine at this stage. Thirty-six of the 84 susceptible patients had undergone high risk dental procedures such as root canal treatment, dental extraction, scaling, dental implant or oral surgery and 35 were given hepatitis B hyperimmune globulin (HBIG) passive immunization (one refused despite counselling by medical personnel). (Appendix 3)

[1] *Source patients were defined as patients who attended the Dental Unit from the morning of October 29, 2012 to the morning of October 30, 2012*

[2] *Exposed patients were defined as patients who attended the Dental Unit from the afternoon of October 30, 2012 to the morning of November 2, 2012*

N.B. 15 patients were in both source and exposed category as they received dental treatment during both periods. These were managed as 'exposed patients'.

VIII. RECOMMEDATIONS

Immediate recommendations (Appendix 4):

8.1 Ask all source patients about risk factors for blood borne virus infection and other infectious diseases. Took blood for assessing HIV, HBV and HCV status after consent and counselling.

8.2 Ask all exposed patients for risk factors for blood borne virus infection and other infectious diseases, and checked their baseline serostatus. They would be checked again at 3 months and 6 months for HIV, HBV and HCV seroconversion after consent and counselling.

8.3 Offer tetanus toxoid to all exposed patients if they had not received booster vaccine in the last 10 years.

8.4 Offer HBV vaccine to all exposed patients if hepatitis B surface antigen/antibody and core antibody were negative and without a history of a full course of HBV vaccination.

8.5 Offer HBV booster to all exposed patients if the patient had received a full course hepatitis B vaccination in the past and was a known responder, but serum HBsAb > 6 mIU/mL and < 10 mIU/mL.

8.6 For exposed patients after invasive dental procedures such as extraction, implant, scaling and oral surgery, HBIG and accelerated course of hepatitis B vaccination would be recommended if the patient was tested negative for HBsAg, HBsAb and HBcAb.

8.7 Exposed patient should be instructed to seek medical attention if they experienced any local or systemic symptoms/signs suggestive of infection.

8.8 If the source or exposed patient is known to be HCV infected or is an injecting drug user with unknown HCV status, baseline ALT should be considered in addition to HCV Ab. Furthermore, HCV Ab, ALT, and HCV-RNA should be determined between 6 – 8 weeks in order to capture those who develop acute hepatitis.

8.9 The autoclaves should be checked for possible intermittent failure by a qualified mechanic immediately.

8.10 Before unloading of dental instrument after autoclaving, the autoclave printout and the autoclave tape must be checked to ascertain that the full autoclave cycle was completed with a colour change on the autoclave chemical indicator strip. The staff should then sign the autoclave printout and the autoclave chemical indicators, which should then be stuck and stored on a logbook with date and time.

8.11 To ensure traceability, date of autoclave and the load number on that day should be marked on every surgical pack and peel pack.

8.12 Pre-sterilization packing of the surgical instruments should not be performed in the clean area.

VIII. RECOMMEDATIONS

Long term recommendations (Appendices 6 - 9):

8.13 There should be spatial separation between the dirty area (pre-sterilization cleansing), clean area (sterilization), and area of storage of post-sterilization items.

8.14 Chemicals involved in X-ray film development should be moved out of the cleansing and sterilization area for fear of chemical cross-contamination.

8.15 There should be regular auditing of compliance to the above suggestions on dating, signing and logging of all autoclave printout, chemical indicator and spore tests.

8.16 UHS should not use the small size autoclaves which have no electronic record function and printout summary on completion of each autoclave cycle.

8.17 UHS should assign a dedicated personnel for cleansing, sterilization and disinfection process

8.18 Protocol should be drawn up for managing and investigating failed autoclave process or spore strip test – failed spore strip test should be followed by an immediate autoclave machine test.

8.19 UHS should appoint a senior dental surgeon to be the in-charge personnel who should be more permanent and ultimately accountable for the dental service, rather than using the present system of rotating arrangement.