

THE INDEPENDENT REVIEW COMMITTEE REPORT

Executive Summary

This report sets out the findings and recommendations of the Independent Review Committee (IRC) appointed by the Ministry of Health (MOH) to provide an objective and critical review of Singapore General Hospital (SGH)'s investigation and actions following an outbreak of Hepatitis C Virus (HCV) infections at the hospital, and to reasonably investigate any activity within its terms of reference.

Background Information on Hepatitis C Virus

2. HCV is primarily a blood-borne virus and the most common modes of infection are through unsafe injection practices, inadequate sterilisation of medical equipment, and transfusion of unscreened blood and blood products.

3. The incubation period for HCV is 2 weeks to 6 months. Acute HCV infection can be asymptomatic, resulting in significant challenges to its surveillance. Approximately 55-85% of those infected develop chronic HCV infection, of which 15-30% of these chronic carriers develop a chronic liver illness known as cirrhosis, while a small proportion may develop liver cancer. HCV infection in immune suppressed patients such as post-transplant patients can cause more profound illnesses.

4. Internationally, many HCV outbreaks have been reported both within and outside hospital settings. Due to the challenges in surveillance of HCV as outlined above, it took some time to discover and identify these documented outbreaks. The virus is resilient and stable in the environment, and such transmission of HCV from environmental contamination has been reported in literature. Viral infectivity on inanimate surfaces has been shown to be detectable from between five days to six weeks.

SGH Hepatitis C Virus Cluster

5. Between April and September 2015, a cluster of 22 cases of acute HCV infection was identified amongst patients admitted to Ward 64A or Ward 67 at SGH. Subsequently, extensive screening of those who had been admitted to these wards from January to September 2015 identified three more cases, giving a total of 25 cases. Of these, 20 were renal transplant cases. There were eight deaths within the cluster.

6. SGH had conducted its own investigation into the cluster and taken actions to tighten infection control in the affected wards. It presented its investigation findings to the Minister for Health on 25 September 2015. On 28 September, MOH appointed an IRC to provide an independent, objective and critical review of SGH's investigation and actions. The IRC was to ascertain if all possible measures had been taken to identify the possible points where there may have been infection control breaches and to remedy any weak points in the overall workflow, particularly with regard to infection control.

7. The IRC set out to investigate the incident via two parallel tracks. In the first, the IRC looked into probable causes of the cluster, while in the second, the IRC looked into the system response and communications between SGH, SingHealth and MOH relating to the cluster.

8. For the first track, the IRC appointed two teams of international experts from the United States' Centers for Disease Control (US CDC) and Prevention and Johns Hopkins University to strengthen its capabilities and to provide additional technical and scientific input to the committee's review.

9. For the second track, the IRC appointed three Resource Persons – Professor Tan Chorh Chuan, President of NUS, Professor Chee Yam Cheng, Senior Advisor to National Healthcare Group, and Mr Ong Pang Thye, Deputy Managing Partner, KPMG. Their role was to provide guidance and work with the IRC to evaluate the various parties' responses to the incident. As the review included reviewing MOH's role in the outbreak, IRC member Dr Jeffery Cutter (Director, Communicable Diseases Division, Ministry of Health) recused himself from this part of the IRC's work.

Investigations into the Outbreak

10. The IRC investigated the outbreak based on the principles set forth in outbreak investigations, which focus on confirming and assessing the extent of the outbreak, creating a case definition and actively searching for cases, epidemiological investigation to develop and test hypotheses and communicating findings to relevant authorities for prevention and control measures.

11. Based on SGH's investigations that were presented to MOH, SGH had by end August identified a cluster of 21 cases (later updated to 22 cases in late September) that were linked epidemiologically in time and place. From their investigations, the cluster of infections had taken place from early April to June 2015. The location at which the infection took place was the Renal Ward that was originally operating in Ward 64A, which subsequently moved to Ward 67 on 6 April 2015 when Ward 64A was under renovation, and back to Ward 64A on 28 August 2015. Laboratory analysis by SGH (and subsequently confirmed by A*STAR) noted the presence of a strain of HCV, of genotype 1b, among cases. Thus an outbreak involving a common strain of HCV was established.

12. To ascertain the extent of spread beyond Wards 64A and 67, the IRC reviewed SGH's data on HCV RNA (a genetic test for HCV) and liver function tests, new HCV cases among major dialysis centres in Singapore and the national notification system. The IRC concluded that there was no evidence that the outbreak had spread beyond the two wards in SGH.

13. Case finding began by extensive screening of patients who passed through Ward 64A and/or Ward 67. This started with the screening of 621 patients, who had been admitted in the two wards from 1 January to 30 June 2015. This period was chosen by SGH on the basis that the vast majority of infected patients would present with positive results within 10 to 12 weeks of infection. Of these patients screened, three additional cases of HCV infection related to the cluster were identified.

14. As the latest HCV infected case could have been infected in late July, the screening period was extended to September. This would also cover the period after migration from Ward 67 back to Ward 64A. An additional 304 patients were screened and no further cases were identified.

15. In all, the HCV cluster comprised 25 patients, 20 of whom had received a kidney transplant before and were more susceptible to infections. The IRC assessed that out of the eight deaths, HCV was a likely contributory factor to the death of seven cases.

16. The earliest infected case was one who was likely to have been admitted to Ward 64A in early March 2015. Residual blood sampling showed that the case was already infected by mid-March, although there were no earlier blood samples available to be more definite regarding the date of infection. The IRC conducted extensive screening for preceding cases, but there was no definitive evidence of other HCV cases during the earliest infected case's stay in SGH and it is uncertain as to where the case had acquired the infection from.

17. A critical review of the literature was done and taking into consideration the circumstances of this outbreak, four specific hypotheses were tested. These were drug diversion; intentional harm; product contamination; and breaches in infection control.

- a. Drug diversion was concluded to be unlikely as there were no missing narcotics and other drugs with potential for abuse in the affected wards.
- b. Extensive search and interview of staff did not yield any evidence supporting intentional harm. 319 staff including 11 of those who had since left SGH all tested negative for HCV. The findings pointed towards a low probability of foul play. This was corroborated by police investigations.
- c. Contaminated medical products were an unlikely source. 0.9% Saline solution was the only product common to all patients in the cluster. 10 randomly selected bottles of 0.9% Saline solution taken from Ward 67 tested negative for HCV.
- d. While there were established processes for the handling of procedures such as blood taking, administering of intravenous medication, environmental cleaning and waste disposal, some staff were observed to have deviated from the established standards. These practices could have led to cross-contamination of equipment (e.g. computerised medical carts and trolleys) and contamination of contact surfaces. Findings pointed towards gaps in infection prevention and control practices that likely contributed to the outbreak.

18. The IRC concluded that a combination of multiple overlapping factors was the most likely explanation for the HCV outbreak, which was found to be contained within Wards 64A and 67 of SGH.

- a. Firstly, susceptible cases comprising mainly immunocompromised kidney transplant patients and the introduction of HCV (probably by the patient identified as the earliest infected case) led to acute infections with extremely high quantities of virus in these patients.
- b. All affected patients had many exposures to intravenous medications and/or laboratory tests that required blood taking, exacerbating the risks of HCV spread through gaps in infection control practices.
- c. There were gaps with regard to infection control practices (in particular processes involving intravenous procedures), environmental cleaning, and prevention of environmental contamination. These potentially facilitated HCV transmission in the two affected wards.
- d. Finally, these could have been accentuated by the shift to another ward where the layout was different from the ward that staff were familiar with.

19. During the course of investigations, the IRC observed several commendable practices by SGH staff. For example, consistent efforts were made to maintain patient privacy and confidentiality, as well as to minimise human errors by consistently verifying the patient's identity prior to performing procedures. SGH was also effective in upskilling their nursing workforce, with nurses trained to take on a significant share of tasks normally performed by junior doctors.

20. The IRC recommends that SGH undertake the following to minimise the risk of infection transmission:

- a. Review standard operating procedures and practices on infection control, with a view to reduce risk of environmental contamination, and to ensure adequate environmental cleaning and disinfection.
- b. Adhere to standard precautions for infection control, as laid out in US CDC guidelines¹.
- c. Strengthen the framework for supervision and monitoring of staff to ensure compliance with standard operating procedures.

System Response and Communications Relating to the Outbreak

21. In this track of work, the IRC interviewed the relevant parties in MOH, SingHealth and SGH involved in the outbreak, requested documentation on their key

¹ US Centers of Disease Control and Prevention. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Accessed on 23 November 2015. Available from: [<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>]

US Centers of Disease Control and Prevention. 2008 Guideline for disinfection and sterilisation in healthcare facilities. Accessed on 23 November 2015. Available from: [http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf]

US Centers of Disease Control and Prevention. 2003 Guidelines for environmental infection control in healthcare facilities. Accessed on 23 November 2015. Available from: [http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf]

actions, and reviewed correspondences among the different parties. A thematic framework was adopted in assessing key actions and responses, according to five categories: (a) recognition of an infectious disease outbreak; (b) notifications to MOH; (c) outbreak management and containment; (d) communications and escalation and, (e) roles and responsibilities of key players during the outbreak.

22. While the current surveillance system works well for community outbreaks of known infectious diseases and hospitals have robust frameworks to handle common Healthcare-Associated Infections (HAIs), the HCV outbreak highlighted a gap. Specific findings of the system response to the outbreak were:

- a. Recognition: The SGH Renal Unit did not recognise the outbreak in a timely manner and there was a delay in reporting to SGH Infection Control for help in containment.
- b. Notifications: MOH was not notified by doctors and laboratories of all the cases in the cluster. In addition, MOH-CDD did not classify the initial communicable diseases notifications as acute HCV infections despite some cases having abnormal liver function tests, as the cases were assessed not to meet the case definition of an acute infection at the time.
- c. Outbreak management and containment: While SGH commenced investigations into the HCV cluster from mid-May 2015, and enhanced infection control measures from early-June, investigations performed by SGH were incomplete. Several elements of outbreak investigation such as assessing the severity and extent of the outbreak were done by SGH only after meeting with the Director of Medical Services (DMS) on 3 September, such as appointing an external party to chair SGH's Medical Review Committee to determine if there were related deaths due to the HCV infection and setting up a Quality Assurance Committee to do a root cause analysis.
- d. Communications and escalation: Within SGH, communication with senior management took place early. However, in the absence of an established framework for the unusual and unfamiliar event of the HCV outbreak, there was a delay in escalation from SGH to SingHealth, and SGH to MOH. In addition, within MOH, there was no single division with clear responsibility and capability to deal with the issue, resulting in a gap in ownership, until the matter was escalated to the DMS.
- e. Roles and responsibilities: Within SGH, there did not appear to be clear roles and responsibilities for the management of unusual hospital outbreaks. SingHealth did not play a part in the incident. Within MOH, the DMS assessed on 3 September 2015 that more information was needed to determine the severity and extent of the outbreak, and requested SGH to complete key pieces of work within two weeks. The Minister was therefore only informed of the issue on 18 September, and briefed on 25 September, after SGH submitted their investigation report on 24 September.

23. In summary, there was a delay in recognising the outbreak as HCV is not easily picked up through regular surveillance due to its unique characteristics. With HCV being an unusual HAI, SGH did not recognise the outbreak in a timely manner. While SGH commenced investigations into the HCV cluster from mid-May, and implemented enhanced infection control measures from early June 2015 onwards which were instrumental in slowing the spread of infection, the IRC is of the view that the outbreak was not investigated and managed optimally. Within MOH, unlike community outbreaks, no one division has clear responsibility to deal with outbreaks of unusual HAIs. This hindered MOH's ability to respond in a timely way to the unexpected event. In addition, the absence of an established framework for unusual and unfamiliar events resulted in delays in escalating the matter from SGH to SingHealth, from SGH to MOH, and within MOH.

24. The IRC noted that DMS was only briefed by SGH on 3 September. His key considerations then were to make his professional evaluation of the severity and extent of the outbreak, to ascertain that adequate infection control measures had indeed been instituted, and to ensure that new transplant patients were not potentially exposed to HCV infection until the issues had been adequately addressed. He therefore asked for specific additional investigations and actions to be taken in relation to each of these within two weeks, and when these were largely done, reported the matter to the Minister. The IRC is of the opinion that the additional investigations and actions required by DMS are professionally valid and appropriate. Overall, while there were gaps in identification, management and reporting of the outbreak, there was no evidence to suggest that escalation to DMS and subsequent notification of the Minister had been deliberately delayed.

25. Beyond community outbreaks, the current surveillance and outbreak response frameworks should be enhanced to cater for unusual and unfamiliar events, with regards to outbreak detection, investigation and management, communication and escalation protocols, and the appropriate roles of MOH and the hospital.

26. The IRC thus recommends that the following measures are undertaken to improve the system response to cater to unusual and unfamiliar outbreaks:

- a. Improve the national notification and surveillance system for acute HCV, taking reference from international best practices and adapting them to the local context. Regardless of the systems in place, healthcare professionals should always be alert to unusual events.
- b. Designate a single team within MOH to carry out surveillance, identify and investigate potential outbreaks, and ensure adequate expertise nationally to facilitate outbreak investigation. Hospitals should continue to take responsibility and develop structures, frameworks and capabilities for HAI outbreaks within their institutions. Capabilities can be supplemented by other public healthcare institutions and MOH where required.
- c. Strengthen the escalation processes for HAIs, especially unusual and unfamiliar ones, within hospitals, public healthcare clusters and MOH, and between them through clearer guidelines on the assessment of the significance and severity of an HAI, and need for escalation.

Conclusion

27. The IRC concluded that this unusual outbreak of a blood-borne infection with low prevalence rates in Singapore was likely due to a combination of multiple overlapping factors concentrated during the period of April to June 2015 in the Renal Wards of SGH. In particular, the concentration of very ill patients and gaps in infection control practices provided an environment for the infection to spread.

28. While existing surveillance and response systems lend themselves well to known community outbreaks and HAIs, the system response to the incident, which is considered an unusual one, revealed some gaps in the system. The IRC thus recommends improving the notification and surveillance system for acute HCV; designating a single team within MOH to oversee surveillance, investigation and management of outbreaks and ensure adequate expertise nationally to facilitate outbreak investigation; and strengthening escalation processes for HAIs and unusual risks.