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Background

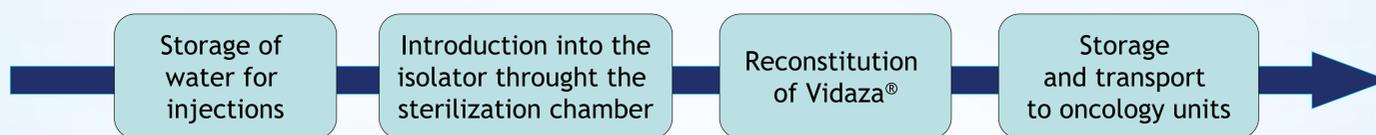
Vidaza® (azacitidine), comes in vials of sterile lyophilized powder for reconstitution with water for injections in controlled environment. After reconstitution, chemical and physical in-use stability of the finished product has been demonstrated at 25 °C for **45 minutes**; at 2- 8 °C for **8 hours** and at 2- 8 °C for **22 hours** when Vidaza® is reconstituted using refrigerated (2-8 °C) water for injections. Our centralized reconstitution unit prepares chemotherapy for a public hospital which is located 47km away.

Objective

→ the conservation of the cold chain for the reconstitution of Vidaza® using refrigerated water in order to assess the feasibility of preparing Vidaza® off-site.

Material and methods

- An organizational chart that illustrates the reconstitution of Vidaza® in order to target critical points :



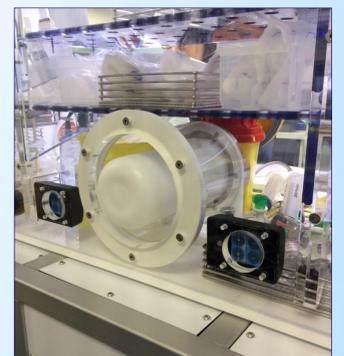
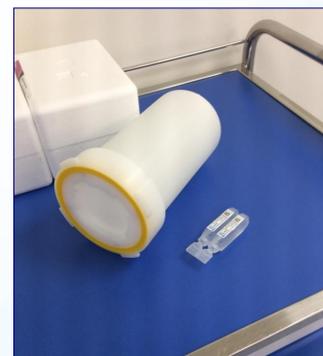
- Average temperature measurements of each step of the Vidaza® reconstitution were obtained using a digital thermometer probe.
- Cold chain compliance is obtained when temperatures are recorded between 2 °C and 8 °C.

Results

Conditions	Temperatures in the isolator	Between 2°C and 8°C
Refrigerated water for injections introduced into the isolator through the sterilization chamber	10.7°C	NO
Frozen water for injections introduced into the isolator through the sterilization chamber	9.6°C	NO

Sterile water for injections once in the isolator can be placed in the **Rapid Transfer Port (RTP)** system. This removable system stored in a freezer and then reconnected to the isolator provides refrigerated water for injections at an average temperature of **3.4 °C** after complete thawing.

After reconstitution, the finished products are immediately stored in the refrigerator and transported to oncology units in coolers with time/temperature recordings to monitor the temperature. Syringes are received at an average temperature of **6 °C** at the public hospital located 47km away.



Conclusion

Therefore syringes of Vidaza® can be prepared using the RTP system and should be sent to oncology units or transported to the external public hospital in coolers. This study confirms the feasibility of cold chain conservation in the reconstitution of Vidaza® in isolators and the feasibility of the subcontracting activity. It also strengthens collaboration between hospitals in the same catchment area and encourages the development of hematology activities in the subcontracting hospital.