Temperature mapping in an air ambulance helicopter

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DOI:
10.1111/trf.16517

Received: 25 November 2020 | Revised: 25 January 2021 | Accepted: 25 January 2021

DOI: 10.1111/trf.16517

SUPPLEMENT ARTICLE

TRANSFUSION

Temperature mapping in an air ambulance helicopter: Implications for the delivery of pre-hospital transfusion

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Funding information
National Institute for Health Research; NIHR EME programme. EudraCT No: 2015-001401-13

Abstract

Background: Pre-hospital blood products, including freeze-dried plasma, are increasingly carried on air ambulance helicopters. The purpose of this study was to map the temperatures within a civilian air ambulance and consider the implications for pre-hospital transfusion.

Materials and Methods: We conducted a single-site prospective observational study in the United Kingdom. Tinytag temperature data-loggers (Gemini, UK) were secured on to three locations throughout an air ambulance, and one was placed inside an insulated drug-pouch. Temperatures were monitored at 5-min intervals. Data were downloaded monthly and processed using R and MKT software to collate maximum, minimum, and day/night mean kinetic temperatures (MKTs). Blood was transported in Crēdo ProMed 4 containers (Peli Products, S.L.U) and monitored with QTA data-loggers (Tridentify, Sweden).

Results: A total of 344,844 temperature recordings were made on 302 days during a 12-month period from January 2019. The external ambient temperatures varied seasonally from −7.1°C to 31.2°C, whereas internal temperatures ranged from −0.3°C to 60.6°C. The warmest area was alongside the left front-crew position (range 1.9–60.6°C, MKT 24.8°C). The lowest daytime MKT (16.9°C) and range (1.7°C–36.4°C) were recorded next to the patient stretcher. Temperatures ranged from 4.2°C to 40.1°C inside the insulated drugs-pouch, exceeding 25°C on 47 days (15%) and falling below 15°C on 192 days (63%) In contrast, thermally packed blood maintained a range of 2–6°C.

Conclusion: The temperatures within an air ambulance varied throughout the cabin and often exceeded the external ambient temperature. Appropriately selected thermal protection and monitoring is required for the successful delivery of pre-hospital transfusion, even in a temperate climate.

KEYWORDS
air ambulance, pre-hospital transfusion, temperature mapping

1 | INTRODUCTION

Pre-hospital blood products (PHBPs), including freeze-dried plasma, are increasingly carried on air ambulance helicopters in the United Kingdom.[1] In other countries, 25% of programs currently carry blood, although others have stopped owing to logistical challenges.[2] The helicopter working environment has more noise, vibration, and greater temperature extremes than that of ground emergency medical services (GEMS). Temperature extremes may adversely affect the crew, patients, and pharmaceuticals. Tolerance of temperature excursions during drug storage may be feasible at the expense of shortened shelf-life.[3] In contrast, blood requires strict storage and transport conditions.[4] Developments in passive thermal packaging have enabled successful pre-hospital transport of blood[5]; however, they impose a logistic burden.[6] In contrast, lightweight drug pouches are more portable but may not always provide adequate temperature control.[7] The purpose of this study was to determine the variation in temperatures inside a newly commissioned civilian air ambulance and consider the implications for the pre-hospital carriage of blood, drugs, and plasma.

2 | METHODS

2.1 | Setting

The project was set up within the governance frameworks of the RePHILL (Resuscitation with Pre-Hospital Blood Products) trial[8] and the Midlands Air Ambulance (MAA). The project was registered as a service evaluation with no access to patient data. A single rotary platform, the Airbus Helicopter H145 (Eurocopter, Marseille), was used from an airfield in Shropshire, UK. The doctor-led crew had 3–4 members. Flying was restricted to daylight hours from 7.00 AM to 7.00 PM. The helicopter was parked on a helipad at ground level during the day when not in use and stored in a hangar at night.

2.2 | Study design and process

The study was conducted as a single-center prospective observational study. A 2-week pilot feasibility trial was conducted before starting the main study in January 2019 for a 12-month period. Continuous-recording temperature monitors were placed throughout the helicopter before being activated simultaneously to collect the maximum and minimum temperatures.

2.3 | Temperature monitoring and data management

Temperatures were monitored at 5-min intervals using four Tinytag Transit 2 data logger, TG-4080, (Gemini Data Loggers, Chichester UK) calibrated to 0°C and 30°C (±0.5°C) to the United Kingdom Accreditation Service (UKAS) standard. Three data loggers were positioned within the airframe throughout the cockpit and cabin. Each was attached securely using cable ties to ensure safe operation and exclude the risk of foreign object and debris (FOD). The orientation minimized light pollution from the green light-emitting diodes (LEDs). The fourth data logger was placed in the critical care drug-pouch stored within the paramedic responder bag stored on the patient stretcher (Figure 1). Crew members were asked to maintain a daily checklist of data loggers together with an activity log to provide contextual information.

Temperature data were downloaded at monthly intervals into Windows Excel 2010 and then exported to and processed using R software (R version 4.0.2, R Core Team, R Foundation for Statistical Computing, Vienna, Austria). The data were also used to calculate the mean kinetic temperature (MKT) using commercially available MKT software (Vacker LLC, Dubai). MKT is widely used in the pharmaceutical industry as a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods. External temperatures were taken from airfield meteorological observations provided for nearby Shawbury (reference temperature 20°C).

2.4 | Cold-chain management

The RePHILL trial interventions blood, Lyoplas-N, and saline were managed in compliance with standards for a Clinical Trial of an Investigational Medicinal Product (CTIMP) using a combination of Crēdo ProMed™ 4 and 22 series containers (Peli Products, S.L.U). Red cells were stored in a 2-L Crēdo ProMed™ 4 container. These were preconditioned for a minimum of 24 h in a freezer below −25°C, and then removed 30 min before use to allow them to reach the required operating temperature before packing. Each transport container was packed with 2 units of red cells, with a QTA temperature data logger attached to each unit (QTA Tracer System, Tridentify, Sweden). Spare space within the container was packed with a yellow clinical waste bag (UN3291) to both fill the dead air space and provide a clinical waste bag for used units. LyoPlas-N and trial saline were stored and transported using a prevalidated Crēdo ProMed™ 22 series container designed to ship medical

FIGURE 1 Location of the temperature loggers within the cockpit and cabin

products in the 15–25°C temperature range. Critical care medications were stored in an insulated drug pouch fitted inside a paramedic responder bag (Rescuer and Medical Ltd, Gwent, UK). Both blood containers and paramedic bags were secured overnight in the Air Ambulance base.

3 | RESULTS

A total of 344,844 temperature readings were recorded on board for 302 days during a 12-month period from January 6, 2019 to January 7, 2020. The weather station returns for this period showed the lowest minimum of −7.1°C in January 2019 and the highest maximum of 31.2°C in July 2019. The trends across the seasons are illustrated for each data logger in Figure 2; the smoothed results are shown in Figure 3. The daytime and night-time lowest, highest, and mean kinetic temperatures for the 12-month period for the four loggers are shown in Table 1. The pattern of temperatures varied considerably diurnally and during the seasons but was most dependent on the location within the helicopter.

The warmest part of the aircraft was position 1 alongside the front crew position. This data logger was placed to the left of the control panel and was close to the heating duct. In addition, the cockpit seats experience heating from direct sunlight through the windscreen. The maximum temperature recorded here was 60.6°C in August 2019. Position 2 on the outer frame of the left rear-facing seat close to the door opening showed a wide range of temperatures from −0.3°C to 56.2°C. The

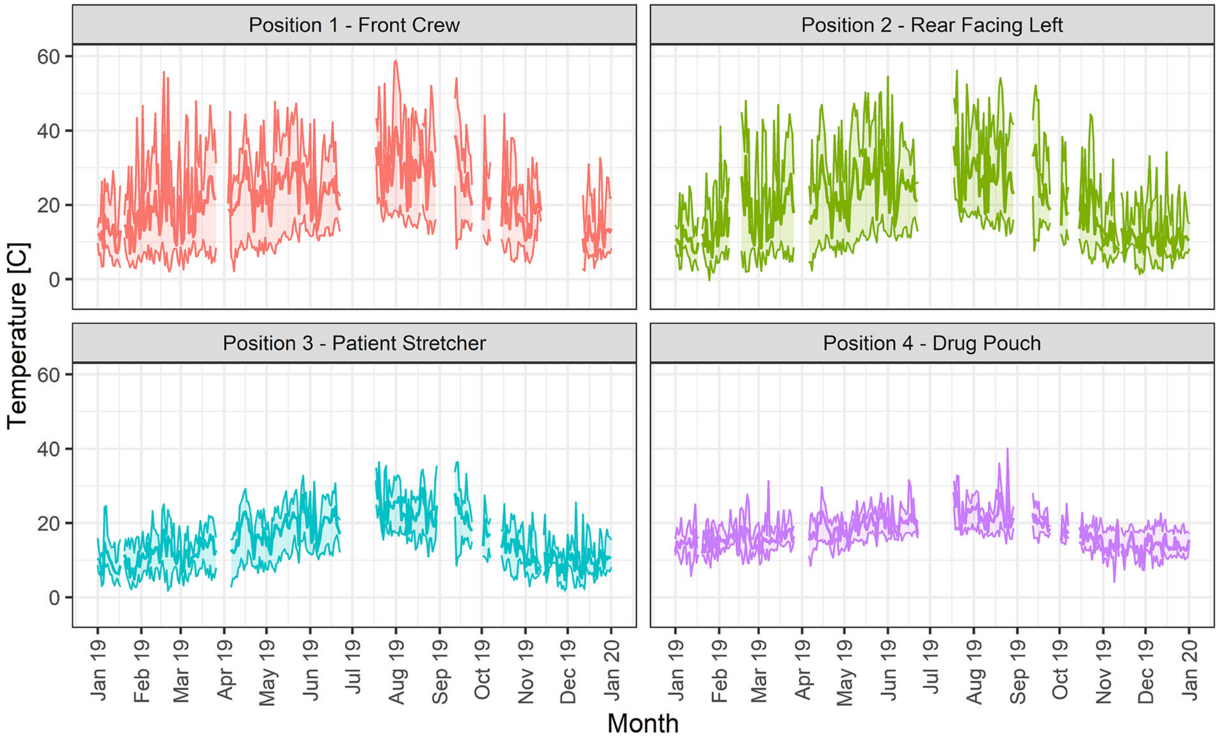

FIGURE 2 Daily daytime temperature mapping showing minimum, maximum, and MKT during the 12- month period

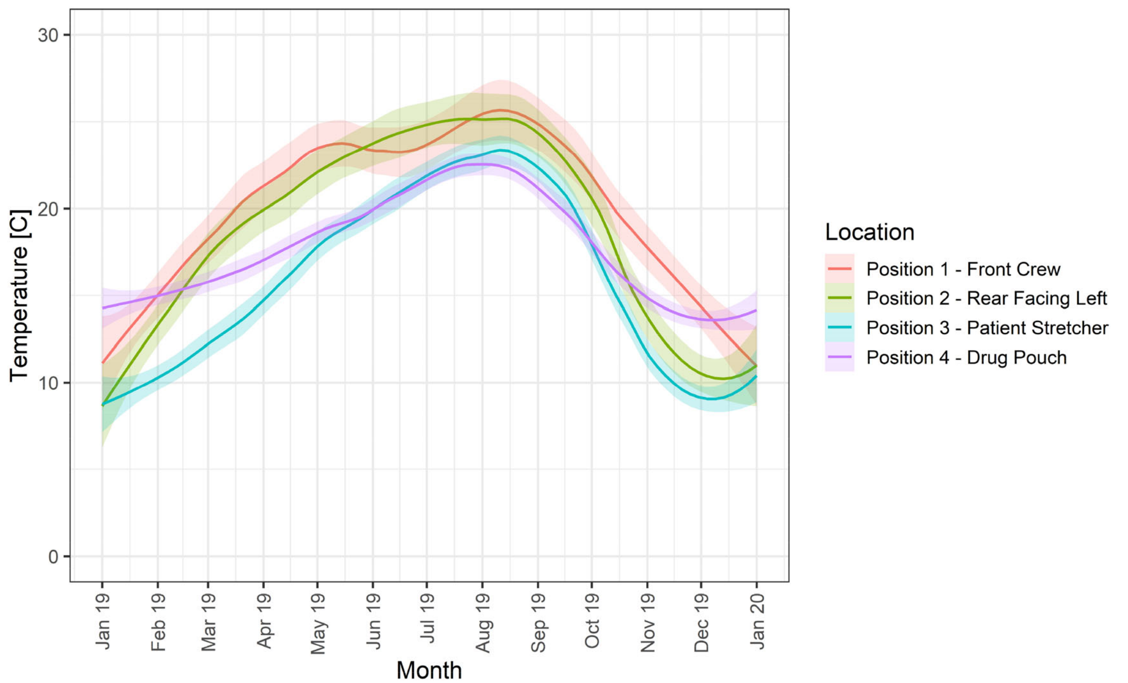

FIGURE 3 Smoothed daytime MKT for four temperature loggers during the 12-month period

location with the lowest MKT and temperature range during the day was position 3 next to the patient stretcher.

The inside of the drugs pouch at position 4 regularly exceeded the recommended drug storage conditions of 15–25°C. The minimum recorded temperature during the

TABLE 1 Annual temperature ranges and mean kinetic temperatures (shown in °C) by day and night

Logger	Location	Day/night	Min temp	Max temp	Temperature variation	MKT
Position 1	Front crew	Day	1.9	60.6	58.6	24.8
		Night	1.9	37.5	35.6	13.9
		All	1.9	60.6	58.7	20.9
Position 2	Left facing rear	Day	−0.3	56.2	56.4	22.4
		Night	1.3	35.8	34.5	12.5
		All	−0.3	56.2	56.4	18.8
Position 3	Patient stretcher	Day	1.7	36.4	34.6	16.9
		Night	0.9	32.7	31.7	12.6
		All	0.9	36.4	35.4	15.0
Position 4	Drug pouch	Day	4.2	40.1	35.9	17.9
		Night	7.1	30.1	23.0	16.8
		All	4.2	40.1	35.9	17.3

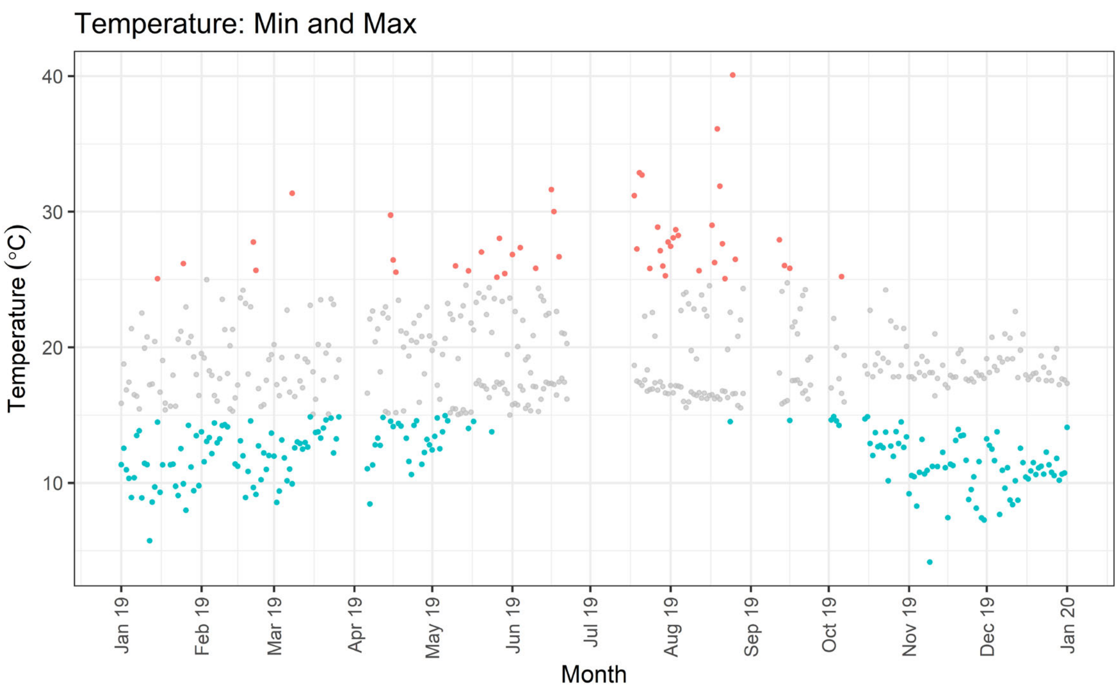

FIGURE 4 Temperature monitoring inside an insulated drug pouch. The red dots correspond to days on which the temperature exceeded 25°C, and the blue dots correspond to days on which the temperature fell below 15°C

day was 4.2°C soon after loading but rose to 40.1°C during the summer, see Figure 4. Overall, of the 302 days on which temperature were recorded, there were 47 days (15%) during which the temperature of the drug pouch sensor exceeded 25°C and 192 days (63%) during which the temperature fell below 15°C. However, the temperatures never fell below 2°C, the recommended lower limit for LyoPlas-N storage.

The trial intervention containers were loaded into the air ambulance for daytime shifts and transferred to the air base at night. The container location was close to position 3. Despite recording a maximum ambient temperature of 36.4°C here, the internal blood box data logger confirmed that red cell storage temperatures were maintained between 2°C and 6°C well beyond the advertised 48 h.

4 | DISCUSSION

This is the first study of its kind in the United Kingdom. It confirms that even in a temperate climate there is considerable temperature variation within an air ambulance during a 12-month period. The use of a conventional drug pouch mitigated these extremes; however, the upper limits of ideal storage conditions for common resuscitation drugs was exceeded during 15% of the study days. Lower temperatures were more common, with 63% of days recording temperatures below 15°C but always above 2°C. These findings echo those of other studies. O'Donnell and Whitfield analyzed temperature variability in drug storage areas for 2-week summer and winter periods in the mid-Atlantic region.[7] They showed that both the medication drawer and bag recorded temperatures that frequently fell outside the recommended range. Earlier studies by Szuczs in the United States had shown that temperature excursions occurred 37% of the time in summer and 83% during winter.[9] Despite the extreme temperatures seen in many pre-hospital environments, including during commercial aviation, Kupper et al. concluded that most drugs can be used after temperature stress of limited duration. However, they recommended that drugs be replaced at least once a year.[3] Further mitigation measures include monitoring and verifying temperature profiles, storing insulated portable carrying cases in climate-controlled areas when not in use, regular stock rotation, and considering temperature exposure when "parking" vehicles, whether they are ground or air platforms.[10]

4.1 | Helicopter thermal environment

The study was performed as part of the baseline evaluation of a newly commissioned civilian air ambulance. The H145 is a twin-engine, light utility helicopter. It is marketed for a range of roles including emergency medical services (EMS). The configuration in this study was one stretchered patient with accompanying medical staff. The cabin is accessed through a sliding door on either side, and the cargo area through the large clamshell doors at the rear of the cabin. Considerable variations in internal temperatures were already well recognized. The temperature reflects the sum of variables such as seasonal weather conditions, helicopter activity, and internal temperature adjustments. The heating is usually provided by directing hot air from the gas turbine engine compressor section into the cabin. Cooling is normally by opening a cabin window, door, or vent. Figure 3 shows that the daytime internal temperatures varied according to the seasons. Our air ambulance, as with most U.K. civilian air ambulances, is not licensed for night flying and is therefore under cover at night when temperatures are most likely to fall. However, practice varies across the globe, and consideration should be given to optimizing storage throughout the 24-h period for blood, "dried" plasma, and drugs.

4.2 | Cold-chain management

Blood is a temperature-sensitive material and strict guidance exists for the storage and transport for distribution outside the hospital. There are some variations between countries, but most cold-chain solution companies refer to a transport standard of 1–10°C, and storage at 2–6°C. The advent of passive transport solutions with phase-change materials and other technologies has revolutionized pre-hospital transfusion. We have demonstrated that such thermal packaging is a definitive solution to keep blood at the proper temperature inside a civilian air ambulance. However, we were keen to explore other options for plasma. The Credo ProMed™ 22 was chosen for Lyoplas-N, which can be stored between 2°C and 25° C, not only to comply with trial regulatory requirements for an interventional medicinal product but also to accelerate the reconstitution of Lyoplas-N. However, the use of two boxes, each with an unladen weight of approximately 4 kg, imposed a logistical burden on the small helicopter emergency medical service (HEMS). The ergonomic problems of using "heavy boxes" have previously been identified by dismounted military foot patrols carrying blood and LyoPlas.[6]

4.3 | Implications for pre-hospital transfusion

The air ambulance is a relatively "austere" environment. However, pre-hospital transfusion can be successfully delivered using appropriate thermal packaging and cold-chain management. An increasing range of commercial options offer a balance between weight, volume, and duration of temperature control. Pre-hospital transfusion can be further simplified by using pre-thawed or liquid plasma together with red cells, or whole blood.[11] Whereas these all require stringent storage conditions with continuous monitoring, lighter, simpler solutions could be considered for dried plasma together with tolerance of temperature excursions. The recommended shelf-life of LyoPlas-N is 15 months when stored optimally at 2–25°C. However, a recent small evaluation of stability under pre-hospital conditions gives greater confidence for shorter storage outside of these guidelines when exposed to high temperatures.[12] In our study, a simple insulated drug pouch partially mitigated the variation in temperature, but we suggest better thermal packaging during seasonal peaks rather than reducing the shelf-life. An alternative approach is moving the critical care packs or drug pouches to a more controlled environment when not on task. However, the preferred concept of operations when using this small airframe was to minimize handling of blood and drugs. Reduced handling on and off the helicopter improves the response time and minimizes the risk of error.

4.4 | Temperature monitoring and mapping

We suggest that drug pouches be positioned in the most appropriate area, both providing ease of access and considering the ambient temperature. Temperature mapping is a well-established concept in blood banking and medicine management; however, it is a novel approach for pre-hospital transfusion. Mapping is normally done for a short period of perhaps 2 weeks and establishes the temperature distribution within a zone and locates hot and cold spots. An initial mapping exercise is normally carried out before use under representative conditions. We suggest that temperature mapping of the transport vehicle could be used to support pre-hospital transfusion as a baseline before service developments and purchase of thermal packaging. All blood should be monitored during transport according to regulatory requirements. We had done this previously for each thermal container. However, the introduction of individual blood bag monitoring has enabled red cells to be returned to stock and has further minimized wastage.

4.5 | Limitations to study

The location of data loggers was restricted to positions where they could be safely secured. Temperature monitoring was discontinued during logger recalibration and vehicle maintenance. The cargo compartment is the subject of further mapping studies and is not included here. Airfield meteorological details were not available for Cosford (elevation 248 ft, reference temperature 20°C), and therefore data from Shawbury were used (elevation 272 ft, reference temperature 20°C). Data were collected on only one air ambulance platform, but we anticipate that the principles apply to others. However, risk assessments should be made using local data and validations.

5 | CONCLUSIONS

Temperature mapping of an air ambulance in the United Kingdom showed significant temperature variation within the helicopter. The temperatures were most dependant on the position, with values reaching 60°C in the cockpit. We have demonstrated that despite such relatively austere conditions, thermal-controlled packaging could ensure protected transport of blood. In contrast, extremes of temperature could be insufficiently attenuated by a standard drug pouch. We suggest that thermal protection, monitoring, and management are essential for the optimal delivery of pre-hospital transfusion, even in a temperate climate.

ACKNOWLEDGMENTS

We thank the RePHILL trial team together with the crew and staff of the Midlands Air Ambulance and its charity. We are also grateful to Dr Emma Watkins, colleagues from DSTL, and Lt. Col. G Fitchett for their valuable comments, and the Met Office, Larkhill, UK, for their contributions. HS is funded by the NIHR EME programme EudraCT No: 2015-001401-13. This report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the Air Ambulance, NHS, NIHR, or the Department of Health and Social Care.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

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How to cite this article: Smith H, Doughty H, Bishop J, Herbert M, Nash M. Temperature mapping in an air ambulance helicopter: Implications for the delivery of pre-hospital transfusion. Transfusion. 2021;61:S206–S213. https://doi.org/10.1111/trf.16517