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Challenges of cold chain quality for routine EPI in south-west Burkina-Faso: An assessment using automated temperature recording devices

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ABSTRACT

Background: Abnormal temperatures are a major issue for vaccines within the Expanded Program of Immunization in tropical climates. Prolonged exposure to temperatures outside the standard +2 °C/+8 °C range can impact vaccine potency.

Methods: The current study used automatic temperature recording devices (Testostore 171-1©) to monitor cold chain in remote areas of Western Burkina Faso. A series of 25 randomly selected health centers representing 33% of the existing 176 EPI facilities in Western Burkina Faso were prospectively assessed for eight months in 2015. Automatic measurements were compared to routine temperature loggers and vaccine vial monitors (VVM).

Results: The median age for all refrigerators was 9 years with 10/25 (42%) older than 10 years. Adverse temperatures were recorded in 20/24 (83%) refrigerators and ranged from −18.5 °C to +34.2 °C with 12,958/128,905 (10%) abnormal hourly records below +2 °C and 7357/128,905 (5.7%) above +8 °C. Time of day significantly affected the rate of temperature excursions, with higher rates from 00 am to 06 am ($p < 0.001$) for low temperatures and 10–12 am ($p < 0.001$) and 13–16 pm ($p < 0.001$) for high temperatures. Abnormal temperatures lasted from 1 h to 24 h below +2 °C and 13–24 h above +8 °C. Standard manual registers reported only 182/2761 (7%) inadequate temperatures and VVM color change detected only 133/2465 (5%) disruptions. Reliability of the refrigerators ranged from 48% to 98.7% with a median of 70%. Risk factors for excursions were old age of the refrigerators, the months of April and May, hours of high activity during the day, and health staff-associated factors such as inappropriate actions or insufficient knowledge.

Conclusion: Important cold chain reliability issues reported in the current study in Western Burkina Faso raise concern about vaccine potency. In the absence of systematic renewal of the cold chain infrastructure or improved staff training and monitoring, antibody response assessment is recommended to study levels of effective immunization coverage.

1. Introduction

Vaccines are highly cost effective biological substances in the first lines of public health strategies against infectious diseases. The World Health Organization (WHO) recommends storage and transportation of all vaccines except oral polio vaccine at a temperature of 2–8 °C [1]. A systematic literature review conducted in 2007 has shown that vaccine get exposed to freezing in 14–35% of cases during transportation [2]. When all segments are considered, 75–100% are exposed to freezing [2]. Failure to maintain a safe temperature range by overheating or freezing may lead to the loss of vaccine potency [2–4]. Even if they were potent upon arrival, vaccines might lose their potency at the health centers [5] and immunization programs might vaccinate their population with ineffective products [6]. Keeping vaccines potent in all circumstances throughout the supply chain without exposing those to adverse temperatures and the consequent risk of nullifying their effect or inducing Adverse Events Following Immunization (AEFI) is

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everywhere a challenge [2,7–10] since the beginning of the Expanded Program of Immunization (EPI). Exposure issues most often relate to lack of continuous monitoring systems for temperature-sensitive vaccines, inappropriate storage equipment such as refrigerators and cold boxes, inadequately trained staff and failure to comply with procedures [11,12]. With new temperature sensitive vaccines being regularly added to EPI such as the Rotateq©, the PCV13, and the MenAfriVac© recently introduced into Burkina Faso's routine EPI, there is an increasing need for cold chain capacity and adequate management to maintain vaccine quality. Primary healthcare providers should have adequate cold chain management knowledge. However, most of the health centers lack trained personnel and sufficient budget for maintenance [13,14].

Traditionally in routine EPI, cold chain monitoring includes bi-daily temperature reporting of instant readings into health center registries from metal-blade or Fridge-tag© thermometers [3,15] and qualitative monitoring using Vaccine Vial Monitors (VVM) checked for color change before use. Automated recording devices such as the « Testostore 171-1© » (Testo), have been used [16,17] in Sub-Saharan countries to provide continuous measurements under predetermined frequency allowing an accurate and sensitive determination of temperature variations over time. While vaccine manufacturers and regulators work towards a future where the vaccine supply chain is without refrigeration, equipment developers and policy makers are engaged in assessing and introducing improvements to achieve more reliable cooling and less burdensome procedures.

To determine EPI capacity to deliver effective and reliable vaccination to the population in a peripheral area in Western Burkina Faso, we have used Testo recorders to conduct a thorough assessment of the cold chain in routine EPI, its management procedures, the training level of its managing staff, and its reliability to maintain vaccines potent.

2. Methodology

2.1. Geographical and operational context

The assessment area spreads over 25,500 km^2 (9.4% of the total surface of the country) around the city of Bobo-Dioulasso and harbors a population of 1,900,000 inhabitants (10.6% of total population of Burkina Faso) (Fig. 1). EPI's target population in the area was approximately 7156 children under 12 months and 7039 pregnant women. Routine EPI service in the *Hauts-Bassins* area is delivered through 176 *Centres de Santé et de Promotion Sociale* (CSPS), among which 25 (14%) were randomly selected and prospectively

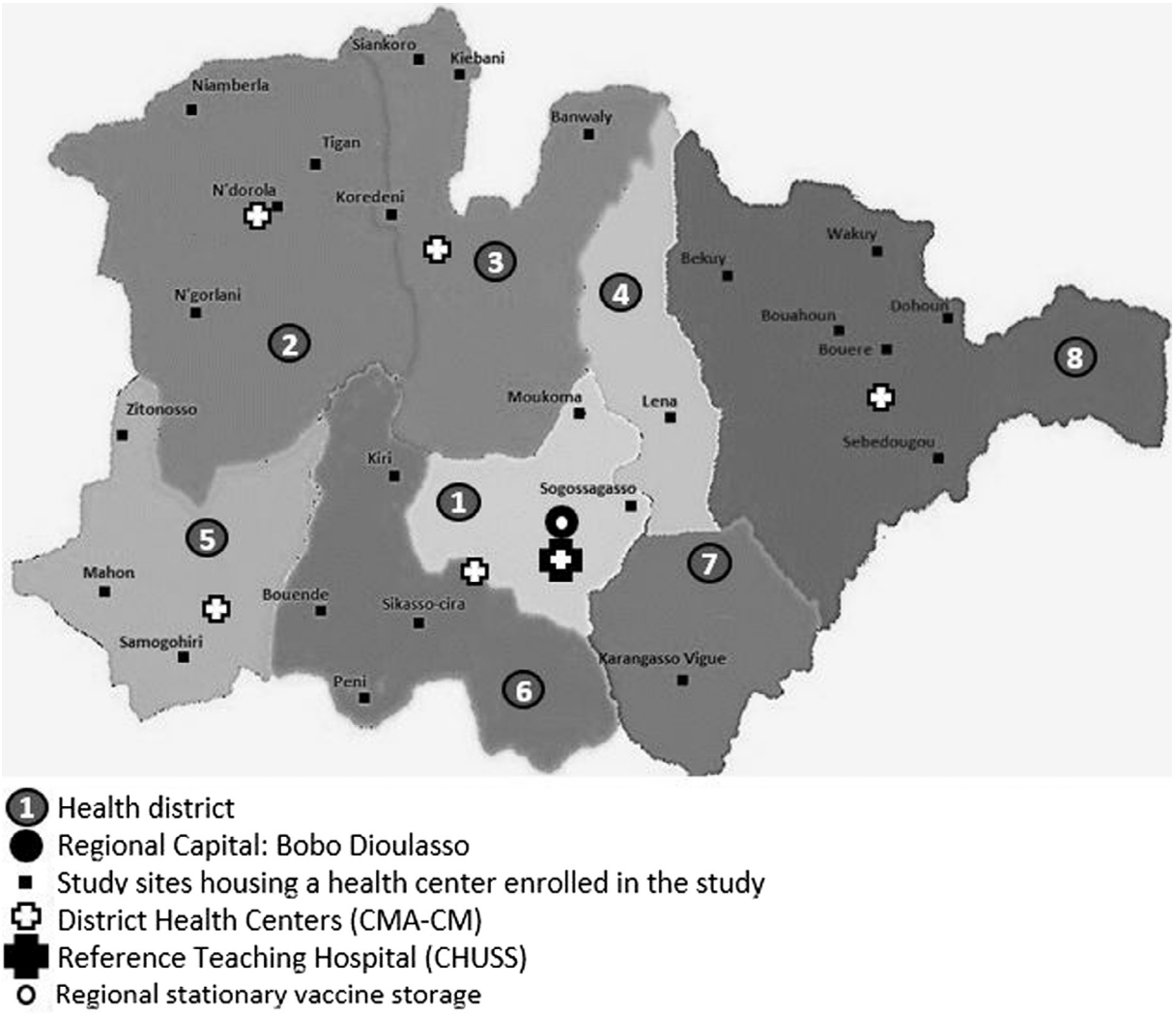

Fig. 1. Geographical distribution of the 25 randomly selected CSPS type health centers across the 8 health districts in the *Hauts-Bassins* area.