Feasibility of Vital Sign Assessment by Community Health Workers during Antenatal Care Community Outreach

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Table of abbreviation

PR	Pulse Rate
RR	Respiratory Rate
IRB	Institutional Review Board
UNZA	University of Zambia
CHW	Community Health Worker
LMIC	Low- and Middle-Income Country
WHD	Wearable Health Device
ANC	Antenatal Care
FDA	Food and Drug Administration
BP	Blood Pressure
PPG	Photoplethysmograph
SPO2	Blood Oxygen Saturation
IDI	In-Depth Interviews
RA	Research Assistant
NHRA	National Health Research Authority
ZAMRA	Zambia Medicines Regulatory Authority

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1.0 Introduction

Continuous vital sign monitoring is a basic tenet of specialized care in the developed world that is vastly underutilized during hospital or clinic admissions or outpatient routine visits in most low-and-middle income countries (LMICs). Despite the positive outcomes associated with vital sign monitoring (i.e., increased survival-to-discharge rates, lower complication rates and shorter length of stay in hospital),[1] the prohibitive costs of conventional patient monitors and the difficulty in maintaining complex medical equipment limit its practice in the developing world.

Wearable health devices (WHDs) are increasingly helping people better monitor their health status both at an activity/fitness level for self-health tracking and at a medical level providing more data to healthcare providers to increase the potential for early diagnosis and guidance of treatment. Key advancements in technology are enabling the creation of smaller computers than ever before; allowing wearable technology to incorporate miniaturized systems to enhance the quality and convenience of patient care.[1] Advances in materials science, chemical analysis techniques, equipment design and manufacturing methods have further laid the foundation for the continuous evolution of wearable systems over the years.[2]

WHDs when properly designed, implemented and adopted can provide ample benefits for healthcare providers and patients. Wearable technologies like Apple watch, Fitbit, Jawbone, ViSi Mobile and Vital Connect wireless patch have been used in tracking personal physiological and biological parameters for routine activity performance and/or clinical monitoring.[3,4] These devices collect data such as heart rate, stress levels, obesity, oxygen saturation, blood pressure and calories; and serve a broad range of use cases from newborn to elderly patients in different settings such as hospitals, nursing homes and homecare settings.

Measurement of vital signs in both in- and out-patient departments and during community outreach activities is necessary to assess the clinical situation of the patient and capture early warning scores for deterioration. The currently practice in most LMICs is for a clinician to take routine vital sign measurements intermittently and manually record these on a clinical chart. However, this leaves a lot of room for missed detection of early warning scores. Delays in diagnosing clinical deterioration prevent clinicians from taking corrective actions and are associated with increased complication rates and mortality. The use of wearable devices for long term monitoring is intended to provide instant diagnosis of acute events that will in turn lead to more effective and timely treatment of patients.[5] Furthermore, the situation becomes more dire during community outreach activities (i.e., child health week, community ANC outreach, etc.), which are usually conducted by limited clinicians and several community health workers (CHWs).

In contrast to the traditional monitoring devices that have been in use in clinical settings, WHDs may be more suited to the constraints of low-resources settings. Conventional medical equipment frequently fail in health facilities in LMICs due to complex design and specifications, and environmental constraints including power instability, internet access, space limitations and availability of spare parts. This calls upon the need for more feasible innovations to improve on the quality of care for people living in LMICs. WHDs offer a promising solution.

Currently, due to lack of medical supplies, most ANC clinics – within the health facilities or during outreach activities – do not monitor for vital signs and blood pressure among pregnant women. While many devices exist, their ease of use and high-cost, including maintenance costs, hinder screening and monitoring programs in low resource settings. Accurate and low-cost vital sign monitoring devices are required to improve identification and treatment of women with danger signs during their routine ANC visits. To meet the growing demand for vital sign monitors during the COVID-19 pandemic, Neopenda has adapted an affordable, wearable, wireless vital sign monitoring solution (neoSpot™), that measures temperature, respiration rate, blood oxygen saturation, pulse rate, and blood pressure.

1.1 Previous research on the neoSpot™ product

The neoSpot™ system is a new prototype in the series of vital sign monitors designed by Neopenda. The product is an iteration of the current vital signs monitor, neoGuard™, which provides continuous measurement of pulse rate (PR), peripheral blood oxygen saturation (SpO_2), respiratory rate (RR) and temperature to patients in tertiary care settings. The neoSpot™ system has been developed to capture instantaneous readings in settings such as community outreaches or lower-level health facilities, where reliable vital sign measurement equipment is not readily accessible. Since the new product will comprise of similar hardware and algorithms to its precursor, neoGuard™, it is expected to perform at the same level of accuracy for measurement of PR, SpO_2, RR and temperature. Measurement of an additional parameter, blood pressure (BP), is in the early stage of development and will add substantial value to the previous product. The data generated from this study will help in the final integration of BP measurement to the neoSpot™ system.While this will be the first field study on neoSpot™ itself, related research has been conducted on the precursor system, neoGuard™, as detailed below. Our path to evaluating and developing neoSpot™ into a commercial product will follow a similar pathway.

Table 1. *Research history of Neopenda's wearable vital signs monitors*

Timeline	**Location**	**Device Version**	**Description**	**Purpose**	**Sample Size**	**Status**
Jul 2019	TMC, Boston, MA, USA	neoGuard V1.0	Pilot study	Evaluate and refine signal quality	22 neonates	Complete
Oct 2019	Jinja RRH	neoGuard V2.0	Pilot study	Evaluate preliminary accuracy	27 infants and stable neonates	Complete
Sep 2020	Clinimark Laboratories	neoGuard V3.0	Accuracy study	Validation of final accuracy	15 healthy adults	Complete
Oct 2020	UCSF Hypoxia Lab	neoGuard V3.0	Accuracy study	Validation of final accuracy	15 healthy adults	Complete
Feb 2021	Jinja RRH	neoGuard V3.0	Feasibility study	Evaluate preliminary accuracy	30 adult patients	Complete
Mar-May 2021	Kenya	neoGuard V3.0	Feasibility study	Evaluate feasibility and efficacy	172 neonates	Complete

Mar-May 2022	Nigeria	neoGuard V3.0	Feasibility study	Evaluate feasibility and efficacy	~225 neonates	Ongoing
Apr 2022 – Apr 2023	Kenya	neoGuard V3.0	Interrupted time series study	Evaluate clinical impact and cost-effectiveness	~3,000 neonates	Ongoing
Jun-Sep 2022	Zambia	neoSpot V1.0	Feasibility study		~100 pregnant women	Submitted for IRB approval

V3.0* - these are commercial equivalent units

2.0 Statement of the problem

Few innovations are currently available to help overburdened clinicians and community health volunteers better manage the high quantity of patients. In the neoSpot solution, researchers are taking a known and proven science of clinical vital signs monitoring, and re-imagining it for the users and the constraints of low-resource environments. The current practice at most ANC clinics in LMIC settings is intermittent, manual measurement of vital signs or blood pressure. Nurses and Community Health Volunteers must manually count heart beats or breaths—at best every few hours—or share the few available, functioning devices, such as pulse oximeters, which only intermittently measure oxygen saturation and pulse. This practice is insufficient for early detection of danger signs and optimal management of critical care patients.

Furthermore, gold standard monitors used in the U.S. and other high-resource areas, such as from Covidien, Masimo or Philips, are prohibitively expensive, inappropriately designed, and challenging to maintain or repair. They fail to meet unique sets of environmental constraints such as unstable power supply, lack of internet access, and heat & humidity. If donated to a low-resource environment, they quickly fail or end up obsolete within short periods of use. Existing products in the global health space do not meet the need for continuous monitoring in the clinical setting (e.g. Lifebox pulse oximeter), only measure 1 or 2 parameters (e.g. BempuTemp Watch and NeMoCare) and/or are geared toward diagnosing specific conditions (e.g. pneumonia diagnostics like the Philips CHARM).

Neopenda's solution intends to improve the quality of patient care over the standard-of-care and addresses the unmet need for a feasible way to monitor multiple key vital signs. The neoGuard™ product is designed to operate in dynamic clinical environments with space constraints, unreliable power supply and limited numbers of health staff. At less than a 1/10th of the average cost of conventional patient monitors ($230 vs. $2,500), the neoSpot™ technology provides and affordable and sustainable vital sign monitoring solution. The wearable band is bio-compatible, reusable and easy to sterilize, ensuring that there are no additional costs spent on single-use accessories.

NeoSpot™ has been developed and tested with feedback from more than 100 health workers with varying levels of clinical expertise and technical prowess to ensure that it is intuitive to a wide range of users including lower skilled personnel like nursing assistants and community health workers in remote settings. This human-centered design approach has been used to preempt the challenge of usability that can occur when transitioning new technologies to diverse users in different cultural contexts.

3.0 Rationale/Justification

Many novel interventions are introduced to LMICs with little-to-no evidence of their successful performance, applicability, effectiveness, and feasibility and acceptability by the providers. There is need for robust testing and evaluation of innovations to ensure that they serve their intended purposes before they are introduced into common practice. The justification for this study is the need to generate evidence of feasibility and acceptability for neoSpot™ on pregnant women, so as to inform any changes or considerations for its use in LMIC settings. This proposed study is unique, impactful, and scalable given the immediate clinical application by CHWs during community ANC visits.

If the NeoSpot device shows to be feasible and acceptable for use by CHWs and by pregnant women, there would be sufficient evidence to support the use of the device to measure vital signs and blood pressure among pregnant women. This study has the potential to improve access vital signs measurements during both community and clinic activities as it would increase identification and improve treatment of pregnant women with danger signs such as eclampsia/pre-eclampsia, fever, etc. in low-resource settings and would serve the larger aim of reducing maternal and neonatal morbidity and mortality.

4.0 Theoretical/conceptual framework

This study is a feasibility trial, which is designed to demonstrate the feasibility and acceptability of this novel platform when used by community health workers (CHWs) on pregnant women to check their vital signs during community ANC outreach activities.

5.0 Literature review

Patient vital signs monitoring is key to disease management and timely intervention. Measurement of vital signs in in- and out-patients is necessary to assess the clinical situation of the patient and to detect clinical deterioration at an earlier stage, which allows clinicians to take corrective actions.[7] WHDs like the ViSi Mobile Wireless Sotera and Health Patch Vital Connect that can be used for continuous collection of physiological data have been cleared by the US Food and Drug Agency (FDA) for home and hospital use. In a 2017 feasibility study, Weenk et al. concluded that both ViSi Mobile and Health Patch were promising for continuously monitoring vital signs in hospitalized patients, if the frequency and duration of artifacts could be minimized. The devices were well received and comfortable for most patients.[3]

In a subsequent study, ViSi Mobile and Health Patch were tested regarding Modified Early Warning Scores (MEWS) calculation and compared to nurse measurements and detection of high MEWS in periods between nurse observations; findings suggested that the wearable devices were more accurate than nurses' observations.[9]

A few other studies about continuous monitoring with wearable technologies on general ward and ICU patients have been published. Martine et al. validated the accuracy of a wireless patch sensor to measure heart and respiratory rate in postsurgical patients at high risk for complications. The novel patch showed high accuracy for measurement of heart rate but accuracy for respiratory rate was outside acceptable limits.[10]In a feasibility study on wearable biosensor devices carried out in Rwanda, researchers observed that wearable devices could be feasibly implemented and that the units provided accurate vital sign measurements in critically ill paediatric and adult patients with sepsis.[11]

Results from a 2018 study carried out by Downey et al. showed that patients on the surgical ward found the monitoring device to be acceptable in terms of comfort and perceived an enhanced sense of safety.[12]Pavic et al. noted that remote monitoring of health care status in palliative cancer patients with a limited life expectancy was feasible and patients were able to handle the smartphone and sensor- equipped bracelet.[13]An early evaluation of the agreement between the SensiumVitals digital patch and a widely used clinical monitor was conducted between Oct 2009 - Jul 2010. Overall agreement for respiration and heart rate measurements between digital patch and clinical monitor was satisfactory.[14]

Multiple studies have been conducted on the Bio-Beat medical smart-monitoring technology, demonstrating that in all of the tested statistical parameters, the Bio-Beat application is almost equal to the gold standard device, with a correlation of 98.9%.[15]

In summary, the published literature on WHDs suggests that these innovative technologies and digital health systems may offer a viable solution towards an affordable, sustainable and scalable model of patient monitoring in resource-limited settings.

6.0 Research questions

1. Is the NeoSpot a feasible, acceptable, and easy to use device when used by CHWs during community ANC outreach activities?
2. Can photoplethysmograph (PPG) sensor data from NeoSpot be used to develop an accurate and reliable blood pressure algorithm?

7.0 Specific Aims

Aim 1: To describe the feasibility, acceptability, ease of use, and perceived confidence of pregnant women and CHWs to use the NeoSpot device during community ANC outreach

The novel test device, NeoSpot will be used by 12 CHWs during community ANC outreach activities to measure vital signs among pregnant women in Lusaka, Zambia. Through in-depth interviews (IDIs), we will determine and feasibility, acceptability, and ease of use, including design feedback, of the device by 12 CHWs and 12 pregnant women.

Aim 2: To obtain raw PPG data from the prototype NeoSpot device which will be used in the development of an accurate and reliable blood pressure algorithm.

During community ANC outreach activities, CHWs will take readings with the NeoSpot device from 125 pregnant women. The raw PPG sensor data will be used to train an autonomous machine learning model to extract arterial blood pressure systolic and diastolic values.

8.0 Methodology

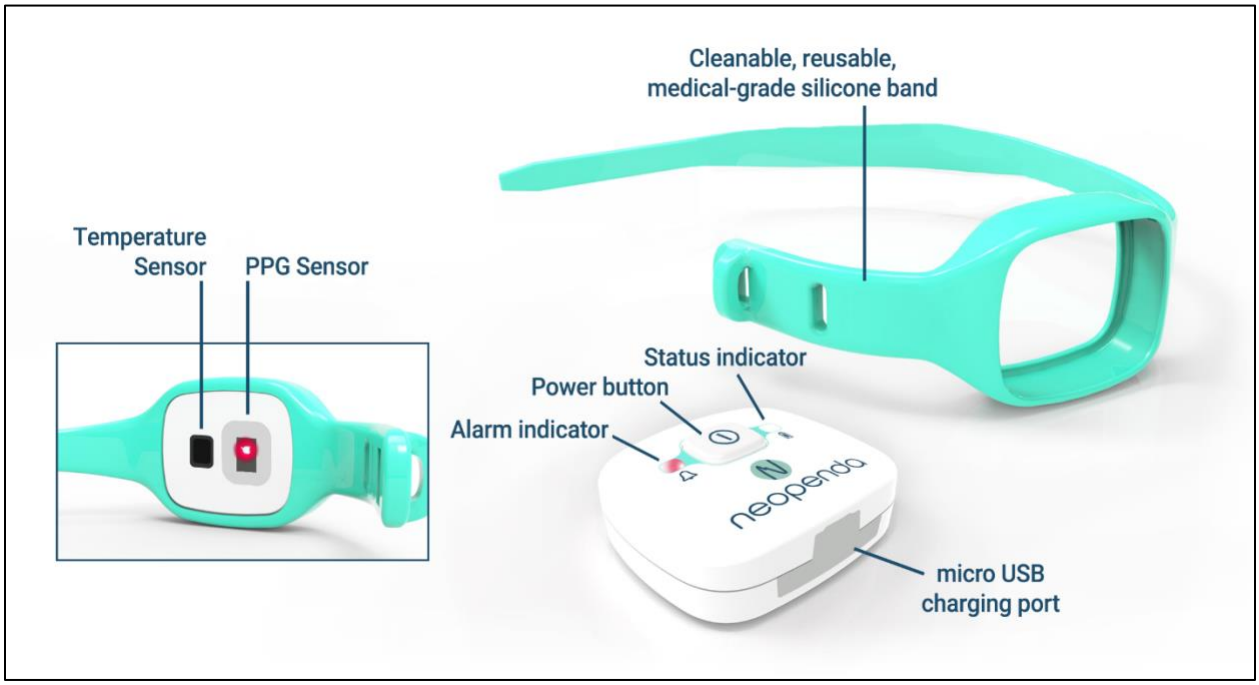
Study Design

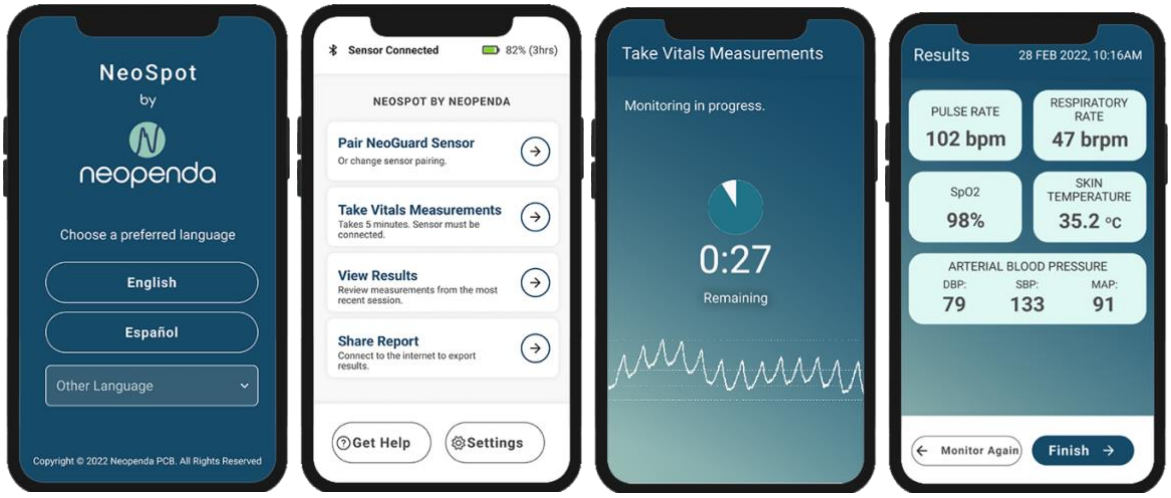
The proposed study is a pilot feasibility trial to be implemented at Kanyama 1st Level Hospital and its wider catchment area among a prospective cohort of pregnant women during community ANC outreach activities. The test device, NeoSpot, will be used by CHWs and will monitor vital signs and blood pressure in each participant.

The neoSpot™ device is a 5-in-1 wearable vital signs monitor designed to measure temperature, pulse rate (PR), respiratory rate (RR), blood oxygen saturation (SpO_2) and blood pressure. It is currently under the final stages of development by Neopenda, PBC (Chicago, IL, USA) under international medical device standards and for feasibility in low-resource settings, including:

low-power design, safe re-usability, ruggedness, portability, and ease of use. The device weighs approximately 15 grams and measures 42 x 36 x 14 mm. It contains two non-invasive sensors: an optical reflectance pulse oximeter and a digital temperature sensor. These sensors measure signals from the surface of the patient's skin, and algorithms within the device calculate the pulse rate, respiratory rate, SpO_2, blood pressure and temperature. The device will be synced with a smartphone, which will be provided to the CHWs by the study.

The device is made of medical grade polyetherimide plastic and can be worn through an adjustable band. The bands are made of medical-grade silicone rubber. The devices are wireless and powered by medically-certified rechargeable batteries. The pulse rate, respiratory rate, temperature, blood pressure and oxygen saturation data are recorded and transmitted to an app on a smart phone. Upon final validation and field testing, Neopenda will pursue CE mark certification for the neoSpot™ technology.





Study site and settings

We propose that this prospective pilot feasibility study take place at the Kaynama 1st Level Hospital wider catchment area in Lusaka, Zambia. The area records around 10,000 deliveries a year, therefore, we are confident that we will screen 125 pregnant women in our stated period.

Study Population

Aim #1

Study participants for the qualitative aim of the study will be comprised of 12 Community Health Workers (CHWs) who have used the NeoSpot device during routine government community ANC outreach activities. All 12 CHWs who consent will undergo in-depth interviews (IDIs) in addition to 12 pregnant women who have consented to participate in Aim #2 of the study (below). Study participants meeting the following inclusion and exclusion criteria will be enrolled:

Inclusion criteria

1. CHWs who have used the NeoSpot device, or
2. Pregnant women who have experienced the device under Aim #2
2. 18+ years of age
3. Willing to consent

Exclusion criteria

1. Pregnant women not enrolled under Aim #2 below
2. Unable to consent

Aim #2

Study participants will be pregnant women recruited during the community ANC outreach (n=125) on the following inclusion and exclusion criteria:

Inclusion criteria

1. Pregnant
2. 18+ years of age
3. Willing to consent

Exclusion criteria

1. Unable to consent
2. Not pregnant
3. Age below 18 years

Sample Size

Aim #1: For the qualitative aim of this pilot study, 12 CHWs who have used the NeoSpot device and 12 pregnant women who have been enrolled into the study under Aim #2 (below) will be approached and, if consented, enrolled into the study. A total of 24 IDIs will be conducted among the target population. The sample size may be increased if saturation is not reached using this sample size.

Aim #2: Twelve CHWs will be trained in the use of the NeoSpot and given the device to use during outreach activities. Potential study participants (i.e., pregnant women) will be approached

during the community ANC outreach activities. If interested, study staff will then discuss the study procedures, risks, and benefits in detail in Nyanja, Bemba, or English based on the study participant's preference. Should they be interested in the study, they will be consented. Following enrollment, the CHWs will measure the pregnant woman's vital signs and her blood pressure. A total of 125 study participants will be enrolled.

Study Procedures

Study hired Research Assistants (RAs) will approach potential study participants for both study aims and consent them for study participation. Following enrollment, for Aim #1, CHWs and pregnant women will undergo IDIs in a safe and secure location. IDIs will last approximately 1 hour and they will be conducted in the preferred language of the consented study participant. All study participants will exit the study following the IDI. For Aim #2, study staff will measure their vital signs and blood pressure using the NeoSpot, which data will be automatically stored into the smartphone provided by the study. Results of the vital signs and the blood pressure will also be shared with the clinical treatment team following screening. The treating clinicians will notify the patient of the results and, if required, refer the pregnant women for appropriate care according to local standard of care. All study participants under Aim #2 will exit the study following this stage.

Data Collection

All data for Aim #1 will be recorded on a study audio recorder and then translated and transcribed onto a word document by a study team member. Once it is transcribed and has been reviewed for completeness, the audio recording will be destroyed.

For Aim #2, PPG data will be automatically collected and stored by the NeoSpot directly into the smartphone, without the use of data collection tools. It will be stored on smartphones provided to the CHWs by the study. Following data storage, PPG data will be used to develop an accurate and reliable blood pressure algorithm for future piloting. Confidentiality of patient identifiers will be protected by using a patient identification key that will be stored separately from the data set. Each study participant will be assigned a unique study identification number. The database will be password protected, accessible only to the study PI and data analyst.

Data Analysis

Aim #1: We will conduct 24 IDIs with pregnant mothers (12) and CHWs (12) from the study sites. Sample size will be increased if thematic saturation is not reached. The study RA will conduct a total of 24 IDIs, among 12 purposively selected pregnant women from Aim #2 and 12 CHWs. IDIs will be audio-recorded, transcribed, and translated into English prior to thematic analysis using NVivo 9.0 (QSR International, Australia). We will conduct hybrid analysis using inductive reasoning to identify themes and deductive reasoning based on the suitability, feasibility and acceptability (SFA) framework.

Aim #2: PPG data will be extracted from the database and used to further develop a reliable and accurate blood pressure algorithm, which will be piloted in the near future.

9.0 Ethical considerations

There will be no obligation to participate in the study, and informed consent will be obtained from each participant who chooses to enroll. There is minimal risk for patients

included in this study. Vital signs and blood pressure testing is non-invasive, and achieved by placing a sensor on the skin. In this study, the NeoSpot device will be in place on the skin for <1minute making the risk for harm to the skin very low. Pregnant women with abnormal vital signs and blood pressure will be referred for further clinical assessment and treatment, which will be provided by the health facility at no cost to the family. The risk of these outcomes is balanced by the benefit of detecting danger signs in a pregnant women during ANC community outreach activities.

We will work hard to protect personal and health information collected in the study as described above. Like all studies there is a small risk that personal or health information could become known to others and this could cause harm to the study participants. To prevent this, research records will be kept confidential in a lockable cabinet to the maximum extent permitted by law.There may be no direct benefit to study participants. In the case that a danger sign, a benefit will be that we can communicate this finding with the pregnant woman's healthcare provider so that she can receive appropriate treatment and additional testing if needed.

The study protocol will undergo review and approval by local (UNZA-BREC, NHRA, and ZAMRA) and international (University of Alabama at Birmingham IRB) regulatory authorities. There are no direct costs to study participants. Participants will receive compensation for their time in the form of cash valued at 100 ZMK.

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