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PROJECT FINAL REPORT

Grant Agreement number: 606088

Project Acronym: BabyCareSleep

Project title: Development of a non-invasive baby sleep monitoring and intelligent control system for the prevention of unexpected death in previously healthy babies and early detection of risky situations

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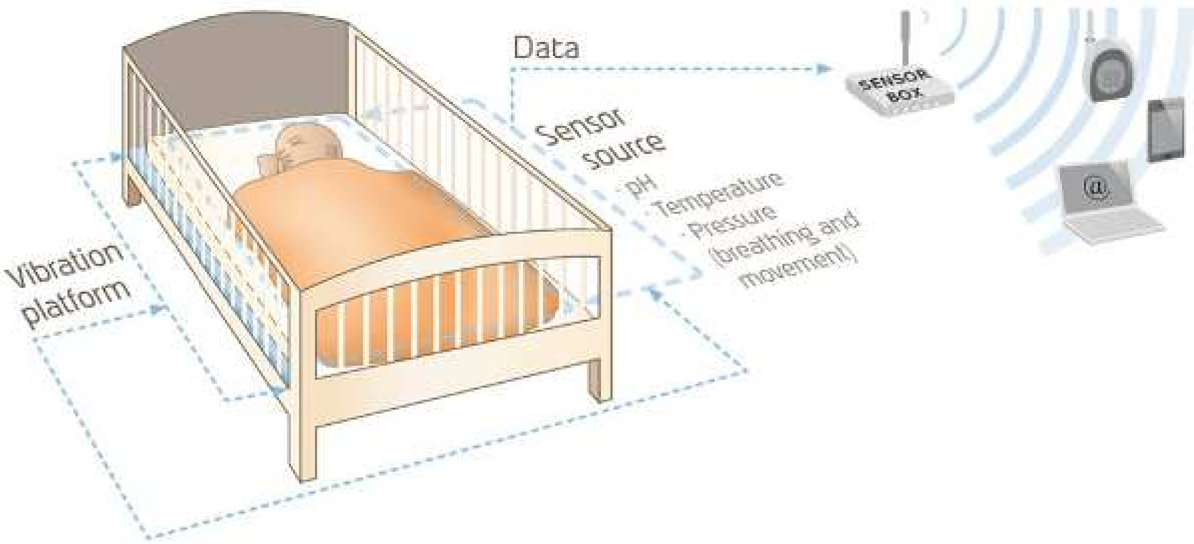
4.1 Final publishable summary report

Executive summary

BabyCareSleep project has developed a novel non-invasive intelligent system to prevent sudden unexpected death in healthy infants and an early detection of risky situations. Integrated into the baby's cot through biosensing textiles, three matrices of sensors will measure relevant biological parameters: pH sensors for gastroesophageal reflux episodes, temperature sensors for hyperthermia (fever) and movement sensors to detect movement and breathing. These biological signals enable the system to detect potential risk situations and, thus, perform the preventive actions: promoting a subcortical arousal through micro-vibrators embedded in the mattress, to re-activate baby's breathing without the need of awaking the baby.



The Baby Care Sleep algorithms for actuation have been developed in trials with 28 new born babies and validated with 6 babies from a different sample, after the development and integration of the different parts that constitute the overall system. Besides, the system has demonstrated its suitability in real-home context. The system has been lent to a family for 15 days.

The Baby Care Sleep system consists of 5 exploitable results:

R1: Smart real-time biosensing textile: A textile layer with a matrix of sensors providing the measurements of temperature and movements (respiration).

R2: Intelligent control system: The system with the communication electronics, capable of reading the sensors and providing the actuation to the vibrators.

R2: Management and control interface: A mobile app that allows the parents consult the status of the mattress sensors and provides an alert in case of detecting a risk situation.

R4: Risk assessment and actuation algorithm, providing the guidelines for the actuation of the system in case of apnoea detection.

R5: Baby Care Sleep integrated system: Integrates all of the sub-components developed in the project into a single product, providing the full capabilities of the system.

Summary description of project context and objectives

Description of the main S&T results/foregrounds

Five main results have been obtained during the Baby Care Sleep Project.

R1 Smart-real time biosensing textile

The textile sensor allows the following objectives:

- Measuring respiratory rate and the absence of breathing of the baby to detect an apnea.
- Measuring the skin temperature of the baby.

A prototype cover mattress has been produced with the optimal sensors for the application (Figure 1).

In this construction, the major material is polyester selected for its low cost and validation for use in health and medical products. The copper yarn is insulated with a strong layer of Polyurethane to avoid any contact. The open and lightweight structure offers a better comfort with thermal regulation and fits with the Babykeeper mattress concept: no fluid retention but allows pass-through.

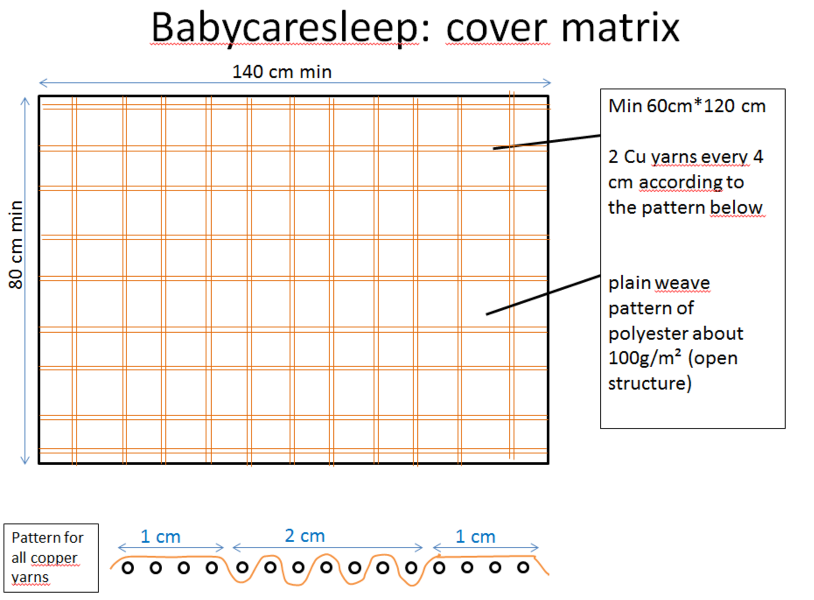


Figure 1. Schematics of the cover matrix for the textile biosensing layer.

The given pattern for the copper is taken in the weave pattern with polyester but every 2 cm the yarn makes a float. That means the yarn is not taken to make a loop on the top of the textile surface. That pattern was made to facilitate the connection to the sensors. With that construction, we can easily catch the yarn and solder it to the different sensors.

The copper yarn placement has been designed to allow the integration of temperature sensors in a way that they cover all the area. If the baby's head is in contact with the mattress on a round shape having a diameter of min. 6 cm, then we are sure at least one sensor is covered by the head. This is how we decided to have a space of 4 cm between each pair of copper yarns.

These dimensions should allow to fully cover the mattress area, and also to get 10 cm of textile available on each edge to attach it and connect the matrix to the electrical box. A special beam has to be prepared for this sample as we need copper yarns in both directions (Figure 2)

Since the breathing sensors are directly woven in the cover, it is necessary a first network to acquire the breathing signal from the most efficient place (according to the baby position). The signal is read in the blue little circuits (Figure 3) and transformed to be transferred from the mattress to the control box. The breathing sensors are represented in red. Each blue square is a small oscillator circuit that connects to the copper wire and is encapsulated in silicone to ensure robustness and waterproofness.

Figure 2. The textile biosensing layer over the breathable mattress.

In addition to this breathing network, there will be a second network for temperature measurement. Each little temperature sensor (Figure 3) is soldered to a horizontal wire and a vertical wire. So, the temperature can be read at each point through to a multiplexing system located on both sides of the mattress.

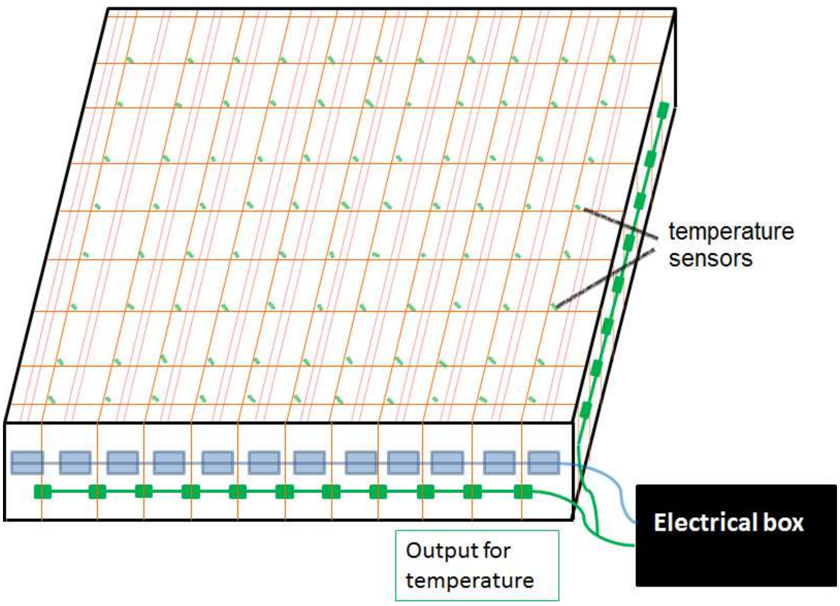


Figura 3. Schemantics of the textile layers with the temperature sensors on top.

R2. Intelligent control system

The Mattress sensors and actuators are connected to the sensor control box which is designed to attach to the Baby's cot and provide the primary interface between the sensors and the pre-installed house Wi-Fi network. The Sensor control box takes the raw temperature and breathing signals and provides signal pre-conditioning to turn the raw signals into sensible digital data that can be interpreted by the algorithms being developed and results communicated to the smartphone application.

Electrical power is used to operate the sensor control box, nonetheless it is connected via a medical approved low voltage power supply unit (EN 60601-1) to ensure that the mattress system is maintained isolated from any potentially harmful voltage sources.

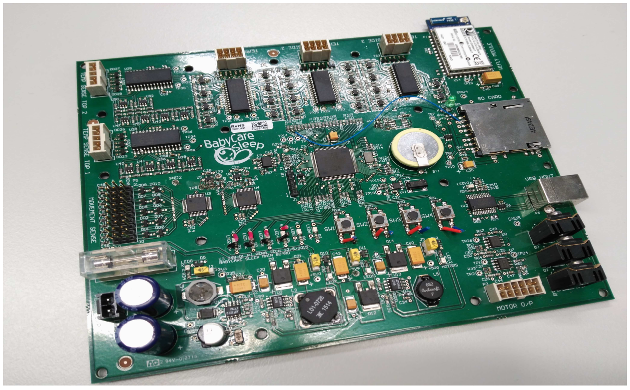


Figura 4. Electronic board for the control of the biosensig textiles of the mattress and the communication.

R3. Risk assessment and actuation algorithm

The risk assessment and actuation algorithm determines the strategy and the responsiveness of the system.

The main inputs of the system are the smart--real time biosensing textile, and the outputs are the vibration system and the management and control interface.

The overall cycle of risk assessment and actuation defines three different states of alert (figure 5):

1. Imminent risky situation.
2. Emergency.
3. Advise scenario.

These three states depend on the measurement of the sensors and the reaction of the baby.

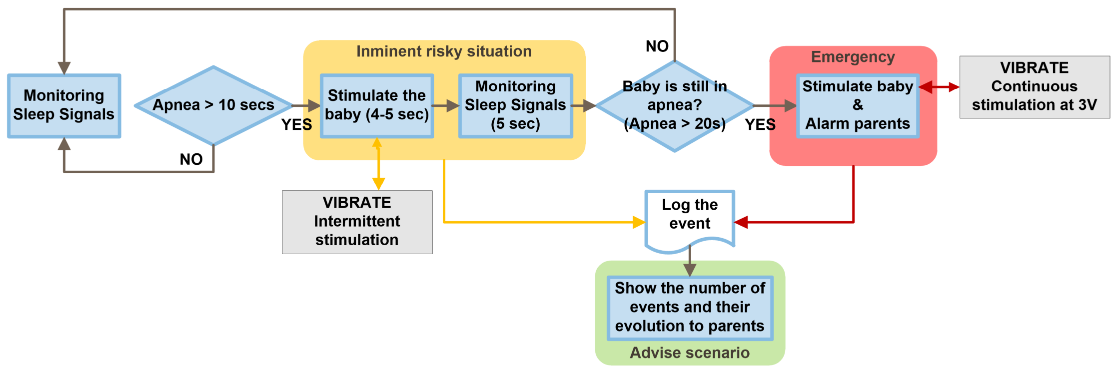


Figure 5. Algorithm for risk asessment and actuation, the three states of alert are shown in colours. Yellow for risk if an apnea is detected, red for emergency if besides the detection of the apnea there is no reaction in the baby, and finally the advise, where the events are shown to the parents.

The first state **Imminent risky situation** raises when an apnoea duration of 10 seconds or more is detected. This state triggers the vibrator that will try to produce a sub--cortical arousal without awaking the baby. If the breath is detected after the vibration, the system recovers to the rest status and produces an entry in the log of the system.

The depth of the vibration depends on the characteristics of the baby, and will be specified later.

If the baby is still in apnoea after the vibration, the system enters in the state of **Emergency**.

The aim of this state is to end the apnoea of the baby as soon as possible. Therefore, the system, in parallel will raise an alarm to advice the parents, and will be set in continuous vibration at maximum level.

Whenever the system is set to the imminent risky situation or the Emergency, it records an event in the log of the system.

The caregivers of the baby can consult the log of the system in order to assess the sleep of the baby. This is the **Advise scenario**.

This state is interesting to check if any apnoea has occurred during the sleep of the baby, and to verify the responsiveness of the system.

False positives

The algorithm of the system has been prepared to reduce as much as possible the inconveniences due to the false positives.

Most false positives occur in the imminent risk situation where the system should be able to deal with the situation in many cases.

The side effects of false positives could be an awakening of the baby, and the subsequent discomfort for the caregivers. To reduce this possibility, the level of vibration can be set--up to produce a sub--cortical arousal without awakening the baby.

Uncomfortable false positives can also be produced if the system raises an alarm. The main source of alarm related false positives are due to the sleeping posture: when the baby is sleeping in a side posture, the Baby Care Sleep system could not detect the respiration and the possibility to produce an arousal is smaller, but at the same time, this posture is not recommended for the paediatricians as it is a risk posture.

Determination of the vibration level

The right level of vibration to produce a *sub--cortical arousal* avoiding at the same time an awakening has been determined through an experiment in which 28 babies between 2 and 8 months took part.

The validation of the model has been done with 6 extra babies with the same conditions of the babies participating in the initial study. Just one awakening has been produced in the sample of babies for the validation.

The level of vibration is determined by the duration of the vibration cycle, the intensity applied to the vibrators and the rest between cycles.

The selection of the vibration level depends on the baby's sleep posture, age and gestational age.

With respect to the sleeping posture, it should be a supine posture for the correct performance of the system. Besides, this is the only posture recommended by paediatricians.

For younger babies (Figure), the vibration level can be milder. According to the model validated in the project, the decision tree (Figure) according to these values is efficient in producing sub--cortical arousals avoiding awakenings.

Therefore, when used correctly, the *Baby Care Sleep* system will be able to manage most of the situations related with apnoea, minimizing the need for caregivers to attend the baby.

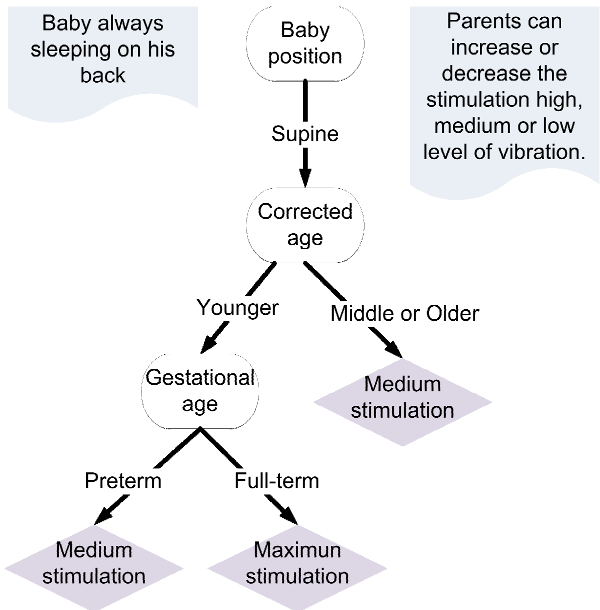


Figure 6. Algorithm for the selection of the vibration level. The algorithm depends on the corrected age and the gestational age of the mother and requires the baby sleeping in supine position.

R4. Management and control interface

An Android application has been developed for the *Baby Care Sleep* (Figure 7).

Figura 7. Splash screen for the Baby Care Sleep Android application.

The application contains recommendations to prevent *Sudden Death Infant Syndrome* (Figure 8). The purpose of the recommendations is twofold: on one hand it provides a repository of good practices to the parents and the caregivers of the baby, on the other hand, the possibility to be downloaded for a repository for public domain information, it provides an outcome for curious people as long as they are able to know the good practices and gather information about the *Baby Care Sleep* product.

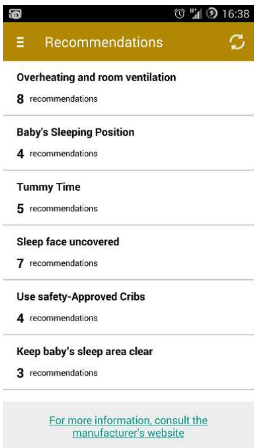


Figure 8. Example screen of the recommendations.

The App allows the communication with the mattress through a domestic WiFi network. To achieve this there is no need for a particular interface in the mattress, in order to keep the hardware as simple as possible. The only thing to be done is pressing the *set-up* button of the mattress (Figure 9), and then using the configuration menu of the App, and the wifi configuration is passed to the hardware of the mattress (Figure 10).

This is achieved through a temporary WiFi network created by the hardware of the mattress. The App will look for this temporary network and will use it to pass the information of the permanent WiFi network to be used.

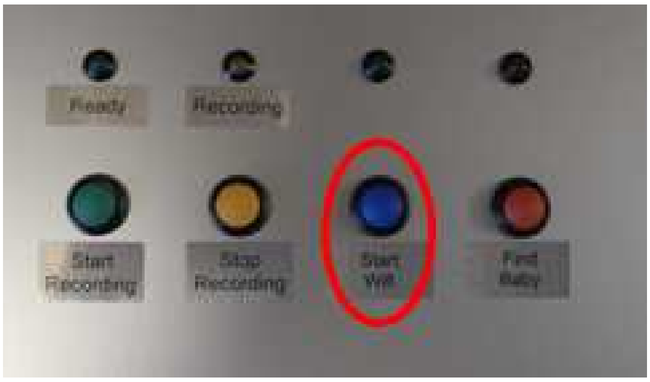


Figure 9. The button to force the set-up mode in the hardware prototype of the mattresss.

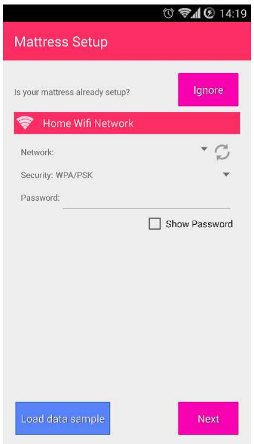


Figura 10. The connection screen of the Android App. The configuration of the wifi network is passed from the App to the mattress hardware through the use of a temporary WiFi network

Once the system is properly configured, the App can receive information from the mattress and the parents and caregivers can consult the information on-line.

The App is ready to manage information related to the body temperature of the children, the breath rate and the pH (related to the presence of threw-up of the baby) (Figure 11).

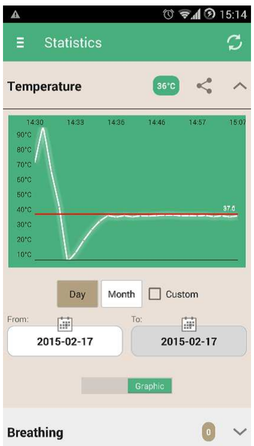


Figure 11. The app can receive information from the mattress and can display charts of the evolution of the information. The example picture shows a chart with the evolution of the temperature (with sham data).

Besides, the App allows the analysis of the log record of the system.

The log is especially important for the analysis of risks: The situations where the *Baby Care Sleep* found a possible apnoea reacted and dealt properly with the situation. This analysis can provide parents useful information and help the clinicians to understand the real status of the baby.

Alert occurs when the system detects an apnoea and it is not able to properly face the problem. It is a potential dangerous situation for the baby.

When an alert occurs the system keeps the stimulation at maximum and the Smartphone App raises an alarm informing the parents or carers of the baby (Figure 12).

Figure 12. Screenshot of an alarm. An emergency alert is shown to parents or carers.

R5. BabyCareSleep Integrated system

The integrated system provides a unified framework for all the above commented results. Despite, all results have separated exploitable characteristics, the Integrated System has a unique value of providing a unified structure to face the problem.

Besides, when a potential harmful situation is detected, the system's actuation algorithm applies the micro-vibrations to elicit the micro arousals of the baby.

Potential impact

Socio-economic impact

Sudden Death Infant Syndrome (SIDS) is the highest cause of death in the post-neonatal period (between 2nd and 6th month of life). Only in Europe, each year 2400 infants still die of SIDS (about 3000 in USA), according to the International Society for the Study and Prevention of Perinatal and Infant Death. Furthermore, as infant mortality has decreased in last decades, *Sudden Death Infant Syndrome* has increased in importance among other death causes.

This syndrome is ten times more frequent in preterm infants and occurs more frequently in infants who have had apparent life-threatening events (ALTEs) ---approximately 7 percent of infants who die from SIDS have a history of ALTEs--- and in siblings of infants who died of SIDS.

Nowadays, the number of preterm births has tended to increase. This tendency is caused by an increasing number of women deferring childbearing and by multiple births linked with fertility treatments. As a result, there is an increased risk of neonatal deaths, which has contributed in some countries to a leveling-off of the downward trend in infant mortality rates. In Europe, the prevalence rate of premature birth ranges from 5.5 to 11.4% - an average of 7.1% of all live births that means around 385 thousand of premature babies per year. Furthermore, approximately 1% infants who weigh less will die of SIDS. For a baby who is born prematurely but who weighs more than 1.58 Kg the risk of SIDS is less but still ten times higher than the overall rate (approximately four in 1,000).

SIDS happens when babies are asleep and newborn babies spend 15 hours per day sleeping. In fact, the term SIDS refer to infants who die in their sleep with no evidence of accidental asphyxia, inflicted injury or organic disease. SIDS is a multifactorial syndrome mainly related to overheating, prolonged apnoea, gastroesophageal reflux or inadequate bedding system and posture. According to the Triple Risk Model, SIDS results when three factors simultaneously influence the infant: (a) an underlying vulnerability in the infant, (b) a critical developmental period, and (c) an exogenous stressor, e.g., hyperthermia. In this model, such exogenous stressors are postulated to induce asphyxia, hypercapnia, and hypoxia.

A failure to arouse is also one of the causes of SIDS, if babies stop breathing during sleep; as a defence mechanism, they usually arouse and start breathing again. In effect, they revive themselves. However, if the baby does not arouse in time ---fail to wake up and take a deep breath to end a prolonged apnoea---, there is a second line of defense, gasping. The infant's brain stimulates slow, deep, labored breaths that temporarily restore his oxygen supply. If this mechanism also fails, the infant will die from a lack of oxygen. The importance of arousal mechanisms related to SIDS is postulated by several reports. In fact two studies have provided evidence of decreased spontaneous arousals during sleep in SIDS compared with control infants.

In principle, the parents of each one of a newborn could be a potential buyer of the BabyCareSleep system in a long-term scenario. So, our long-term global market could involve yearly around 5.4 million babies per annum, this is the number of children born each of the last three years for which data are available (2008-2010) in the EU-27.

Nevertheless, SIDS is ten times more frequent within preterm newborns, higher even in case of a extremely preterm [6]. This is the reason why we consider preterm newborn as our potential market for BabyCareSleep system. In Europe, the prevalence rate of premature birth ranges from 5.5 to 11.4% depending on the county; an average of 7.1% of all live births that means around 385 thousand of premature babies per year.

In addition, number of preterm births is increasing every year. This trend is caused by an increasing number of women deferring childbearing and by multiple births linked with fertility treatments. One in six couples worldwide experience some form of infertility problem at least once during their reproductive lifetime. The current prevalence of infertility lasting for at least 12 months is estimated to be around 9% worldwide for women aged 20-44. As a result, there is an increased risk of neonatal deaths, which has contributed in some countries to a leveling-off of the downward trend in infant mortality rates.

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