

# The Case for a Study on Infant Monitoring

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## Introduction

Monitoring of infants for the prevention of SIDS and similar infant sleep related deaths (SUID) has been suggested for many years as a possible means of reducing the number of deaths. Infant monitoring is performed in hospital ICUs with success. There are also several programs around the country that claim to have significant reduction in the infant death rate through the use of monitoring.

Typically, heart rate and breathing are monitored, as well as the oxygen level in the blood in some cases. The assumption is that by monitoring these parameters, and sounding an alarm if a measurement goes out of limits, there will give enough time to intervene and prevent death.

Physiologically, most of these deaths appear to be caused by insufficient oxygen in the blood, a condition known as hypoxia and asphyxia. During autopsy, most SIDS deaths are indistinguishable from suffocation. In order for a case to be classified as a SIDS death means, there can be no determinable cause, either in the autopsy report or from investigation of the home environment. In other words, from all indications, the infant is completely normal and healthy when it died unexpectedly in its sleep.

**Given that these are perfectly healthy infants, and that the final cause of death appears to be oxygen deprivation, there is no scientific explanation why monitoring would not save many of these infants, particularly if the blood oxygen of the infant is monitored as one of the parameters.**

## Magnitude of the Problem

SIDS and other forms of unexpected death in healthy and relative healthy infants is the leading cause of death in infants from the age of 1 month to 12 months, causing more deaths than all other causes of death combined. Each year, more than 3500 infants die of SIDS and SUID (Sudden and Unexpected Infant Death). This rate has not declined in the last 15 years, in spite of all the research into SIDS and the introduction of the Back to Sleep Program. A healthy infant is 20 times more likely to die in its sleep than in an automobile accident, and yet the use of approved infant car seats is mandatory.

## History of Monitoring

Monitoring of infants to reduce the SIDS rate was started in the 1970's and earlier. Several studies were conducted, with mixed results and with the conclusion that monitoring was not shown to reduce the risk of SIDS. It also caused too much burden on the parents in both inconvenience and cost. By the 1990's, it was formally recommended not to use monitoring to reduce the risk of SIDS, and that recommendation remains firmly in effect by health professionals to this day.

However, the monitoring done in those earlier years did not incorporate the technology available today, and did not use pulse oximetry to monitor oxygen levels in the blood. Data storage technology was also limited, so that often the entire measurement history was not available. Because of the complexity and inconvenience of these older monitoring systems, compliancy of the users was low, and in many cases it could not be determined how well the monitor was working, if at all, at the time of death.

## CHIME Study

The Collaborative Home Infant Monitoring Evaluation<sup>[1]</sup> (CHIME Study) was the largest scientific study conducted using home monitoring. From 1994 to 1998, 1079 infants were monitored for a total of 718,385 hours at a cost of \$25M. The purpose of the study was to determine if preterm infants, siblings of infants who died of SIDS, and infants who had

experienced Apparent Life Threatening Events (ALTE's), had a higher risk of future cardio-respiratory events. The conclusion of the study was that the risk for **future** events, including future SIDS death, could not be predetermined with monitoring.

Unfortunately, this study has been used to justify the recommendation to not monitor infants for the prevention of SIDS and SUID, which was neither the conclusion of the study nor the purpose of the study.<sup>[2]</sup> The following are a few quotes from the CHIME study report<sup>[1]</sup>

**“The CHIME study was also not designed to determine whether use of a monitor decreases the rate of SIDS.”**

**“Six infants died during the study, but none was being monitored at the time of death.”**

**“Since many conventional and extreme events caused a monitor alarm, it is possible that the duration of some events in the risk groups was shortened by either an alarm-induced auditory arousal or by caretaker intervention.”**

During the study, there were no SIDS deaths while infants were being monitored, even though many infants were considered to be in a high risk category. The 4 SIDS deaths that did occur, occurred while the infants were not being monitored.

The study also admitted that the monitor alarm may have shortened and/or lessened the severity of the extreme events, because either the alarm aroused the infant or notified the care-giver to intervene. Even though the CHIME study does not "prove" with rigorous statistical data that monitoring can prevent SIDS deaths, it does give evidence to that effect.

**In the analysis of the data taken from the CHIME monitor, it was found that most critical events were preceded by low levels of oxygen in the blood (Hypoxia). The pulse oximetry used in the CHIME study was primitive by today's standards, but even so, it was able to indicate that a problem existed well in advance of the alarm, providing additional warning time for intervention.**

In the 25 years since the CHIME monitor was specified and designed, there has been a revolution in computing and medical monitoring technology, but these advances have not been used in a scientific study to the test if an infant monitor can prevent many of these deaths.

## **Other Monitoring Programs**

There are several active infant monitoring programs in the country, typically used for high risk infants and those suffering from apnea and sleep problems. These programs claim a very high reduction in the rate of infant death. In the few cases where death was the outcome, most of these too could have been prevented if proper procedures were followed after the alarm sounded.

The Southwest SIDS Research Center has been monitoring high risk infants since 1990. In that time, there has only been one death of an infant while being monitored, and this was because proper procedure was not followed by the caregiver when the alarm sounded. Their program, although not conducted as a scientific study, gives evidence that monitoring is affective at reducing the death rate.

The Children's Health Care of Atlanta performs home monitoring on up to 700 high risk infants at a time, and has monitored several thousand high risk infants over the last 20 years. During the period from 1996 and 2002, 8998 high risk infants were monitored through a program at Emory University. During the study, 13 of 14 infants who died were not being monitored at the time of death. The only one died while being monitored, and in that case, the caregiver refused to give proper intervention when the alarm was sounded. Again, their program, although not conducted as a scientific study, gives evidence that monitoring is affective at preventing these deaths.

## Hypoxia and SIDS

**One of the most compelling factors from the studies is that most SIDS or SUID deaths are preceded by a lack of oxygen in the blood (hypoxia), which occurs gradually over several minutes or hours preceding the deaths.**<sup>[3,4,6,7,8,9,10,11,12]</sup> **The CHIME study also found that hypoxia preceded many of the extreme events.**<sup>[14]</sup>

Frequently, the hypoxia is a repetitive condition, in which the infant recovers automatically through a mechanism known as auto-resuscitation. However, the repeated hypoxic condition may damage internal respiratory mechanisms such that the auto-resuscitation eventually fails.

More than 90% of the SIDS deaths are a result of respiratory failure, and when respiratory failure occurs, the blood of the infant becomes deprived of oxygen. There are many reasons why infants become hypoxic, but typically, the ultimate cause of death is lack of oxygen intake.<sup>[3]</sup> This is the basis for the success of the Back-to-Sleep Program, and oxygen deprivation (hypoxia/asphyxia) is supported by numerous studies as the leading cause of death in SIDS and SUID.

### Success of Back-to-Sleep Program

Since the Back-to-Sleep Program<sup>[12,17]</sup> was introduced in the early 1990's, the rate of death due to SIDS has been cut in half. The Back-to-Sleep program reduced the number of deaths by giving recommendations that would improve oxygen intake. When an infant lies on its back with no pressure on its abdomen, it takes less effort to breathe. It also reduces internal breathing obstructions from the head being turned to the side. Having no blankets or soft bedding allows the infant access to fresh air and prevents re-breathing of oxygen depleted air. Not sleeping in the same bed as the parents prevents the infant from re-breathing oxygen depleted air and also prevents over-heating. Over-heating may cause an infant to fall into a deeper state of sleep where the infant may take shallower breaths and may not respond to oxygen deprivation. Having a smoke-free environment prevents an infant from having problems with oxygen intake due to the smoke and to the infant's response to a low oxygen situation.

**The Back-to-Sleep program recommendations are primarily intended to improve the infant's oxygen intake, and the success of this program is confirmation that the cause of many SIDS and some SUID deaths is the result of oxygen deprivation. This reduced oxygen intake can be easily monitored with current technology.**

### SIDS Deaths are not instantaneous

From several recordings of SIDS deaths, it is clear that a SIDS death occurs over several minutes, and possibly hours. Indications of a pending death include hypoxic apnea, auto-resuscitation gasping, low heart rate, and low oxygen saturation in the blood (SpO<sub>2</sub>). All of these conditions can be monitored.

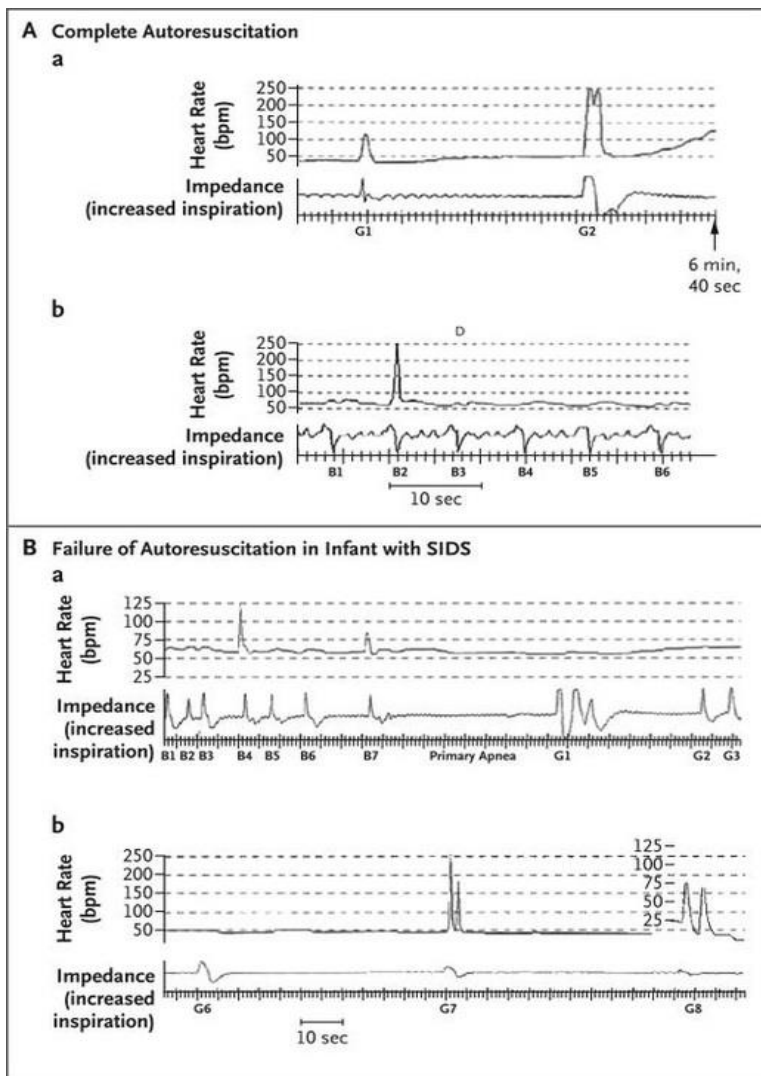
The 2 graphs below are from Figure 2 in Reference 3, and show the home monitor recordings of 2 infants. In the top graph (A), the infant successfully overcomes hypoxic apnea through auto-resuscitation after 6 minutes of not breathing. The auto-resuscitation gasps are noted as G1 and G2.

In the lower graph, the auto-resuscitation failed, with the auto-resuscitation gasps noted as G1 to G8. In this case, the hypoxic apnea and repeated gasping lasted for more than 10 minutes before the heart rate finally dropped below 50 bpm, leading to the death of this infant from SIDS.

In these cases, it is clear that the conditions were not instantaneous. In the case where the infant died, there was 10 minutes of notification of a serious condition just from monitoring the breathing. It is also most likely that the SpO<sub>2</sub> dropped long before the onset of the hypoxic apnea, which if monitored, could have given much earlier notification of the critical problem.

It was not explained in the article why intervention was not attempted on either of these infants.<sup>[3]</sup>

In another study<sup>[4]</sup>, they found evidence of repeated full and partial auto-resuscitation events in infants who eventually died of SIDS. There has been evidence since the 1980's that hypoxia is common in infants prior to a SIDS death.<sup>[9]</sup>



Hypoxia is not an instantaneous condition, and it is easily treated when detected. It typically develops gradually when an infant has an insufficient intake of oxygen. This can be caused by shallow breathing, obstructed breathing, re-breathing oxygen depleted air. A respiratory infection can also result in inadequate oxygen intake. Normally, simple stimulation of the infant, awakening them from sleep, is adequate intervention for bringing their oxygen level back to normal.

Pulse Oximetry is one method of measuring oxygen in the blood, typically giving a reading of SpO<sub>2</sub>, which is the measure of saturation of the hemoglobin in the blood, given as a percentage of maximum saturation. Generally a range of 95% to 99% is normal, but there are times when SpO<sub>2</sub> may momentarily fall below 90%. A sustained SpO<sub>2</sub> level below 85% to 90% is typically set as an alarm condition in a hospital.

For monitoring infants for SpO<sub>2</sub>, there have been problems in the past with false alarms caused by motion and perfusion artifacts. The excessive false alarms of the Pulse Oximeter in the CHIME study prevented SpO<sub>2</sub> from being used as an alarm condition. In the 25 years since CHIME monitor was designed, significant progress has been made to improve Pulse Oximetry to eliminate problems with motion and perfusion artifacts, giving a much more reliable measurement with a minimum of false alarms.

**It is not clear why using today's more advanced Pulse Oximetry would not be a useful means of providing early detection of a serious condition in an infant, given that hypoxia develops gradually in most cases.**

## Issues with Use of Monitors

In the 1980s, it was speculated that monitoring could be used to prevent SIDS deaths. However, after several attempts, it was concluded that monitoring was ineffective. There were several reasons for this conclusion:

- 1) Early monitors were large and complex, with multiple wires that needed to be connected to the infant. This was very inconvenient, and also posed a strangulation risk.
- 2) Early monitors only monitored cardio-respiratory events, and did not monitor SpO<sub>2</sub>. By the time an infant shows signs of cardio-respiratory problems, the infant may have already suffered internal injury to the brain and cardio-respiratory system due to prolonged and severe hypoxia, sometimes preventing resuscitation.
- 3) There were many false alarms that caused stress to the parents.
- 4) Because of the false alarms and inconvenience of connecting the infant every time it was placed in his/her bed, there was a low compliance of using the monitors consistently.
- 5) There is a difficulty in training parents on the proper use of the complex monitoring system, and on how to respond to an alarm event.
- 6) When an infant did die of SIDS, either because the monitor was turned off, or because the alarm conditions were ineffective or sounded too late, it added significantly to the "guilt" factor experienced by the parents.

7) **There has been no formal study that proved monitoring is effective in preventing SIDS deaths.**

It was basically concluded that the problems with monitoring, coupled with the lack of a statistically proven study, out-weighed the possible benefits of monitoring. It is now the recommendation of the American medical establishment that monitoring should not be used as a means to prevent SIDS.

## **Demand for Infant Monitors**

There are several commercial infant monitoring products on the market, none of which claim to prevent SIDS deaths. They are legally prohibited from making such claims, because there are no studies that “prove” monitoring can prevent these deaths. These products typically monitor breathing, or lack of breathing, either as motion detector pads placed under the infant, or devices that attach to the diaper or clothing, and monitor either motion or changes in pressure from the diaphragm. There are a couple of new wireless products that monitor ECG or SpO2, along with motion and orientation.

The demand for these products is very high, with several million being sold over the last 10 years. Even though there are no lifesaving claims by the manufacturers, parents are desperate to find products that will notify them of any serious problem while there is still time to intervene. **There are also many testimonials from users claiming that these products saved the lives of their babies, which is probably true in many cases.**

## **The Need for a Study on Infant Monitoring**

In spite of the conclusion by the American medical establishment to not recommend home monitoring of infants, the questions of whether monitoring infants would prevent many of these deaths goes unanswered. **There has been no physiological or medical explanation given why monitoring would not be effective in preventing SIDS and SUID deaths.** Even so, monitoring of infants continues to be used in hospitals, particularly with preterm infants and those in intensive care units without the scientific studies that proves its effectiveness.

Even though the CHIME study monitored 1079 infants, and the no deaths occurred during the study while infants were being monitored, this does not meet the standards for statistically proving that monitoring is effective. When the rate of death is only 1 in 1000 infants, to have a valid test requires monitoring many more infants. Because the monitoring of infants at the Southwest SIDS institute and at Children’s Health Care of Atlanta were not conducted in a scientific manner, these monitoring programs also cannot be used to **prove** that monitoring is effective. Many studies, including CHIME study, have recommended that more study is needed to determine the effectiveness of monitoring infant.

This brings up a question: If it appears that monitoring is a possible solution to preventing some of these deaths, and there is evidence to support this conclusion, why hasn’t a formal study been conducted on infant monitoring to determine its effectiveness, particularly in light of the fact that millions of dollars are spent every year on SIDS research? This is the #1 cause of death in infants between the age of 1 month and 12 months, and in the last 20 years, no further scientific study has been conducted on this very possible solution, in spite of the advancements in monitoring technology.

Monitoring has not been proven effective in preventing SIDS because there has been no comprehensive test done to evaluate the effectiveness of infant monitoring. There are many factors that contribute to SIDS deaths, many possible contributing causes, but most of the evidence points to the fact that oxygen intake is a primary factor, and the lack of oxygen is the final cause of most of these deaths.

There have been many technological improvements in the last 25 years since the development of the CHIME monitor, which may give more effective early warning indication of a problem. In particular, advancements in the measurement of Oxygen and CO2 in the blood have become more accurate, reliable, and easy to use. There has been no explanation given why monitoring for oxygen and CO2 in the blood would not prevent many of these deaths. These deaths are not instantaneous. Oxygen and CO2 levels change gradually, over minutes to hours. Cardiac arrest does not occur for several minutes in cases of complete oxygen deprivation, and in most SIDS cases, there is not complete oxygen deprivation, but a gradual decrease in oxygen intake into the lungs. Based on evidence from SIDS research over the last

40+ years and the advancement of medical technology, isn't time to conduct another study on the effectiveness of monitoring to prevent these many or most of these deaths?

## Conclusion

There has been much research done about the cause of SIDS, and several factors have been linked to possible increased risk: brain stem problems and serotonin levels, inner ear problems, repeated episodes of hypoxia, the effect of smoke on response to breathing, high levels of CO<sub>2</sub> in rebreathing air, vaccinations, and more. All of these may have an effect, but if so, there has been no proposed method to prevent these deaths, other than those in the Back to Sleep Program. All of these potential contributing factors have one thing in common. The final result of all of these possible causes is death by asphyxiation. An Infant Monitor capable of detecting blood oxygen level can give sufficient warning to intervene and prevent death. There is a large public demand for a product that will notify parents of a critical situation with their infant while that is still time to intervene. Such a product has the potential of saving thousands of lives a year. **There is sufficient justification for funding a comprehensive study to determine once and for all, if infant monitoring can prevent many of these tragic deaths of healthy infants.**

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