Kangoofix - Clinical Study Report, June 2015

KangooFix

SLL Innovation

A study conducted in co-operation with:

Samariten Ambulans AB , EMS Stockholm Sweden

OT-Center Ortopedteknik AB , Speciaslists in Orthotics

SLL Innovation, Innovation and product development

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Participating Organisations

Nacka Ambulance 336-9110 and 336-8160 Samariten Ambulans AB

Åkersberga Ambulance 334-9310 Samariten Ambulans AB

Sollentuna Rapid EMS responder 339-9590 Samariten Ambulans AB

Upplands Väsby Ambulance 335-8210 Samariten Ambulans AB

Södertälje Ambulance 338-9110 and 338-9120 Falck Ambulans AB

Kiruna Ambulance 349-9510 NLL

Farsta Ambulance 332-9120 Samariten Ambulans AB

Background

Studies have shown the importance of ensuring that baby is kept with its mother immediately after childbirth, to aid bonding and to keep both baby and mother calm.

Pre-hospital childbirth transportation is a part of the EMS/Ambulance Service's role. The Ambulance crew work as an extended arm to the hospital labour ward. After a pre-hospital childbirth, the mother and infant are usually transported to the labour ward in an ambulance. The mother is safely strapped into the stretcher using the stretcher restraint system, whilst the infant is placed on the mother's chest without any restraint.

This has led to a debate in which paediatricians speak of the importance of mother/infant closeness before safety. Swedish law allows this type of transportation by exception.

Alternatively the mother and baby are sometimes transported in separate ambulances, incurring double cost in terms of 2 vehicles and 2 sets of ambulance crew.

Guideline 5.2.1 for prehospital childbirth in Stockholm County, Sweden.

Item 9: Wipe the baby dry and keep warm to prevent hypothermia.

Item 10: The newly delivered child transported on the mother's chest.

Purpose of the clinical study

To investigate the parent's and EMS crew's experiences using Kangoofix as pre-hospital equipment, to allow mother and baby to be safely transported together on an ambulance stretcher. Also identify and analyse all associated benefits in using Kangoofix.

Method / implementation

- Product development and completed safety testing in cooperation with SLL Innovation and the Swedish Traffic Safety Administration.
- Completed risk analysis for management.
- The training of the EMS Crew participating in the project.
- Development of documents for evaluation.
- Information to the Stockholm Prehospital Center regarding project content.
- Parents and EMS crew respond to a specific evaluation form on completion of assignment.

Timetable

Education of EMS Crew November 2013

Project start in December 2013

Project closure May 2015 after 32 completed transports.

Product Information

Kangoofix Paediatric Ambulance Restraint System - For the safe & effective transfer of mother and baby both together, eliminating the need to use two ambulance vehicles & crew. Designed and developed to safely and effectively envelop and harness a NEWBORN during ambulance transportation, allowing baby to travel with their mother, maintaining close contact at all times.

Not only does this eliminate the need to use two vehicles and crew for transfers, it also ensures a safer and improved environment for both mother and baby throughout the journey.

The Kangoofix consists of an inner harness and outer warming cover with Skull cap, which together hold the baby in a cocoon-type system. The baby is then safely attached to mother on the ambulance trolley using the supplied Kangoofix 5-point outer harness, which simply attaches to the main trolley harness.

Inner harness and warming cover is made of “Breath-o-prene” Oeko-Tex 100 material and clinically tested to ensure no reaction on the baby’s skin, Kangoofix inner harness and warming cover ensures breathability and comfort. The warming cover also includes a skull cap, helping to maintain baby’s body heat. A quick-release system and “face-up” mode also allows the midwife /paramedic to monitor the baby and mother, and intervene quickly if a medical situation should arise.

Dynamic tested to EN1789 (10G) and TSF2010:2 (20G), CEN compliant

Evaluation results, based on 32 transports

32 transport performed between December 14th 2014 and May 18th 2015

23 childbirths, 5 transports to the E.R and 4 transfers between hospitals.

11 births were transported with the umbilical cord uncut.

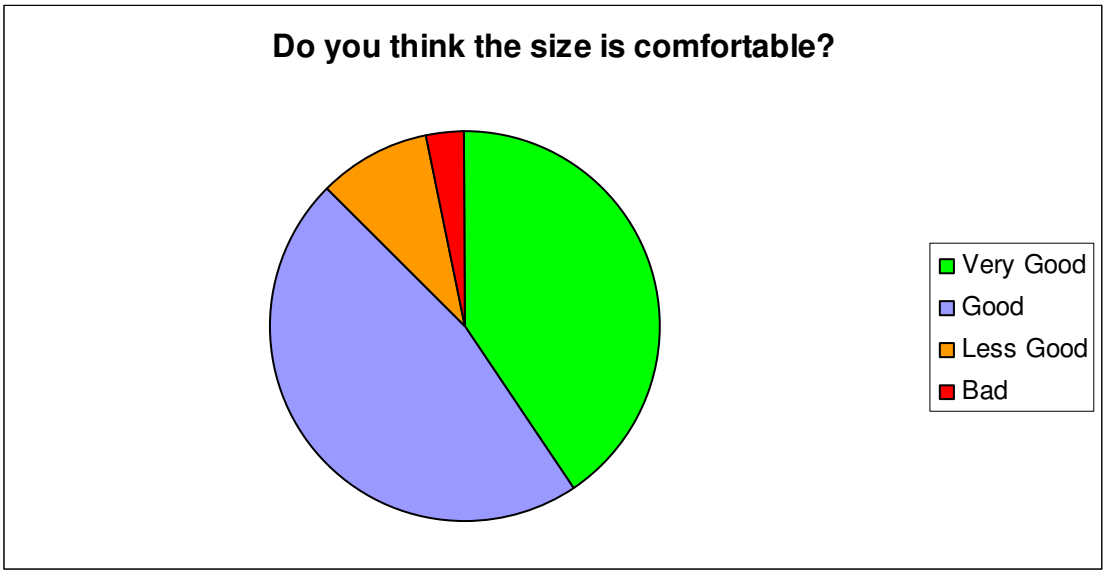
21 transports with Pensi Stretcher and 11 with Allfa Europé

The newborns weighed between 2 and 6 kg

The fastest transport was made in 10 minutes and the longest 1,5 hour.

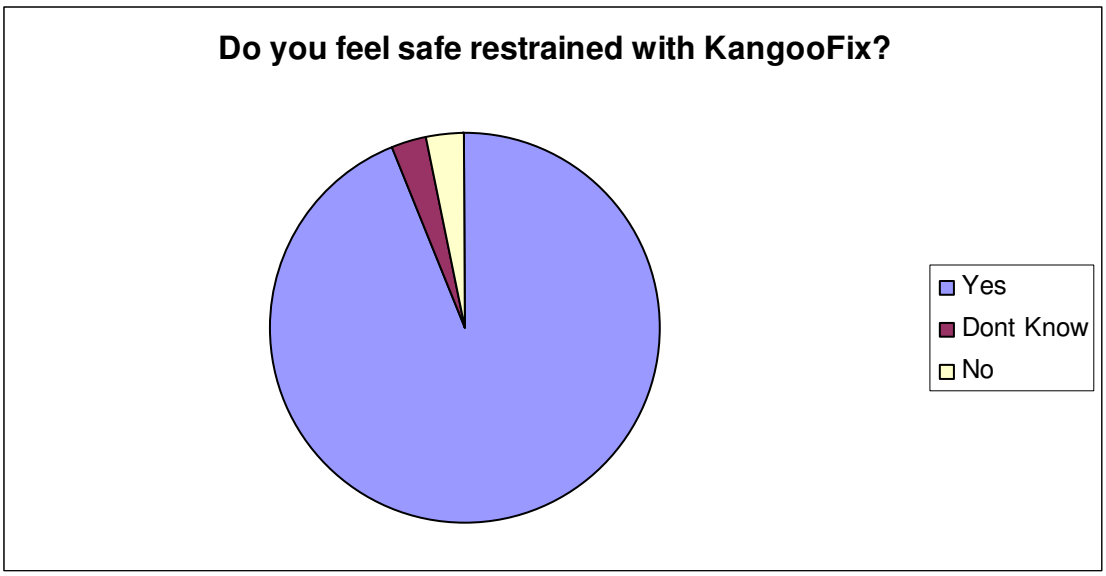
3 scheduled incubator transports was replaced with Kangoofix.

The following questions were answered by the parents:



13 thought it fit "Very well", 15 thought it fit "Well" and 1 thought it "Did not fit at all"

Comments: The one instance where the inner harness did not fit at all the patient was outside current product size range. To reach better fit it may require one or two more sizes of the inner harness to bridge additional sizes.



30 answered "Yes", 1 did not know and 1 answered "No".

Comments: We have registered that the transport which replied No in first question also replied NO on this question. We have not a clear explanation of why one transport did not know if they felt safe.

28 believed that the child was "Comfortable", 3 did not know and 1 "did not think the child was comfortable".

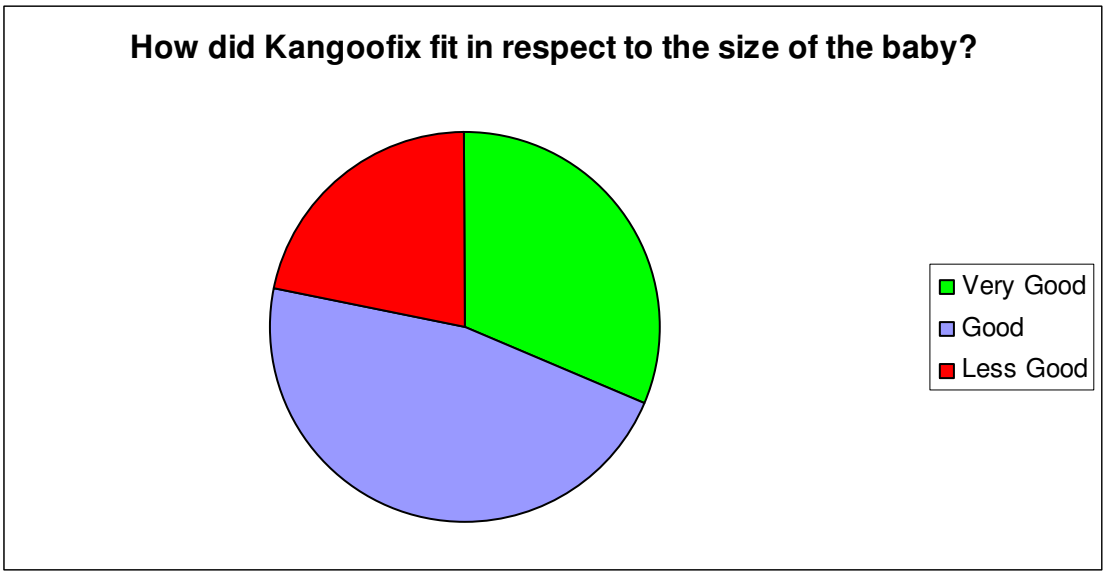
Comments: We have registered that the transport which replied No in first and second question also replied NO on this third question. No clear explanation given for why three parent did not believe that the baby was comfortable. Maybe it is difficult to evaluate the how the baby experience if you have no earlier experience of giving birth outside hospital and in general a stressful situation.

29 answered "No", 2 did not know and 1 answered "would rather see that the child was transported separately"

Individual feedback comments*:*
"Mother very happy with the restraint system" "Pressing the stomach which is sore" "Mother believed that the child became cold in the outer warming cover" "Mother thought the child got too warm wearing the outer Warming cover" "Mom happy, her 9 day old daughter could go with her to the E.R" "Great work"

Comments: We have registered that the transport which replied No in first, second and third question also replied NO on this question. One parent was very uncomfortable and stressed of this new experience of giving birth and has responded No on almost all questions. The situation was very stressful for the parent, no other explanation given as to why parent preferred to have baby transported separately.

Following questions was answered by the EMS/Ambulance Staff:

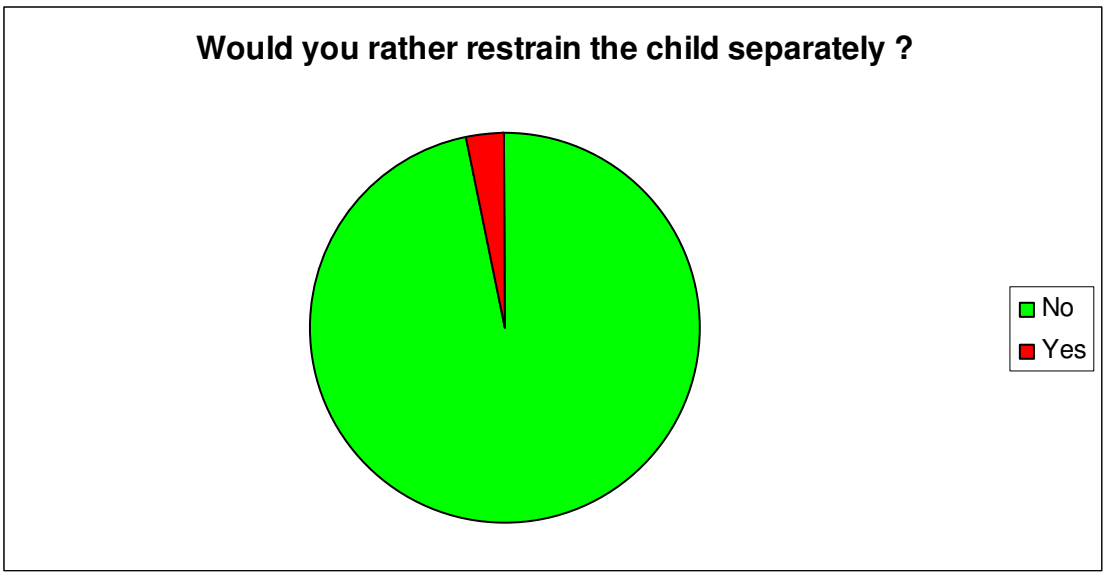


10 thought it fit "Very well", 15 believed it fit "Well" and 1 thought it "Did not fit at all"

Comments: One instance where the inner harness did not fit at all the patient was outside current product size range. To reach better fit inner harness may require one or two more sizes to bridge additional sizes.

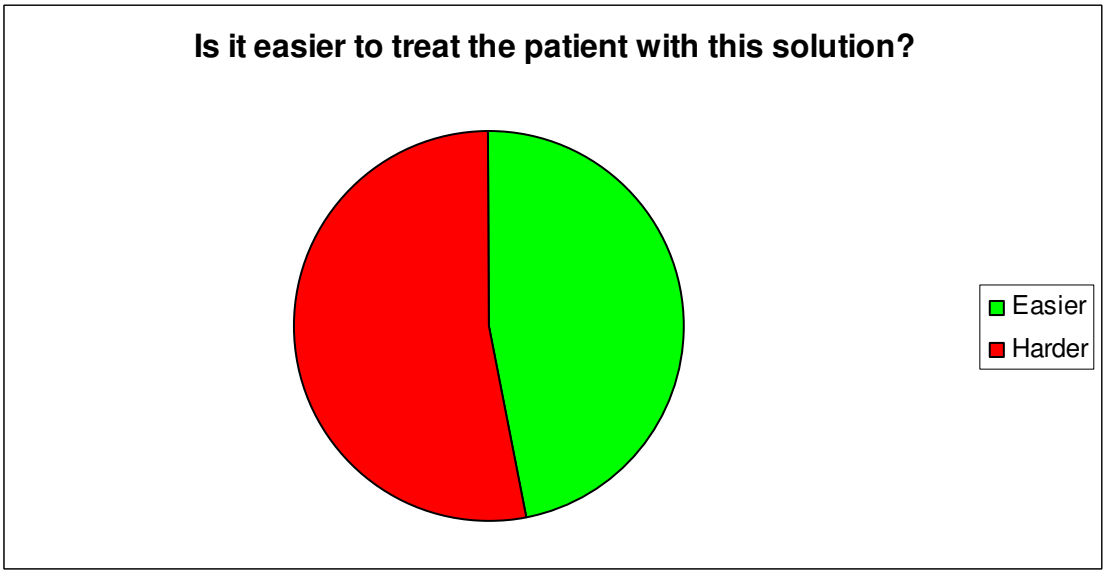
30 answered "Yes", 2 answered "No"

Comments: We have registered that the transport which replied No in first question also replied NO on this question and one additional paramedic. We have an explanation why one additional transport did not felt safe due to clear visibility to the baby under the warming bag



31 answered "No" and 1 answered "Yes"

Comments: We have registered that the transport which replied No in first, second and third question also replied NO on this question. One parent was very uncomfortable and stressed in this new experience of giving birth outside hospital and has responded No on all questions. The situation was very stressful for the parent, no other explanation was given as to why parent preferred to have baby transported separately.

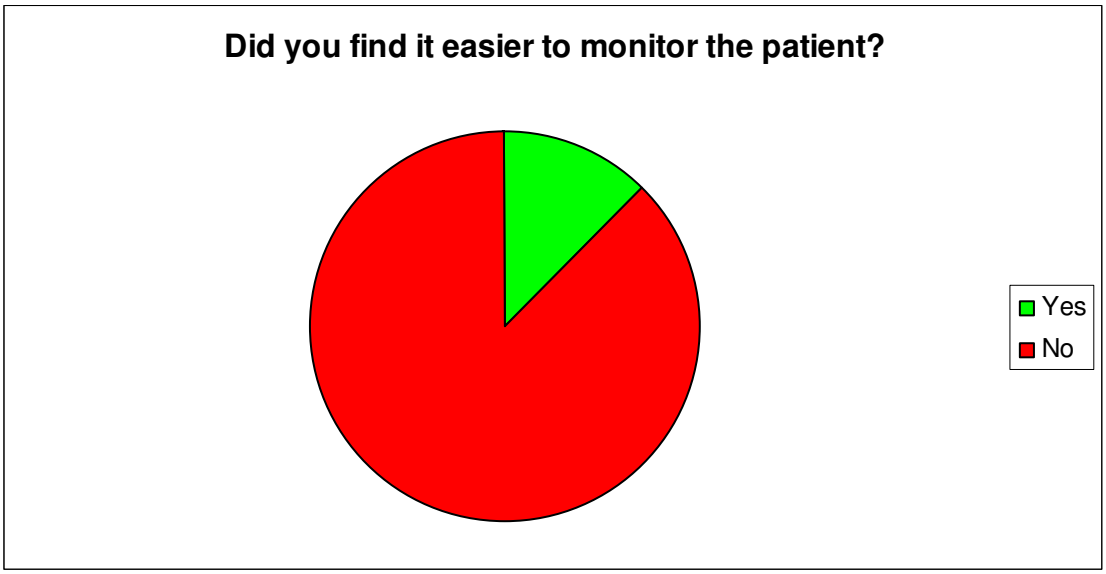


15 thought it was "Easier" and 17 thought it was "More difficult when child is turned with face to mother"

Specific feedback comments:
"More covered" "Yes, turned towards me" "No treatment needed"

Comments: Paramedic experienced decreased visibility to the babies face and body, became unsure of the babies' health e g colour, breathing and other important checkpoints and functions if they are normal. Potential for improvement on the visibility both in use of product and design.

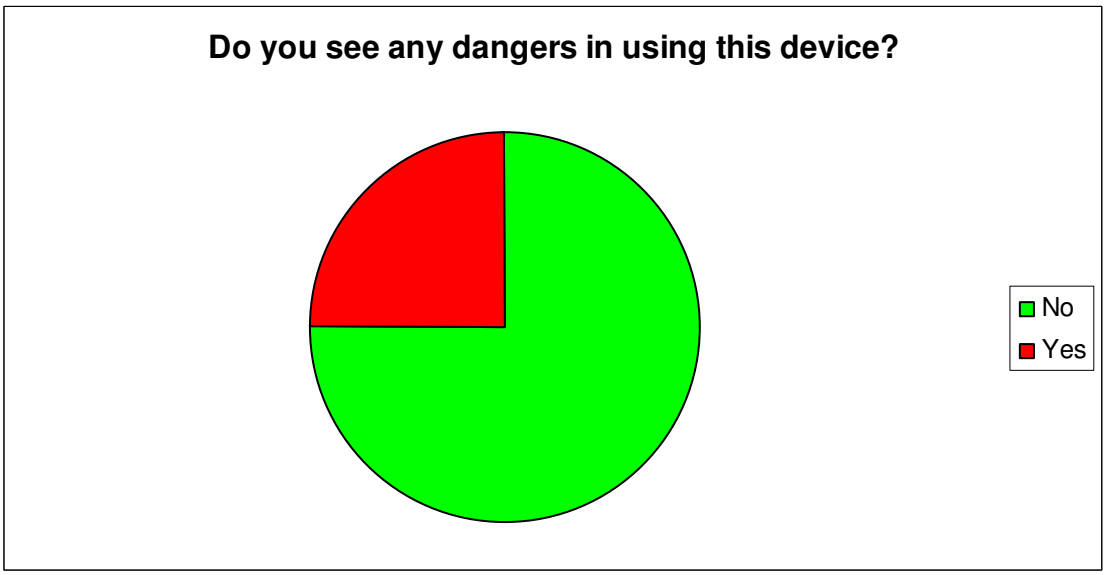
Above these addressed experiences the study showed that Paramedics who have had additional experience of using this equipment for comfortable, confident and reduce risk where much more positive.



4 answered "Yes", 28 answered "No".

Specific feedback comments:
"Difficult to assess respiration and skin colour - warming cover" "Works either way"

Comments: The warming cover with skull cap should be used whenever applicable to minimise the risk of hypothermia. In the same way as using a blanket or other protective layer, it is important that the EMT regularly checks the baby's skin colour by opening the warming cover at regular intervals.



24 answered "No" and 8 answered "Yes"

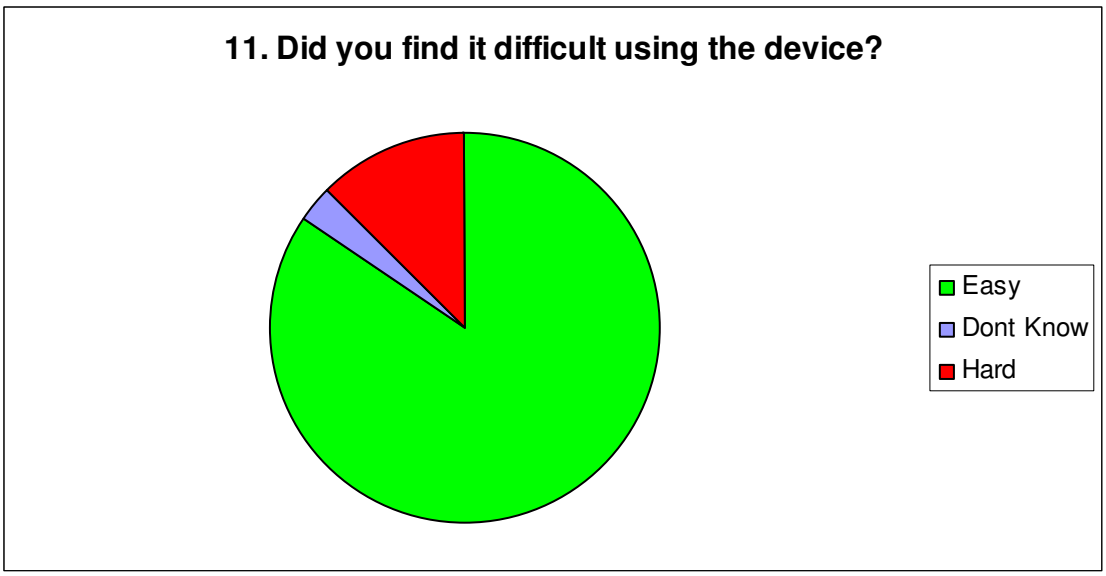
Specific feedback comments:
"Difficult to monitor the patient - because of the warming cover " "Parent has to be properly retrained before use" "Awkward to release - did not know about the quick-release function"

Comments: The warming cover with skull cap should be used whenever applicable to minimise the risk of hypothermia. In the same way as using a blanket or other protective layer, it is important that the EMT regularly checks the baby's skin colour by opening the warming cover at regular intervals.

For all ambulance transports all passengers including patients shall at all times be properly restrained with the approved stretcher harness system. This shall for safety reason be used properly and that means that Kangoofix can be properly assembled for safe transport of the baby in Kangoofix.

Quick release function is available for the paramedics to very quick in seconds release the baby from the harness system for required treatment when needed. Important to make sure that onward journey shall be performed safely. NOTE the baby can be transported face up and restrained in the Kangoofix, important to have control over the baby.

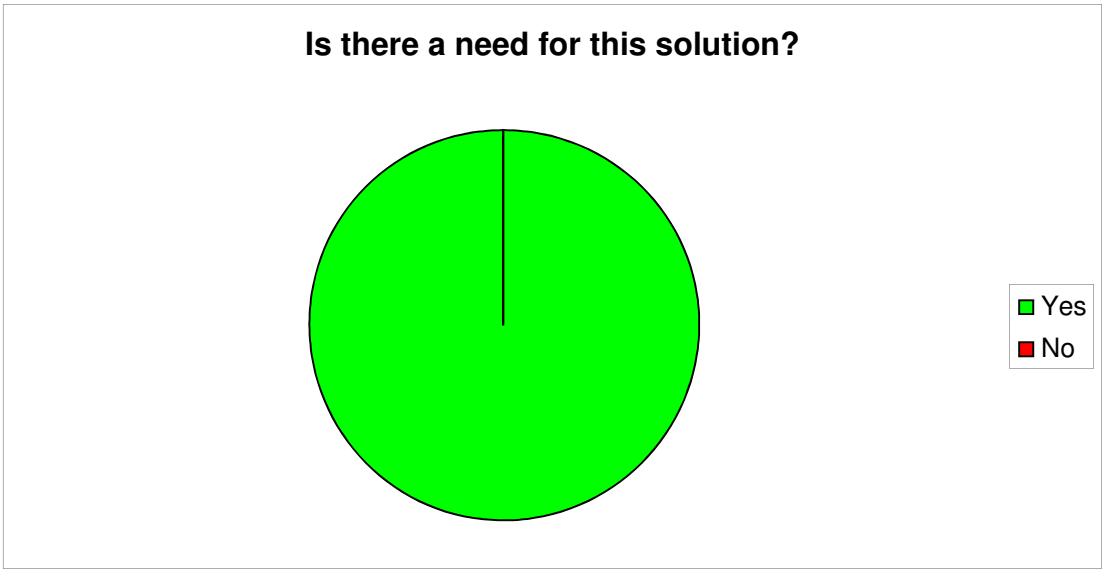
Training for EMT how to treat the patients with this Kangoofix equipment in use is important for comfortable, confident and to reduce risk.



27 thought it was "Easy", 1 did not know and 4 thought it was "difficult needs retraining"

Specific feedback comments:
"I am experienced in monitoring infants and think it is easy, though I know that some of my colleagues think otherwise" "Many straps" "Requires training" "Safe and easy" "I have been training a lot" "Have no practical training though it went OK" "We restrained the child inside the ambulance, awkward because of the stress and lack of space in the ambulance!"

Comments: A majority evaluated the handling of Kangoofix as Easy. There is additional work involved to restraint the baby on top of the parent, we belief extra time and effort to assembly the system is affordable then we can create a very safe, comfortable and secure transport.
Training for the EMT how to treat the patients with this equipment to be comfortable, confident and reduce risk.



Everyone saw a need for this solution in the Ambulance

Specific feedback comments:
"Safe and Easy" "Great Concept" "Admirably that EVERYONE is restrained"
"Finally a good solution"

Summary

The first transport in this study was completed 14th December 2014. A premature boy in birth week 34 was born at his parent's home. This boy, weighing 2.4kg, was successfully transferred with his mother in the vehicle to the hospital using Kangoofix. During this study Kangoofix was mainly used for pre-hospital childbirths. Though in 3 of the cases, scheduled incubator transfers where replaced with Kangoofix, 4 of the cases concerned children who needed to visit the E.R., where one of them received medical treatment as inhalation and Oxygen during the transport and 1 of the transports concerned an ill mother with a 9 day old child needing breastfeeding.

For the transport of newborn babies, there is currently no effective alternative for maintaining vital closeness between parent and child for safely transfers to the maternity ward.

Under the directive of Swedish obstetricians, the baby's umbilical cord should preferably remain in place during transport to the maternity ward unless the placenta is still in the mother's uterus. This causes problems in the safe fixation of newborns without a restraint system allowing mother/child closeness.

With the help and support of Samariten Ambulans AB (EMS Service operating in Sweden), we were able to conduct this field study using KangooFix paediatric restraint system, to determine the effectiveness and safety of the product in terms of transporting a baby with its mother in a single ambulance.

The important feedback and comments from the EMS crew and baby's parents during the study helped KangooFix to evolve from its initial prototype stage to a now proven and registered medical device.

Incubator transports in Sweden are carried out by emergency ambulances, where the standard stretcher has to be unloaded before the incubator can be loaded on. This results in longer periods where vehicles remain unused, which ultimately cost money as well as minimising the effectiveness of the fleet. 3 of the transports in the study replaced scheduled incubator transports, which is very interesting considering logistics for the EMS.

Between December 2013 and May 2015, 32 babies transferred together with their mother and staff from the EMS and the labour ward. The babies involved in the trials weighed between 2 and 6 kg. The shortest transfer took 10 minutes, the longest transfer being 1½ hours duration, 130 km distance along country roads. In 11 of the childbirths the umbilical cord remained uncut during the transfer. 2 types of stretcher were used, Pensi and Alfa Europe.

Everyone involved in the study concluded that there was a real need for such a device, allowing mother/child to be kept together and safely transported in an ambulance. The participators in the study are positive to use Kangoofix in their ambulance services, this will give them the great possibility to offer safety, comfort and trust to the patients and themselves as health professionals.