



BABYLUX

# Newsletter n° 6

June 2016 / December 2016

## News

**The time has come for BabyLux to start the clinical demonstration. The device has just reached Rigshospitalet in Copenhagen (Denmark) and is now being tested in a real clinical environment to monitor cerebral oxygenation and hemodynamics in critically ill preterm and term babies.**

Rigshospitalet, thanks to its 24 doctors and 120 nurses, treats about 1,000 newborns per year. Three groups of infants will be studied during BabyLux clinical phase: twenty term newborn infants immediately after delivery by caesarian section; twenty preterm infants when their respirator is adjusted to normalize blood pCO<sub>2</sub>; twenty unstable newborn infants during a 24 hour period.

The tool has undergone significant changes and improvements in the last few months. Safety procedures have been enhanced, adjustments have been made to both TRS and DCS modules, hardware and software have been fine-tuned and passed multiple tests. **The clinical protocol has been authorized by the Danish Medical Agency and by the Italian Ministry of Health.**

Doctors, nurses and parents are now being trained on the tool's functionalities. During measurements, data will be analyzed online by a dedicated software giving an immediate feedback. Data will then be post-processed by ICFO and Politecnico di Milano to unveil possible correlation with other parameters simultaneously acquired according to the clinical routine.

A second trial phase will take place at Ospedale Maggiore Policlinico in Milan (Italy) next September, whereas **final results will be delivered and openly discussed during a public conference taking place in November 2016.** More details will follow soon.



## Who's who?

**This issue is dedicated to the mothers and fathers of all the children "born too soon" and to the doctors and nurses taking care of them.** Their role and engagement in the BabyLux project is central and we thank all of those who are helping us in reaching a goal which is not restricted to the pure domain of science, but it addresses society as a whole.

Though they are overwhelmed by the circumstances, parents of extremely preterm babies never give up. They have to spend a lot of time in an unfamiliar environment such as a NICU (neonatal intensive care unit) and need support and encouragement to find their way as parents.



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It is unquestionable that the bond between the clinical staff, doctors and nurses, and the parents is deep and central in protecting and sheltering babies' lives. Trust and hope, together with daily clinical procedures, tubes and wires, accompany them for two, even three months in the NICU. Quite a long time to know each other and to face serious matters together. **Gorm Griesen and Monica Fumagalli, responsible for the clinical validation of BabyLux device, explain to us what is going to happen during the trial phase in Copenhagen and Milan and what is their role and experience in such a delicate context.**

In Copenhagen, we met **Janni and Kristian**, whose son, Elliott, was born at 25 weeks plus three days. He weighed 820 grams and had serious lungs problems. Luckily, Elliott is now doing fine and by time you read this, he will be at home already. While smiling all the time and looking into each other eyes, **Janni and Kristian**, who have accepted to take part to BabyLux clinical validation, **told us about their experience in the NICU.**

Of course, Janni and Kristian are not alone. Some of you might have read or heard about a book called **"Girl in Glass"**. We had the chance and the privilege to interview the author, **Deanna Fei**. On Oct. 9, 2012, at 8 a.m., Ms. Fei gave birth prematurely to a baby girl. Mila weighed 1 pound 9 ounces. Unfortunately, one day the chief executive of AOL, where Mila's father used to work, blamed the company's decision to cut benefits on the medical costs caused by two "distressed babies." Mila was one of them. Unable to accept this cruel "label", Deanna wrote this moving memoir, later becoming a best-selling book in the United States.

## Read the interviews...



**GORM GRIESEN**  
Professor of Paediatrics at the  
Department of Neonatology at  
The Juliane Marie Centre,  
Rigshospitalet, Copenhagen  
University Hospital and the  
University of Copenhagen,  
Denmark

### *Prof. Griesen, what is going to happen during the clinical phase of the project?*

We are going to put a sensor, a very small sensor, onto the head of babies. We will put it just a few minutes after birth, when the baby is still blue. Then, when the baby starts breathing and crying and pinking up, we will see if the signal in the brain is picking up in the expected degree. In particular, we want to see what's happening to the blood flow. When the baby recovers his circulation just after birth, you expect his blood flow also to pick up. We want to calculate the ratio between the two and see if it meets the expectations.

This is going to be a critical test for the validity of the measurement. When you put a sensor on the head of a baby who is unstable, that means in a critical phase of illness, there might be adjustments to the respiratory and circulatory treatments. We will keep it on for 24 hours and see if the values provided make sense in a clinical context.

### *What are the risks of brain damage in this very early stage of life? How do you prepare parents to face them?*

The problems of having born extremely preterm are mainly two. One is that there is a risk of dying: 20, 25% of these babies do not survive to discharge. The other big risk is brain injury. A significant proportion of these infants live with smaller or greater handicaps due to brain injury. In the best cases, when we take charge of an extremely preterm child, we are able to speak to the mother and the father before delivery. We explain them that we collaborate with the obstetricians to choose the best possible time of birth.

We are always prepared to inform parents about the outlook. Actually, this is a very important part of neonatology. Once you see the baby, you have a much better impression of his abilities and chances. But in some cases, we diagnose a brain injury and have to inform the parents. If the prospects of a normal development are poor, we decide to discontinue life support.

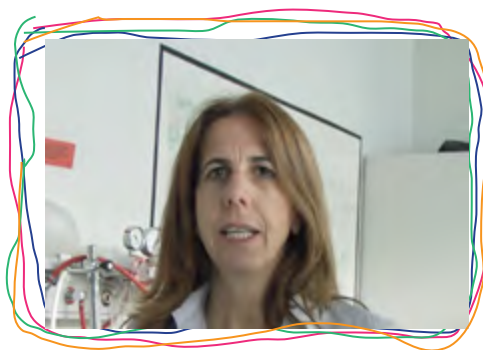


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## *What is BabyLux project to you?*

BabyLux project is important to me because I have been working with brain injuries and preterm babies for 30 years. I have been using a range of different methods. This particular instrument is integrating a measure of oxygenation to the brain and a measure of blood flow to the brain. It is precisely that aspect of oxygenation that we have not been able to monitor and manage yet. I have great expectations that this will be a significant addition to the tools we have already.



### **MONICA FUMAGALLI**

**Neonatologist at the Neonatology and Neonatal Intensive Care Unit at Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico of Milan, Italy.**

## *The testing of the tool is pivotal for the success of the project. What is to you, as a doctor, the role of technology and how much do parents interact with it?*

In perinatal medicine, we rely on technology very much. A NICU is a very high-tech environment. Technology helps us to keep babies alive, but, of course, it has a human cost. As a doctor, I think that we always have to find a balance between the need of technology and the human cost of technology.

When parents start visiting their babies, they just seat and stare at the monitor. After a few days or months, they are highly dependent on technology. Sometimes even too much. We try to talk to them and tell them that they should look at their babies and not at the screen. They become dependent on technology and sometimes they are afraid of going home without these systems.

## *Do you keep in touch with babies once they are discharged? What do you know about them after they leave the hospital?*

Prematurity does not finish when the baby is discharged. We know that some of these babies can develop neurodevelopmental impairments later on in childhood. In our unit, we follow up these babies up to 10 years of age. We have the opportunity of following them and supporting their families. And particularly so, during the first years of life, when babies develop some kind of impairments. Fortunately, we can also see these babies growing up as healthy babies, coping with their prematurity.

In particular, home discharge is a very special and stressful moment for parents. During this phase they need to be supported quite a lot. They experience fear and doubts and they rely on medical support. The time spent talking with them is never too much. They didn't expect to have a preterm baby and a preterm baby does not look like the healthy term baby they were expecting to have. We have to support them and let them understand that these babies can have good opportunities in life and a good quality of life.

## *What is BabyLux project to you?*

As a neonatologist involved in brain injury research, I really believe in BabyLux. One of the most frustrating experiences is to realize that a baby will develop brain injury and brain damage. There is almost anything you can do to prevent it. We know that most of these brain injuries are related to the quantity of oxygen and blood in the brain during the first days of life. That's why BabyLux device could provide physicians with a new monitoring system to understand what is going on in the brain of these small children and guide therapeutic interventions and clinical decisions in order to try to protect their vulnerable brains. I do believe in this project and I think that BabyLux has the potential to help medical doctors in taking the good decisions and try to protect the brains of these babies.



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**JANNI RISE LARSEN & KRISTIAN  
MALVANG FRELLSEN**  
Elliott's mom and dad

## *Janni and Kristian, could you tell us your story?*

Elliott, our son, was born in week 25 plus 3 days. He is actually 14 weeks preterm, which means that he can be categorized as an extremely preterm baby. He was quite small, 820 grams. We are not quite sure of what happened...

I just went into labor one night, in the middle of the night and we came here to the hospital, expecting to have a check up and then go back home. They found out that I had gone into labor and that the heart rate of our son was dropping every time I had a contraction. They wanted to do a C-section, but before they had the time to do it, he came out by himself. He was just ready to come out. It took 9 minutes.

We were not prepared at all... Some parents are admitted here, because they know that there is going to be a risk for the mother if she gives birth too soon. They have days, maybe weeks, to get prepared to it. To us, it was quite a shock! We are not sure we have fully comprehended everything yet...

## *How long have you been here?*

14 weeks yesterday, so almost 3 months and a half, so far. We will stay here for a couple of weeks more. Elliott is getting much better and making good progress. We can see the end of the tunnel. He just hit three kilos yesterday, so that's a huge progress. He is now almost like a normal born baby. He was supposed to be born on Sunday, June 12. He has had a lot of problems with his lungs. But he is all right now, which is great!

## *What is your feeling toward technology, as a fundamental component in this kind of environment, and your relationship with the clinical staff?*

Technology is extremely important to monitor the condition of a child. It is essential, of course in a combination with the doctors and the nurses. I mean, if we didn't have the technology, it couldn't be done. Elliott has got so much help from different machines and monitors... he has been really unstable in the beginning, so we had a lot of alarms going on every time he wasn't breathing or his saturation went down...

People here are very informative and helpful. Most of the nurses are very committed. They are really caring about the children. It is more than just a job. They pass by, they ask how things are going, they comment on your baby getting bigger and bigger... You get a kind of personal relationship with most of them. Doctors are also very informative and helpful in explaining to you what's going on, in asking questions and in telling you what it should be done.

## *Are you ready to go back home?*

We are scared and excited at the same time. We really want to get back home, but on Elliott's terms and on his conditions. He has to be ready. He will probably go home with an apnea sensor so that, if there's an alarm we can help him. Janis is mostly scared...

## *Janis?*

I am really excited to go home after so long, of course. But, as we are getting closer to it, I feel more and more scared. I can see Elliott is getting better, but I think it's just the whole experience of seeing him so unstable and knowing what an infection can do to him... he could suddenly turn unstable again, and being alone with the baby... I mean, here there are people all the time, doctors and nurses, and alarms and everything... It's a nice security. Or maybe it's simply scaring just to have your first child. And if he is a preterm child, I think you can kind of multiply the feeling for a thousand times... But it will be fantastic! It will take some time before the nerves are calm. We will probably stay up at nights during the first couple of weeks or months... looking at him constantly!

## *Is everything ready at home?*

We have bought most of the essential stuff. We are getting there. When Elliott was born, we had only bought a bed. That was all we had and it was actually used as storage for everything else. It was like "Oh, no. We have another three months. No worries." Now we are trying to manage being at the hospital and going out to buy stuff. We are getting there.

## An outside glance @ BabyLux



### DEANNA FEI

**Author of "Girl in Glass: How My 'Distressed Baby' Defied the Odds, Shamed a CEO, and Taught Me the Essence of Love, Heartbreak, and Miracles"**

*Ms Fei, at the beginning of your book, "Girl in Glass..." you describe your daughter as "walled in glass, obscured by a tangle of tubes and wires". You picture her very clearly: the way medical instruments connect her body to the machines.*

*You say: "When my vision clears, I try to gaze into her eyes, but in the panes of her isolette I see the reflection of flickering numbers on the screen, and my wrecked face". It's the glass giving back to you, and to us as readers, the image of your emotions mingled up with the artificial tools keeping your daughter alive. How would you comment this passage and what's the balance between technology and emotions? Between technology and human care in a NICU environment?*

For parents in the NICU, the balance between technology and emotion is terrifying to confront. It's a suspension of our children's lives between birth and death, hope and fear, nature and science. But it's also an extraordinary arena of life that illuminates our shared humanity.

During my daughter's first days, all of the technology seemed to symbolize my failure as a mother: I couldn't keep my own baby safe inside my body. I couldn't feed her, I couldn't hold her. I could only watch helplessly as she clung to life inside this glass box, connected to machines. I think these profoundly conflicted emotions are universal among mothers of medically fragile newborns: We're overwhelmed with awe and gratitude for the technology keeping our babies alive. And yet -- what could feel more unnatural? To a newcomer, a NICU can look like a scene from a futuristic, creepy sci-fi movie. And the fact that entire lives hang in the balance can invoke fears about doctors "playing God" with the fates of these tiny, helpless beings.

More broadly, there's often no way of knowing the consequences of sustaining a baby born at the edge of life. Throughout our months in the NICU, I was tormented by unanswerable questions: Were the medical interventions keeping my daughter alive also causing her to suffer? If she survived, what kind of life would she live? How could I become attached to a child I could lose at any moment? What if she wasn't meant to survive? The doctors and nurses weren't oblivious to these dilemmas, but they needed to focus on doing their daily work. The machines are, of course, inhuman: impervious to philosophical questions, never mind a mother's worst fears.

But through the research and writing of my memoir, GIRL IN GLASS, I eventually came to see that the technology is fundamentally an extension of our humanity. All of that high-tech equipment is designed with one goal: to help our babies survive. This is an impulse we've shared from the beginning of civilization. Breathing tubes, feeding tubes, artificial resuscitation: all of these technologies have roots in antiquity. This isn't playing God; it's an integral part of what makes us human.

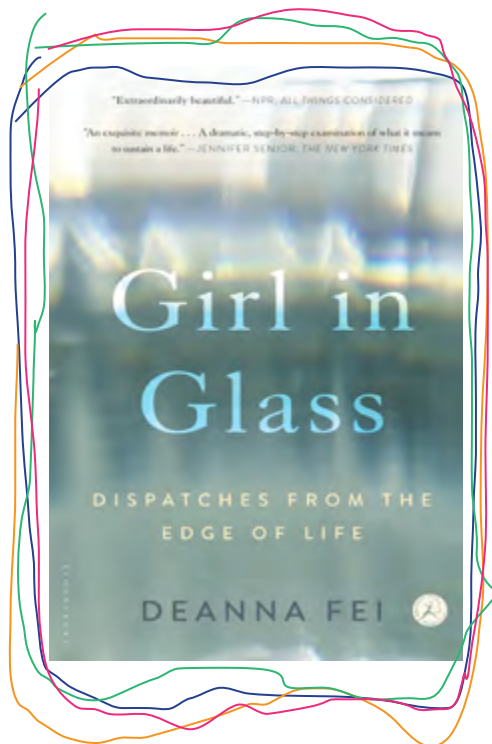
The truth is, no one can control these babies' fates. All we can do is give them a chance. The technology that once invoked such terror for me is what gave my daughter her chance, and she seized it with all her might. Now she's a thriving, irrepressible 3-year-old, and every single day, I'm grateful for every doctor and nurse, every painstaking procedure, every pane of glass, every puff of oxygen, every tube and wire that gave her that chance.



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*At the end of the book you have a more distant view on technology. You describe the evolution of the neonatal care from the first incubator, and even before that, up to today. A project such as BabyLux, in a sort of way, comes at the end of this parabola. How do you evaluate our project ? And to what extent is research central in saving human life?*

I see the BabyLux project in simple terms: as a development that could improve the lives of countless children like my daughter.

Among the many repercussions of prematurity that Mila suffered, the most devastating was a severe intraventricular hemorrhage (IVH). This was a bleed in the right ventricle of her brain that spread to the brain tissue, causing damage that was both untreatable and immeasurable. The IVH significantly reduced her already daunting odds of ever living a normal life, and exponentially amplified the trauma and uncertainty for me and my family. The BabyLux project has the potential to give NICU practitioners the chance to prevent and treat such an injury, at a stage in care when a minute can make all the difference in a child's future.

The research involved in a project like this is absolutely central – not only to save individual lives, but to advance the overall progress of our society. A century and a half ago, as many as one in five newborns died before their first birthday. It was common for babies to die of ailments like diarrhea and hypothermia. Research and development in neonatal care has led us to where we are now, with newborn deaths relegated to relatively rare occurrences. As for premature babies, these days we routinely save more than 90% of them – most of whom survive without long-term health problems.

But premature birth is still the number one cause of death among newborns and the number one cause of disability among children. It can happen to any pregnant woman. To this day, we know very little about what causes premature labor, and even less about how to prevent it. Worldwide, for the foreseeable future, 15 million babies will continue to be born prematurely every year. So it's crucial that we do everything we can to improve the prognoses for their future. The BabyLux project is one way to do that.

*You have decided to write this book on a particular and sad occasion, when your daughter was “labelled” as a “distressed baby”. You had the courage to stand out of the crowd and to denounce the shame of it. Is there a price for human life? Wouldn't that be better to shift the perspective from the money spent to the money invested in saving human life?*

In the media firestorm that surrounded my family after my husband's CEO publicly blamed our daughter for being a financial burden and slapped a price tag on her life, there was a lot of discussion of the costs of saving a premature baby. Was a million dollars too much? Two million? Half a million? At first, my instinct was to cower in shame – but then I realized that I needed to speak out to defend the basic worth of my daughter's life.



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In GIRL IN GLASS, I explore this question – How much is a human life worth? – not only as a mother, but also in terms of socioeconomics and bioethics. It turns out that investing in the care of premature babies is one of the best investments we can make – not only for a family like mine, but for us as a society. I don't personally believe that human lives should be reduced to cost-benefit analyses, but even here, the data is very clear: Investing in the care of premature babies is actually extremely cost-effective. Most of them grow up to become healthy, productive members of society. The medical innovations developed in NICUs have also exponentially improved the care of full-term infants. And even though NICUs tend to get singled out as extravagant hospital departments, the large majority of resources are spent on babies who ultimately survive, whereas the opposite is true in an adult ICU. Yet we don't generally demand that people who have spinal cord injuries or need heart surgery prove themselves deserving of medical care the way that we demand that sick newborns justify the costs of their existence.

At a time when so many people feel financially squeezed one way or another, it might be tempting to shake our heads over the hospital bills of such a tiny, fragile creature. But when we start to debate the value of a human life, I think the real question is this: What could possibly be worth more? Ultimately, this is an issue that affects us all: how we care for the most vulnerable members of our society.

*We have just started the clinical phase of the BabyLux project. The medical staff is directly involved into it. To what degree is the support of doctors and nurses essential for parents while at NICU?*

Doctors and nurses are a lifeline for parents as well as their babies. Having a baby in the NICU is one of the most traumatic – and transformative – experiences in life. The stress levels for parents are comparable to those for soldiers in combat, and so are the rates of PTSD. But most people in the outside world don't understand or know how to acknowledge these experiences, and NICU parents often suffer in isolation and silence. Counseling services should be offered to every parent in the NICU, but at least in the US, this is very rare. So the support of the doctors and nurses is absolutely essential.

Parents know that the main job of the medical staff is to tend to our babies. But when parents feel emotionally supported, they're better able to cope with their own trauma and bond with their babies, which helps improve outcomes overall. For doctors and nurses to acknowledge a parent's fears and doubts, to reassure them that they aren't to blame, to remind them that they aren't alone: These efforts can make a world of difference to a parent on the edge.

When Mila was discharged from the NICU after three months, I wanted to flee and never look back. But I thought of our doctors and nurses every single day. When she turned two, we visited our NICU to thank everyone for taking such wonderful care of her. They instantly recognized her eyes, her face. They felt like family. To me, they will always be heroes.



Watch the video interviews

## Episode #7 & Episode #8

## Next events

If you want to know more about BabyLux, you'll find us here:

**October 13, 2016**

**fNIRS 2016**

**Paris, France**

**October 15, 2016**

**PolimiOpenLabs - La Fisica e la Matematica scendono in piazza  
Milan, Italy**

**BabyLux final conference will be held at the end of November.**

Results will be presented and discussed. Stay tuned!



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