

PALISI Consenting Improvement Recap

1. **Why do you think you and/or your site has had such a high success rate in enrolling patients?**

Many staff noted that they were consistently introduced by a member of the clinical team caring for the patient (MD or RN), and that this helped substantially to build rapport. Having a background as an ICU RN has also greatly aided some HALF-PINT coordinators as they have extensive experience with relating to families in the critical care setting and are more likely to know – and receive positive reinforcement from - the clinical staff. Being present and visible as a member of the wider ICU team was also important—some coordinators make a habit of being present for rounds so that they are recognized by clinical teams and families, and can act as an extra resource for families with clinical questions.

Projecting compassion was emphasized as a key to success—before going into detail about the study, almost everyone recommended asking the parent(s) about how they were doing, asking about their child, and paying close attention to body language cues to gauge the parent’s ability to digest and handle info about the study. Coordinators should try to speak calmly and quietly and make eye contact with parents. Breaking the large amount of information contained in the study into small sections makes it is easier for parents to understand and creates natural pauses for questions. It was also noted that parents and children should be addressed by name; even if the child is sedated, addressing him/her (when inserting the sensor, for example) and briefly explaining what you are doing is a powerful way to show parents that you recognize their child as an individual. Constantly validating the parent(s) is critical—welcome their questions and tell them you understand their concerns. Make sure they know you care about their child, not just your own study.

Having good buy-in from clinical staff and a well-prepared unit was also found to be helpful in creating an atmosphere conducive to success. In units with particularly good buy-in, charge nurses or attending MDs often call the team to notify them of eligible patients. They also reinforce our message to parents that the study is well-run, well-designed to minimize risks, and that the glucose ranges we are studying are both within the range of what is commonly done in ICUs as standard care.

1. **What are some highlights of the study you are always sure to mention?**

It is helpful to highlight that Children’s Hospitals have three major purposes: care, education, and research, and that we need all of these to better treat children both now, and in the future. Mentioning the importance of this research in determining the best ways to treat children has been very helpful. The altruistic notion of helping critically ill children in the future, in addition to the potential benefits for their own child, also appeals to many parents.

It is important to assure the family that you have spoken with the child’s medical team and they approved the child’s participation in the study. Coordinators also emphasized early in the conversation that participation in the study was completely voluntary and open-ended - that parents could opt out at any time if they wanted. Mentioning that hyperglycemia is very common in ICU patients (due to the amount of stress the children are under while very sick) was important in helping parents to understand what we do and why they were not previously notified about their child’s hyperglycemia. It may also be helpful to frame the hyperglycemia as just one small piece of their child’s condition that you’d like to speak with them about.

Another helpful tool was to mention that the study is being conducted at over 30 hospitals nationwide, and that this is a protocol that has been under close study for over 8 years and was carried out very safely in the past. This study provides proven tools that enable the clinical team to manage blood sugar with a high degree of safety. As a result we have an extremely low rate of hypoglycemia in study patients because we monitor them so carefully.

1. **Do most sites have a well-defined TGC protocol being used in their units prior to joining HALF-PINT?**

While some sites did note having a pre-existing hospital TGC protocol and how this was helpful, especially in patients already being treated with insulin, most sites did not have TGC standards in place outside of the study. When approaching a family whose child is already receiving insulin, it is helpful to mention this, and explain that the study would offer the team additional tools intended to improve the safety and effectiveness of a therapy that is already being offered.

1. **What are some major hurdles you have come across? And how have you overcome them?**

Staff buy-in has been a problem across many sites. Some physicians take issue with the protocol itself or question whether there is equipoise between the treatment arms. Opposition from bedside nurses typically stems from a feeling that the study is too much extra work. Having Site PIs explain the significance of the study to individuals and at staff meetings has helped in many cases. Making an effort to be visible in the ICU and demonstrating to nurses that you are available for help as often as they would like it (entering hourly glucose values, on-call for questions, etc), as well as highlighting the features within CHECKS that can facilitate their work (Early Entry buttons, Observation Mode when applicable, etc.) has eased concerns about bedside workload. Keeping the clinical staff updated and aware of the study’s progressand giving them ownership of their part in the study (their concerns are important, and they should contact study staff whenever they have a problem) was noted to promote staff acceptance of the study. Always remaining friendly, communicating clearly and knowledgeably, and thanking staff for their help can further facilitate good working relationships with the clinical team.

1. **How do you handle consenting one parent vs. two?**

Most staff found it helpful to present the study to whichever parent is present at the bedside and then offer to come back if another parent would be in later. It is important to address everyone present (grandparents, friends, etc.). If a parent would like to wait for the other parent to be there, or would like to privately discuss the study with someone else, reassure them that this is completely fine and try to establish a time to come back to check in on them, so that you are not bothering them unnecessarily before they have decided and so that they don’t forget about the study once you leave the room. This also avoids the unpleasant feeling of “hovering” at the bedside. If one parent does consent, you can offer to explain the study to the other parent or any other relatives that will be in later, rather than forcing the parent to try and explain it. If the parents decide to give consent, make it known that you are always available for questions via their nurse and that you will be checking in daily anyway.

1. **What are the most frequent reasons you get parent refusals, if at all?**

Most often parents refuse the study because they are overwhelmed and simply cannot handle adding anything to their child’s care that is not absolutely necessary, or because they are uncomfortable with some aspect of the study (usually the sensor). There may be times when parents are simply not interested in participating in research and will not have their minds changed, no matter what the coordinator may say. However, there are other times when parents may refuse because they do not fully understand the information being given to them. By presenting information in small chunks, emphasizing the safety emphasis and potential benefits of the study, and allowing them to ask questions, you may be able to solve this issue!

When feasible, if it seems that parents may be leaning toward declining the study, it can be helpful to suggest inviting the PI to speak with them about the study. This will give the parents some more time to think about the study, to formulate any questions they may have, and to hear about the study in different words in case there were any aspects that they were previously misunderstanding.

1. **How do you respond when parents say that their child is just too sick for the study and they do not want him/her to go through anything else?**

Validate the parents’ concerns, and remind them of the potential benefits of the study. It is helpful to frame the study as an extra safety measure that will introduce another set of eyes looking in on the child’s care. The study can be helpful to the nurses because it provides them with real-time glucose readings; if the child does need insulin, by giving it to them we’re helping to relieve some of the effect of the stress of their bodies. Reassure parents that we would never do anything to put more stress on their children, and that if at any time during the study the clinical team feel that the study is too much for either the child or the team to handle, they are empowered to suspend the study.

1. **How do you respond to parent questions about whether or not the child truly needs to be enrolled if his/her BGs have come down after the initial high blood glucoses that made them meet randomization criteria?**

It is helpful to explain that critically ill patients have a lot of variance in their blood sugar and that even though their child’s sugars may be normal currently, these could go up or down in a very short amount of time. The study allows us to quickly identify these ups and downs so that we can help patients maintain steadier blood sugar levels.

1. **Do you use any props (e.g., sensors, vamp, etc.) when you describe the study to families? If so, how do you use them?**

Coordinators vary in what they bring in to the consent conversation: some bring a sensor and receiver, or an iPad with pictures, while others bring in the whole cart so parents could see the HALF-PINT setup. In most case it is helpful to show parents a deployed sensor so that they can touch the wire and see how small and flexible it is. As it can be hard to picture the sensor otherwise, this is the most intimidating aspect of the study for some parents. Seeing it can help solve this! Showing them the VAMP can also be helpful as a lead in to explain how it decreases the risk of infection, another great feature of the study that wouldn’t necessarily be available otherwise.

When explaining the study and its devices, it is always better to use nonthreatening language: “placing the sensor” vs “inserting the needle,” “trying to better understand high blood sugar” vs “conducting a clinical trial.”

1. **Are there any parts of the HALF-PINT study that you find difficult to explain during the consent? How do you ensure that you’ve included all the details and made them easily understandable?**

Many coordinators go through the consent page by page with parents—this will ensure that you’ve covered everything, and will make the parents feel confident that nothing is being left out.

Some parents find the concept of randomization difficult to understand. An easy way to explain it is that it the child will be put into one of two groups, similar to the flip of a coin. We don’t intentionally choose which group they are put into because we don’t know for sure which one is better; this is the whole reason why we need to do the study.

1. **What is the setting of where you meet with families to describe the study? Are some settings more conducive to successful consenting than others?**

It depends on the parent and what their comfort level is, but it seems as if most conversations take place at the bedside or close by within the patient’s room. If the parents are willing to leave the bedside, it may be easier to have the consent conversation in a different setting (e.g., office or family room) where they can better focus on the information you’re conveying to them. In any scenario it is helpful to sit down with the parents so that you are not standing over them.

1. **How do you transition from getting consent for HALF-PINT to discussing consent for CAF-PINT?**

It is helpful to start the conversation off by telling parents you’re going to invite them to participate in two studies. If the parents decide they want to participate in HALF-PINT, then you can move on to CAF-PINT. Some families are uncomfortable with the idea of their child’s blood being shipped off to another location. For this you can ensure them of the study’s confidentiality and de-identification processes, and that the blood will only be used for the purpose of the study, and will be discarded once the study is finished. Another concern comes with the idea of ‘coagulation’ which can be hard for parents to understand. An easy way of explaining the study is to say that we have evidence that TGC is beneficial for critically ill children, but we don’t fully understand why, and that’s what CAF-PINT is aiming to discover. The theory is that blood clotting plays a role in this process, and so the study is trying to look at factors that help blood to clot and how these are affected by blood sugar.

For this study, you can also remind parents that though it would require a small amount of extra blood to be taken from their child, study staff can pair those draws with the bedside team’s routine blood draws that are already being done, so we wouldn’t have to access the child’s lines any more than usual (meaning we wouldn’t increase risk of infection). If parents are worried about the amount of blood being drawn, you can reassure them that the child’s doctor approved participation in this study as well, and the draws would only amount to a few teaspoons of blood total, and should not contribute to any blood volume issues or anemia. As always, we will defer to the clinical team and avoid doing anything that they feel is not in the best interest of the child.