

Dear Medical Director,

I would like to make you aware of our institution's participation in an international quality improvement initiative involving patient safety and ask for further your support of this project. This initiative concerns the practice of sedating children for medical procedures and involves the formation of the Pediatric Sedation Research Consortium (PSRC). The consortium consists of 28 participating institutions in North America and Europe and will involve data collection and information sharing in an effort to determine the nature of pediatric sedation practice and to explore the best practices in this field.

Background (Why do we need the PSRC):

Each day thousands of children enter hospitals across the United States requiring sedation for diagnostic and therapeutic procedures. The approach taken to achieve the goals of sedation for a particular procedure vary widely from one institution to another. In addition, the number of requests for sedation often outstrips the availability of sedation experts. The systems solutions developed to accommodate these requests also vary across the country and even within a given hospital or organization. Some services employ direct physician involvement while others rely on trained nursing personnel. Still others have developed the concept of a "sedation room" or a "sedation team".

The major goals of pediatric procedural sedation are to provide anxiety relief, pain control, and (usually) a still child. The rate of *failure* to achieve these goals has been reported by various investigators to be as low as 2-3% and by others to be 10-20%.

The safety of pediatric procedural sedation is also problematic. In 2000 Coté and coworkers published a review of a series of sedation "critical incidents". Their analysis reveals that the overwhelming majority of these critical events were preventable and due to operator error.

Expert consensus that respiratory depression caused by sedative drugs should not lead to morbidity or mortality catalyzed the American Academy of Pediatrics (AAP), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Society of Anesthesiology, the American Academy of Pediatric Dentistry, and the American Dental Society of Anesthesiologists to issue practice guidelines for sedation. Unfortunately, reports of inefficient and unsafe pediatric sedation practice exist even when guidelines are in place.

Quality Improvement:

A major difficulty with pediatric sedation quality improvement efforts lies in the difficulty that exists in collecting data from the various locations within an institution where sedation is performed. In addition, it has been difficult to come up with generally agreed upon outcomes of sedation that were important to measure. Finally all published reports (to date) lack the power to yield a reasonable estimate of critical incident

occurrence largely because the rate is relatively low (1 in 1,000's) and the data used is generally that of small randomized study groups (10's to 100's).

The PSRC will help on all these fronts. 1) An interactive web-based data collection tool has been created that will allow rapid and convenient storage of important outcome data on pediatric sedation activity from all areas of our institution. (visit at <https://sport.dartmouth.edu/psrc/enter> - username and password "guest") 2) As a member of PSRC, we will be able to compare our own data on efficiency and safety of sedation practice with that of the group on a regular basis. At this time we plan to have a quarterly formal report given to each institution. In addition, the data will reside on a server which will be secure and accessible to each institution for their own data at all times. 3) The collective data produced by the group will give us the power to estimate the true incidence of critical incidents related to pediatric sedation activity. 4) Finally, in evaluating the data, we believe we will be able to identify "best practice" institutions and evaluate their practice with site visits and develop model processes which will further improve the care at all participating institutions.

Organizing Principles for PSRC:

The PSRC has formed around several key principles.

1. All participants should be considered equal partners – any publications or reports generated through the data compiled by the group would be cited as having come from the entire group.
2. The group would have to meet in person once before starting to collect information and at least once a year thereafter – all other business will be conducted over electronic communication.
3. The first meeting of the group would be focused on developing a one page reporting document that would be completed for each sedation. The information on this "data sheet" would include patient demographic data, procedure, medications employed, techniques used, basic outcome data etc. The key elements of this data sheet would include simplicity and collection of the most important information relating to a given sedation.
4. The information collected from the data sheets would be compiled and kept in a database that would be maintained at the Bioinformatics Group at Dartmouth Hitchcock College – this data would be available at all times to any investigator who would like to evaluate the data.
5. At periodic intervals, members of the consortium would visit other sites or institutions involved in the consortium. These "site visits" have proven extremely informative in other study groups such as this – allowing institutions to benefit from seeing how different providers attack similar problems.
6. IMPORTANT: Participation in this group would in no way preclude any participant from continuing their quality improvement efforts or current sedation research projects.
7. Grant money would be sought to support the operation of this consortium. It is expected that any monies that are obtained using the name of the consortium in

the grant request will be used to further the work of the PSRC in some direct way. Any individual that requests funds in the name of the PSRC will be required to report the request to the research committee. Any funding that is obtained will be reported to the group as a whole at the time of the award. Yearly reports on the use of the funds will also be expected.

What have we done so far?:

The institutions involved in PSRC have been working for 8 months on organization and principles of its operation. (Please see the attached enclosure for the names and contact information of all those involved in this effort.) We have clearly outlined its mission statement, goals, organizing principles. Efforts to secure grant funding for future operations have already been started. The web-based data collection tool has been developed to date under the auspices of the group – paid for by private funds. We have met as a group in Chicago on May 17, 2003 for the purposes of ironing out organizational issues and refining the data elements for the data collection tool. Joseph Cravero MD of Dartmouth Hitchcock Medical Center will serve as the Chair of this group for the first two years of operation. A steering committee for data management has been formed along with a research committee and an annual meeting committee. All involved to date are convinced that this effort will result in a group that will be uniquely positioned to help improve the practice of pediatric sedation internationally for the next several years.

What we are asking:

We are seeking institutional support from the administration of DHMC with respect to participation in the PSRC. We would like the institution to recognize this effort as an active part of its QI efforts with respect to pediatric sedation. The information gained will be more accurate and more meaningful than any other effort we are aware of at this time. I believe it will be very useful in our future interactions with JCAHO. We are also asking that each institution contribute \$600 to support the final development of the web-based data collection tool. This money would also be used for data maintenance and report generation for the first year of work by the group. All monies would be sent directly to the Bioinformatics Group at Dartmouth College and a full accounting of fund utilization would be sent at the end of the year. We strongly believe that future operations of the consortium will be supported by grants and we have already begun the process of applying for that funding. Unfortunately the best we could hope for at this point would be funding that would begin early in 2004 and we believe that this project is too important to wait that long. We also believe that as a functioning entity our future requests for funding will be that much stronger.

A number of documents regarding the PSRC are available directly on line at <http://an.hitchcock.org/pedisedation/> under the “Research” Consortium button. Please let me know if there is any further clarification I can give you concerning this matter. I look forward to hearing from you.

Summary:

The Pediatric Sedation Research Consortium has been formed to aid in the evaluation and improvement of pediatric sedation practice internationally. We firmly believe that this consortium will be the reference point for quality improvement in pediatric sedation in the coming years. Participation in this effort will directly benefit our institution in terms of secure, meaningful data collection and place us in the position to be part of the best process improvement effort for pediatric sedation that is currently available. At this time we are asking for your support by making the PSRC a major part of the QI process at our institution and by allotting \$600 to aid in completing the data collection tool and help in data management over the next year.

Thanks,

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