The research to practice continuum: Development of an evidence-based visual aid to improve informed consent for procedural sedation

M. Fernanda Bellolio1,2*, Lucas Oliveira J. e Silva1,3, Henrique Alencastro Puls4, Ian G. Hargraves5,6 and Daniel Cabrera1

1 Department of Emergency Medicine, Mayo Clinic, Rochester, MN, USA
2 Department Health Science Research, Division of Health Care Policy and Research, Mayo Clinic, Rochester, MN, USA
3 Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil
4 Universidade Federal das Ciências da Saúde de Porto Alegre, Porto Alegre, RS, Brazil
5 Center for Clinical and Translational Science, Mayo Clinic, Rochester, MN, USA
6 Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester, MN, USA


Informed Consent, in Part a Problem of Knowledge Translation

In order to fully participate in informed consent, patients must understand what it is that they are agreeing, or not agreeing, to. In most cases, patients look to their clinicians to help develop the appropriate understanding required to give informed consent. Often the quality of the information available as well as the delivery methods are not optimal.

Methods. Using a visual aid as an adjunct to risk communication in a stressful setting as the Emergency Department has a clear potential in facilitating the communication process. To support more accurate and consistent presentation of risk, we formed a team with implementation scientists, patient education specialists, nurses, physicians, and professional designers to transform the information available into a 6th grade reading level visual aid tool. We applied a DMAIC (Define, Measure, Analyze, Improve and Control) process to design the tool. We measured and analyzed its effectiveness through feedback from providers, patients, and caregivers. This cycle happened 3 times until we reached the final version of the visual aid.

Results. We utilized a DMAIC methodology as well as modified Delphi method to create and refine a visual aid tool. Several rounds of end-user feedback along with DMAIC allowed us to create a tool that was consistently better with each round of development, analysis and feedback. After arriving at the final version of the tool, we surveyed physicians in our Emergency Department. We measured the difficulty to understand the information, whether doctors think the visual aid will help patients to understand the data, and the appropriateness of the tool’s length and the amount of information in it.

Conclusions. We believe that our experience can be replicated by other researchers and clinicians in the endeavor of translating the evidence into clinical practice. An effort should be made to fully translate research findings until the end of the research to practice continuum in order to better translate knowledge into a useful and useable form for informed consent decisions in busy clinical practice.

Received 21 July 2017; Revised 20 September 2017; Accepted 3 October 2017; First published online 14 December 2017

Key words: Procedural sedation, informed consent, communication, Emergency Department, risk.
evidence when it is shared. These challenges are exacerbated in the Emergency Department, where time and emotional pressures operate.

In 2013, we identified an instance in which lack of patient and clinician understanding was resulting in less than informed consent. Frequently in emergency care, we need to provide optimal procedural sedation and analgesia (PSA) to allow for life-saving painful procedures. We found that the benefits of PSA were apparent to patients, caregivers, and clinicians, while the magnitude of the risks associated to PSA were unclear to all parties.

We had identified a translational gap between the best evidence available and proper informed decisions in the Emergency Department. Namely,
with respect to the 5-step framework of the Research to Practice Continuum (Fig. 1), we discovered that in practice, we were not been able to overcome step 4—the bringing of evidence to the clinical encounter where it can contribute to informed, and shared, decisions.

In this article, we describe the development of a visual aid to communicate the risks associated with PSA performed in Emergency Department pediatric and adult patients.

Finding the Evidence Is Not Enough

In order to respond to the translational gap, we used knowledge synthesis research strategies to make the vast amount of data available comprehensible for clinicians and by extension their patients. We published 2 systematic reviews and meta-analyses evaluating the risks of performing PSA in the Emergency Department for both the pediatric [1] and adult [2] populations. We found that serious adverse events are exceedingly rare, regardless of the different medications used for sedation.

As a product of our synthesis work, we created a pocket card to help clinicians cite consistent risk information regarding PSA to patients. Healthcare professionals received this bedside tool enthusiastically. However, the informal feedback we received from patients and caregivers showed that the pocket card was suboptimal. Patients recognized that their clinicians were sharing risk information with them but did not understand the information, or were not able to make use of this information in decision making.

In response to these findings, we examined strategies from shared decision making (SDM), a related process to informed consent, as a potential way of making the synthesized data accessible and useful for patients. In so doing, we considered that informed consent goes beyond acquiring patient treatment permission, it represents an active decision that patients are making with their clinicians. To engage patients in healthcare decisions, the evidence about risks of a particular treatment must be clear for both providers and patients.

SDM in healthcare is a collaborative process that allows patients and health professionals to consider the best evidence available, along with patients’ values and preferences, to make healthcare decisions [3]. SDM includes the clear communication of the benefits and harms of interventions to patients [3] making it a potential means for translating knowledge into a useful and useable resource in clinical care.

Evidence-Based Medicine and Knowledge Translation

Evidence-based medicine, when first described by Gordon Guyatt and his colleagues in the early 1990s, was proposed to be the intersection of clinical expertise, patient values, and the best evidence available [4, 5]. Significant criticism throughout the years argued that it has focused too much on the data itself and it turned out to tie the hands of clinicians and patients of their choices in deciding optimal care [6]. However, constant efforts have been made to align the evidence-based medicine core concepts with the translation of evidence into practice, especially regarding patient-centered perspectives [7]. The need for more knowledge translation as part of evidence-based medicine has emerged primarily from a gap between what is known from high-quality evidence and what is consistently done in clinical practice [8].

Translating research into practice is a complex process that involves creating or finding the evidence, its appraisal, dissemination, and awareness by clinicians, and adoption and implementation into a specific environment [9]. Communication of risks before informed consent acquisition requires more than knowing the best evidence available. It requires delivering and using this information in a meaningful and understandable way to improve the ability for patients to make an informed consent decisions.

Translating the Evidence into Practice

In 2015, 225 children and 278 adults underwent procedural sedation at our Emergency Department. Clinicians treating these patients were provided with a pocket card summarizing the harms and benefits of PSA to prepare them for informed consent discussions. The communication of the need and benefits of PSA was more straightforward for clinicians exposed to the card, but the communication of risks to patients remained challenging. The presentation of risks of PSA to patients in verbal form still led to significant differences among providers.

Fig. 3. Results of the survey with Emergency Department (ED) Physicians.
To support more accurate and consistent presentation of risk, we formed a team with implementation scientists, patient education specialists, nurses, physicians, and professional designers to transform the pocket card into a 6th grade reading level visual aid tool. Starting with the visual aid’s first version, we applied a DMAIC (Define, Measure, Analyze, Improve and Control) process [10] to design the tool. We measured and analyze its effectiveness through Delphi-type feedback from providers, patients, and caregivers. This cycle happened 3 times until we reached the final version of the visual aid (Supplementary Figs. S1 and S2, and Fig. 2).

After arriving at the final version of the tool, we surveyed 26 physicians in our Emergency Department. We measured the difficulty to understand the information, whether doctors think the visual aid will help patients to understand the data, and the appropriateness of the tool’s length and the amount of information in it. The results were positive and are shown in Fig. 3. Our next steps include to obtain provider feedback on the frequency of visual aid utilization and the efficacy in relaying information, and to explore the consequences of using the tool, such as delays in care and refusal to perform the procedure.

Conclusion

Using a visual aid as an adjunct to risk communication in a stressful setting as the Emergency Department has a clear potential in facilitating the communication process. Contemporary evidence shows that the addition of visual displays of data to numerical formats increases accuracy and comprehension. In particular, icon arrays showed improved accuracy and understanding and were seen as more helpful, effective, trustworthy, scientific, and useful when compared with natural frequencies. Despite our visual aid being consistent with current recommendations on risk communication, a post-implementation evaluation of our visual aid is still needed.

An effort should be made to fully translate research findings until the end of the Research to Practice Continuum. In order to better translate knowledge into a useful and usable form for informed consent decisions in busy clinical practice, we created a visual aid to facilitate risk communication for Procedural Sedation and Analgesia in the Emergency Department. We believe that our experience can be replicated by other researchers and clinicians in the endeavor of translating the evidence into clinical practice.

Acknowledgments

The authors thank Ms. Alyssa Frank for her design of the 5-step framework figure.

Authors’ Contribution

MFB and DC conceived and designed the study. MFB and LOJS drafted the manuscript and all authors contributed substantially to its revision with critical revision of the manuscript for important intellectual content.

Financial Support

The authors received funding through the Small Grant Program of Mayo Clinic Foundation for medical education and research (Award number SGPh91579004) and Mayo Clinic CTSA through grant number UL1TR000135 from the National Center for Advancing Translational Sciences (NCATS), a component of the National Institutes of Health (NIH).

Disclosures

The authors have no conflicts of interest to declare.

Supplementary Material

To view supplementary material for this article, please visit https://doi.org/10.1017/cts.2017.303

References