

# Outcomes for Trauma: Is There an End (Result) in Sight?

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In the following address I will discuss the role that EAST has had in developing an evidence-based approach to the practice of trauma, why it is important, who has made it important, and what the future of trauma outcomes will likely resemble. This talk is the third in a series, a series that started in the early 1990s, and hopefully will continue into the future. It also reinforces and extends the thoughts that Dr. Russell left us with yesterday in his address regarding the future of quality assessment in surgery.

In 1994, in his presidential address to the Seventh Scientific Assembly of EAST, Dr. Michael Rhodes introduced us to the concepts of evidence-based medicine and practice management guidelines.<sup>1</sup> Evidence-based medicine is defined as a method of patient care, decision making, and teaching that integrates high-quality research evidence with physiologic reasoning, experience, and patient preference.<sup>2</sup> Patient management guidelines are systematically developed statements designed to assist practitioners in making decisions about appropriate healthcare for specific clinical circumstances.<sup>3</sup> The five major purposes of practice management guidelines are to assist clinical decision making by patients and practitioners, educate individuals or groups of individuals, assess quality of care, guide the allocation of resources, and reduce the risk for legal liability.

In his discussion, Dr. Rhodes stressed that the idea was to base clinical decisions on the best available evidence and understand the power or quality of that evidence. Evidence-based practice involves, at its core, a fundamental acknowledgment that our clinical convictions can be wrong as well as the fact that we invariably underestimate the power of the placebo effect and assume that because most patients we treat in a certain way feel better, the treatment must be effective. Obviously, these concepts were not universally embraced

when they were first introduced, and a great deal of work has been put forth to arrive at where we are today with evidence-based practice.

In addition to patients and practitioners, it was felt that guidelines could be useful to purchasers of healthcare, legislators, and regulators. Further, it was felt that guidelines must be used to decrease unnecessary practice variation, formulate necessary research proposals, and most importantly, evaluate outcomes of care. Only through such measures can patient-specific guidelines be developed and improvements in care be realized. Dr. Rhodes challenged the organization to move forward in developing such guidelines and EAST responded.

Subsequent to his address, a jointly sponsored conference by EAST and HRSA (Health Resources and Services Administration) was held to define the methodology for practice management guideline development, leading to the creation of the first subcommittees addressing specific trauma related topics for guideline creation. This ultimately led to the 1998 *Journal of Trauma* article in which practice management guidelines for screening for blunt cardiac injury, cervical spine clearance, prophylaxis for venous thromboembolic disease, and antibiotic prophylaxis for penetrating abdominal trauma were presented.<sup>4</sup> At around the same time, EAST established its Website and began placing the guidelines on the site thereby making them available to the membership and others interested in trauma care. Today, there are 27 guidelines, as well as a primer describing the evidence-based methodology for guideline development available for viewing. To date, there have been 283,056 downloads of the various guidelines, and on average, there are 775 hits per day on the guideline section of the EAST Website.

Importantly, EAST, recognizing the evolution of acute care surgery, has charged the Guidelines Committee to begin to develop guidelines on emergency and acute care surgery subjects, and they have responded by preparing several relevant guidelines that will be presented later at this meeting during the plenary session on Friday.

In 1999, Dr. Timothy Fabian addressed the 12th Scientific Assembly, reminding us that EAST had made an early and profound impact on evidence-based medicine through the management guidelines project.<sup>5</sup> In a Star Wars analogy, he noted that we, like the crew of the Millennium Falcon, had begun a journey not quite sure whether our ship would make it to wherever we were going, but knowing that we could adapt and

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fine-tune the process as we made our way. He also introduced us to Ernest Codman and his end result idea,<sup>6</sup> which simply stated is that every hospital should follow every patient it treats long enough to determine whether the treatment rendered was successful and if not, why. Codman kept an end result card on each patient and developed a classification of errors for adverse outcomes. In this classification scheme, he noted that all results of surgical treatment that lack perfection may be explained by either errors in technique, judgment, care, or diagnosis, whereas other adverse outcomes could be explained by patient causes and still others by the calamities of surgery over which we have no control. He further thought that these results should be acknowledged by the surgeon and made available to the public. The concept of end result treatment outcome and accountability was also extended to hospitals, and Codman argued that hospitals were responsible for the care given by their staff and thus, they should carefully note the results of each surgeon and all of this should be made public. It sounds eerily familiar to some of the issues that are confronting us today; clearly the surgeons and hospitals of 1914 were not ready for this concept, and Ernest Codman was forced into resignation and exclusion.<sup>6</sup>

Dr. Fabian thought that multidisciplinary development of trauma practice management guidelines was key and that the process should be physician-directed, nonthreatening, developed from evidence-based outcomes, and integrated into performance improvement programs. He also argued that collaboration between the various trauma organizations would be key to future advances in evidence-based trauma care and he challenged EAST to continue to attempt to resolve the issues of guideline consistency, continuity of the process, monitoring of utilization and validity, and coordination of clinical trials. He noted that the development, classification, and distribution of trauma and surgical critical care related evidence-based guidelines had progressed rapidly.<sup>5</sup> However, the implementation of and outcome studies on the effect of guidelines were lagging.

Staying with Dr. Fabian's Star Wars analogy and in keeping with the trilogy concept, I would suggest that our evidence-based ideas have moved from the dark side and that the Force is now with us. The question at this point is where do we go and to answer that, we must answer several separate questions. The first is how do we assess quality of care? To answer this question, we must realize that there are three dimensions of health care that can be used to assess quality: structure, process, and outcome.<sup>7</sup> *Structure* refers to the attributes of how healthcare systems are organized to deliver care, whereas *process* refers to what we do to and for our patients, and *outcomes* are the results of that care. The standard outcome parameters of mortality and morbidity have been extended to include length of stay, cost, quality of life, patient satisfaction, and compliance with guidelines.

Outcome tools used to measure these parameters have included audits, surveys, severity scoring, cost accounting, and research studies but until very recently, outcome research has been primarily comprised of descriptive or retrospective

analyses of data that have been collected either retrospectively or prospectively.<sup>3</sup>

Using the "Algebra of Effectiveness" described by Lisa Iezzoni (Fig. 1), we see there are three major predictors of outcome of healthcare: a set of patient factors that constitute the patient's prehospital, preoperative, or preinjury risk; the effectiveness of care, which encompasses the quality of the providing facility's structure and processes of care as well as the competence of the providers and random events.<sup>8</sup> Thus, theoretically, if one can account for patient risk factors by proper risk-adjustment models and for random variation by statistical models, one can then equate outcome to effectiveness of care and thus, make it possible to use outcome as a measure of quality of care.

As we discuss these quality measures, it is important to realize that there are multiple organizations involved in this process, i.e., Institute of Medicine (IOM), Agency for Healthcare Research and Quality, the Leapfrog Group, the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations), American College of Surgeons-Committee on Trauma (ACS-COT), and National Institute of General Medical Sciences. Each of them are trying to assess quality, often in different ways and highlighting the need to collaborate and educate each other to avoid duplication of efforts and improve the efficiencies of each organization as we move forward.

The next question to address is what are the problems that we are facing, as hopefully outcomes evaluations will help us find answers and resolve some of the significant issues. With the IOM publication of "To Err is Human"<sup>9</sup> and "Crossing the Quality Chasm",<sup>10</sup> attention was focused on a number of preventable provider errors and iatrogenic injuries that were occurring in hospitals across the country. Conversations among healthcare policy makers emphasized the implementation of quality improvement processes and outcome measures across the healthcare system. The anesthesia and



Fig. 1. Algebra of effectiveness of major predictors of outcome of health care.<sup>8</sup>

surgery communities, in part through the efforts of the Anesthesia Patient Safety Foundation, the ACS, and the Veterans Health Administration (VHA), put forth efforts to develop new structures and processes to enhance the safety of the surgical patient. The IOM report set as a goal for these national efforts a 50% reduction in error-related deaths during a period of 5 years. In addition, the report stressed the need for an evidence-based approach to patient care and evaluation, but more than 7 years later, there is little concrete evidence to suggest that any of these efforts have resulted in an overall reduction in error-related deaths. One of the important reasons for the failure to properly evaluate the impact and efficacy of these initiatives is the lack of a proper metric for assessment of patient safety.

Clearly, another significant problem in the United States is the cost of healthcare, and compounding this is the fact that the increased costs of care have caused differences in how care is provided. This has resulted in differences in access of care, quality of care, and availability of adequate preventative efforts.<sup>11</sup> Further, it is felt that these are directly linked to the method of payment. In short, our healthcare plan is dependent on a payment plan rather than a care plan.<sup>12</sup> What about trauma? Do we have a problem? I would argue yes, and these problems are nicely articulated in the recently released IOM report on the future of emergency care.<sup>13</sup> I would encourage all of you to read this document carefully and begin to educate your community representatives about the problems that trauma care faces. The problems in trauma care are similar to the ones I've mentioned: access, quality, prevention, and, of course, cost.<sup>13</sup>

What are the potential solutions and can they be applied to trauma? What I would like to do is look at some of things that have been performed in surgery and then see how those could be applied to trauma. Prompted by a 1987 congressional mandate that required the VHA to report outcomes of major surgery as per national average and risk-adjusted for severity of patient illness, the National Surgical Quality Improvement Program, or NSQIP, was born.<sup>14</sup> The development of NSQIP has provided surgeons with new tools to assess and improve the quality of surgical care.

NSQIP is the first national validated state-of-the-art system for the comparative measurement and continuous improvement of the quality of major surgery. The comparative metric employed is risk-adjusted outcome with focus on risk-adjusted 30-day morbidity and mortality. The program was initiated in the Veterans Administration Hospital in 1994, and because of its success in reducing postoperative morbidity and mortality, it became available to all eligible hospitals through the ACS in 2004.

The distinguishing feature of NSQIP is that it applies to outcome-based quality measurement, the same scientific rigor that is normally applied to clinical trials in fundamental research. A trained and dedicated clinical nurse reviewer at each medical center prospectively collects prospectively preoperative, intraoperative, and 30-day outcome variables on patients undergoing major surgery. The data collection meth-

odology is standardized and nurse competency and inter-rater reliability are periodically checked and validated. Data are subsequently transmitted to a national trauma data coordination center, where it is analyzed on an annual basis. These analyses identify the independent predictors of various 30-day outcomes for all operations in a hospital and then calculate a beta coefficient for each predicted variable. This coefficient is used to calculate the expected 30-day outcome of patients and an observed to expected ratio can then be calculated and used as a risk-adjusted metric for that outcome and appropriate benchmarking can then be performed (Fig. 2).

Hence, to use outcome as a measure of effectiveness, quality, or competence, two basic ingredients are needed, a reliable clinical database of patient characteristics and outcomes and valid analytical risk-adjustment models that would account for random events. These two factors are at the core of NSQIP, and I think they can be applied to trauma<sup>15</sup> (Fig. 3).

In the initial 10 years of NSQIP, the participating hospitals noted a 45% reduction in morbidity for all major operations and a 27% reduction in mortality.<sup>16</sup> These results led to the expansion of the program into the private sector; today approximately 150 hospitals nationwide are enrolled in the program.<sup>17</sup> In its current format, however, NSQIP is not easily transposable to trauma because of several limitations. Thirty-day follow-up is a barrier due to trauma patient non-compliance with scheduled follow-up visits and the variety of providers involved in the care of any one trauma patient. Additional full-time equivalent (FTE) support will be required to collect additional customized outcome data not currently tracked by our trauma registries which would add cost. There is also data collected by NSQIP that is irrelevant to trauma patients, and NSQIP clearly is better at assessing systems and hospitals, as opposed to surgeons and procedures. Despite these limitations, the core principles can be applied to trauma.

Another potential solution argues that we need to change our focus from a system that restricts cost and care to one that

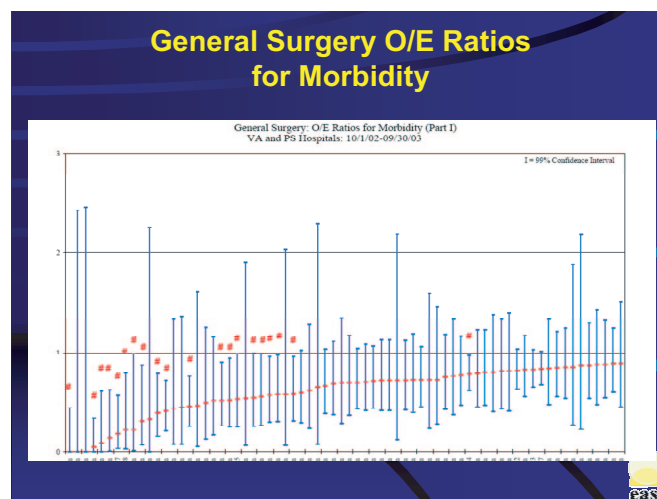
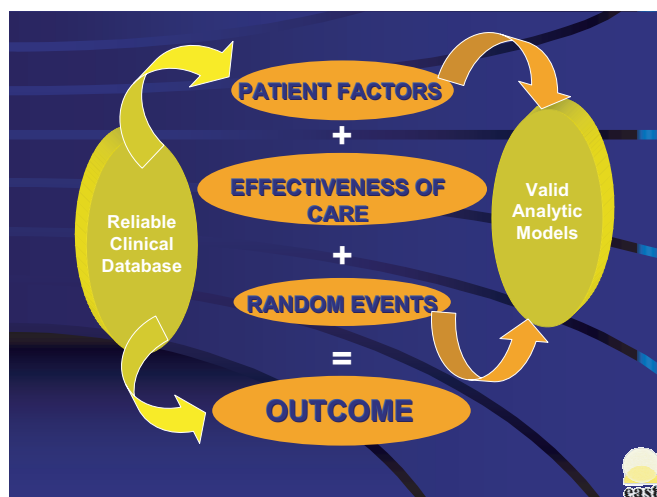


Fig. 2. General surgery O/E ratios for morbidity.





**Fig. 3.** Key components necessary to determine outcome.

rewards high quality care, the much discussed pay for performance system, or as is referred to by our legislators, value-based purchasing for physicians.<sup>18</sup> Clearly, Medicare intends to follow the lead established by private health plans and business to evolve into a system where payment is based on providing services effectively and efficiently. The question arises as to who should decide on the effectiveness and efficiency of care, and I would argue that it has to be the trauma surgeons that provide the care. We must provide the necessary information to model the future trauma system.

Trauma surgeons must provide evidence-based processes and evidence-based outcome measures by which we will be judged. If we don't do this, someone else will, and they will most likely not understand the needs of the trauma patient and the trauma surgeon as well as we do. Again, there is a model to which we can use to make such recommendations. The Centers for Medicare and Medicaid Services (CMS) are partnering with physicians and hospitals on a broad array of quality and safety outcomes and processes; in the new contract cycle, the CMS will be working to implement the goals established by the Surgical Care Improvement Project (SCIP).<sup>19</sup> The goal of SCIP is to use evidence-based processes to reduce surgical complications by 25% during the next 3 years. Complications are the focus as the available data would suggest that complications not only increase our cost of care and length of stay, but they also increase the mortality risk in hospitalized patients.

SCIP is initially focusing on four areas: (1) cardiac complications, namely the prevention and treatment of myocardial infarction; (2) reduction of postoperative infection through the appropriate use of perioperative antibiotics, maintenance of euglycemia, and maintaining normothermia in the perioperative period; (3) prevention of DVT (deep venous thrombosis) and PE (pulmonary embolism) by appropriate use of prophylactic measures, because of the fact that major operations are complicated by DVT and PE in 25% and 7% of cases, respectively; and finally; (4) diagnosis and treatment of ventilator-associated

pneumonia, which has been reported to increase the hospital mortality rate by as much as 30% to 45%. This focus on process is aimed at decreasing perioperative complications and it seems that trauma could borrow from such a model, particularly when you look at focus areas 2, 3, and 4.

We have problems and we have potential solutions, but before we apply these solutions to trauma, we must ask the question as to whether or not trauma is a worthwhile expenditure of the energy and the cost it would take to do this. That is, do trauma programs, trauma centers, and trauma systems make a difference? The answer is a resounding Yes! The recent study by Ellen MacKenzie et al.<sup>20</sup> at both the Johns Hopkins Bloomberg School of Public Health and the University of Washington School of Medicine showed that care at a trauma center lowered by 25% the risk of death for injured patients compared with the treatment received at nontrauma centers. This represents the kind of work that we must do so that as trauma surgeons we can continue to demonstrate our effectiveness and efficiencies of care. If it is worth it, how should we go about doing that and at the same time improve our outcomes?

Realizing that the number one obstacle to implementing performance measurement systems is the lack of evidence-based process and outcome measures and drawing from the work that I have just described, the COT has tasked the committees of Performance Improvement, Trauma Registry, and Outcomes to develop a NSQIP-like system for trauma. The work being put forth by this combined group is now referred to as the Trauma Quality Improvement Project (TQIP), the name coined by Dr. Mark Hemmilla in his trauma outcome research at the University of Michigan. Looking at the key factors involved in NSQIP, namely robust data definitions for comorbidities and complications, education of data reviewers and collectors, establishment of inter-rater reliability audits, and the development of risk-adjusted analysis for semiannual reports, you can see that trauma is the ideal arena to employ the NSQIP methodology.

The Performance Improvement and Patient Safety and Outcomes Committees of the ACS-COT are currently developing definitions for appropriate comorbidities and complications, while the databank infrastructure within our institutions, our trauma registries, and nationally with the National Trauma Data Bank (NTDB) already exists. We also have a means to perform inter-rater reliability audits, as once the appropriate risk-adjusted analyses are performed they can be incorporated into our current verification process. The overall goals of TQIP are to create a customized module for collection of comorbidity and complication data, couple this module with the NTDB to create one database for trauma patients, produce risk-adjusted analyses and reporting to identify best practices with feedback mechanisms and, in doing so, improve the quality of care delivered to the critically injured. Looking at defining outcomes, we have to realize that there are problems and one of these is that there are a number of different trauma and surgical organizations that are looking at outcomes and defining them differently. The outcomes that are being followed largely depend on what group is

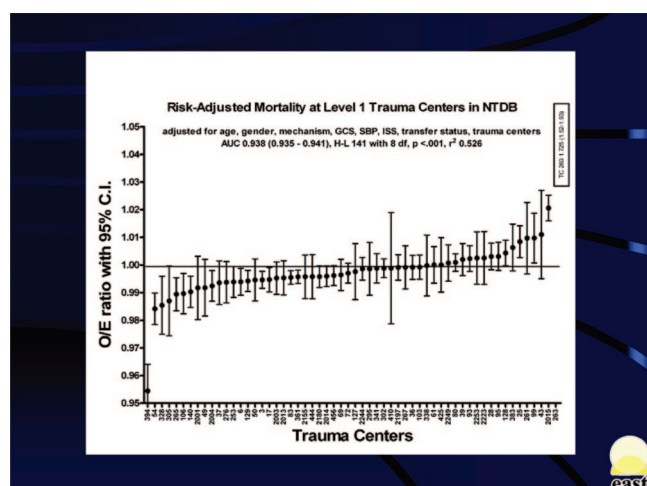


Fig. 4. O:E ratio for trauma mortality created by risk-adjusted equation.

**Table 1** Impact of Age on Survival

Age	OR	CI
≥55	2.50	2.28–2.74
≥65	2.84	2.57–3.13
≥75	3.20	2.85–3.59
≥85	3.47	2.77–4.34

**Table 2** Impact of Comorbidity on Survival

Comorbidity	OR	CI
Cardiac	2.98	2.39–3.72
Respiratory	2.02	1.37–2.98
Diabetes Mellitus	2.14	1.67–2.73
Coagulopathy	4.21	2.90–6.12
Obesity	1.38	0.49–3.83

**Table 3** Impact of Complication on Survival

Complication	OR	CI
Renal failure	7.22	4.19–12.46
DVT	1.34	0.63–2.86
PE	1.93	0.58–6.42
Pneumonia	1.14	0.95–1.37

being considered. This problem can only be overcome by providing uniform definitions for those things that we think are important to improve our trauma care. To that end, the following have been suggested as outcomes that we can immediately begin to collect and evaluate: adjusted mortality rate with time and location of death and exclusion of patients who arrive to our facilities dead, information on length of stay, and discharge destinations. Work is currently being performed to define or better define how we track functional status after discharge, explore how we deal with both withdrawal of care and the assignment of a do not resuscitate (DNR) status, and unplanned readmissions within 14 days of discharge. Long-term, we must look at assigning the more difficult definitions, those dealing

with cost-to-charge ratios, multiple organ dysfunction syndrome, resource utilization, and unplanned interventions.

The next steps in TQIP involve submission of a list of proposed immediate outcomes with definitions to the NTDB, continued work on defining intermediate and long-term outcomes, training of data abstractors on appropriate data collection and submission, and finally, the development of risk-adjusted equations for assessment and analysis. Similar to Figure 2, Figure 4 shows an O:E ratio for trauma mortality created by a risk-adjusted equation proposed by Shahid Shafi, MD, one of the young and energetic members of the TQIP subcommittee. Shahid, Mark Hemmilla, and Avery Nathans are putting forth tremendous efforts on behalf of this committee.

One of the main problems with our current system is the lack of adequate risk adjustment, which makes benchmarking and quality improvement difficult. As an example I would ask you to look at nonpublished material presented at the 2005 Annual Meeting of the ACS-COT regarding mortality after isolated severe closed head injury. Looking at Tables 1 through 3, it can be seen that age, by decade of life, significantly increased the risk of death when compared with patients under the age of 55. In addition, a history of cardiac or respiratory problems, diabetes, coagulopathy, and complications also significantly increased the risk of death in these patients, factors that our current scoring systems simply do not acknowledge in a meaningful way. It was concluded that age, comorbidities, and complications have a significant impact on mortality for isolated head injuries and uniform definitions, appropriate risk adjustment, and compliance with reporting are desperately needed.

One other important consideration in discussing mortality is the assignment of preventability, and I would like to share with you some of the results from a recent study that we just completed in Pennsylvania. Special thanks to Juliet Geiger, the Pennsylvania Trauma Systems Foundation, and Mary Ann Spott, Program Manager, Joint Theater Trauma Systems Program of the Institute of Surgical Research, for their help in allowing us to get this project funded and completed.

Mortalities were submitted by individual institutions and evaluated by a panel of trauma surgeons in the state. Each submitted case was reviewed by at least 10 trauma surgeons and a comparison was made between the institutional and reviewer's assignment of preventability. The PI tool used to make the comparison was the previously established Pennsylvania Outcomes and Performance Improvement Measurements System software.<sup>21</sup> At first glance, it appeared as though there was reasonable correlation between the institutional and reviewer's classifications of mortality (Table 4); however, a closer look shows that there was a significant difference in the reviewer's classification when compared with the institutional classification (Table 5). As shown, roughly only 50% of the time was there correlation between the institution's assignment of preventability and the expert panel of reviewers' assignment of preventability. Another interesting finding was that our current scoring systems

**Table 4 Institution or Reviewer Agreement**

Mortality Class	Institution (%)	Reviewers* (%)
Preventable (P)	33	26
Potentially preventable (PP)	35	42
Nonpreventable (NP)	32	31

\* Approximately 1% of the ratings were not completed.

**Table 5 Institution or Reviewer Agreement**

Institution	Reviewer	Proportion (%)
Preventable (P)	P	53
	PP	28
	NP	18
Potentially preventable (PP)	P	22
	PP	59
	NP	17
Nonpreventable (NP)	P	3
	PP	39
	NP	57

(Trauma Related Injury Severity Score [TRISS] and ISS) did not seem to be helpful in assigning preventability and this was most striking when looking at preventable and potentially preventable mortalities. Two of the conclusions from this study were that reviewers provided different mortality classifications than the institutions and TRISS and ISS did not seem to be helpful in making a preventability classification. The question that arises as we move forward is whether or not preventability classification is the best way to look at mortality. Perhaps with the creation of better risk-adjusted measures, the focus will change from preventability classification to improving processes of care identified by outcomes and facilitated by learning from benchmark institutions.

I think that we all agree that there are problems in trauma and we must address them. We are responsible for demonstrating effectiveness and efficient processes of care, as well as sharing our outcomes of care. There are models available and we should begin to apply these to trauma. I would argue that we are responding by defining outcomes and processes, using our reliable clinical database, the NTDB, and beginning to develop the appropriate risk-adjusted equations so that we can use outcome as our measure of quality and provide feedback to improve our processes and quality programs so that trauma care in this country will continue to be outstanding.

I would like to close by noting that it has been a privilege to be part of this wonderful organization and an honor to serve as your president. I have received so much more than I have given, and for that, I am extremely thankful. To EAST and to you today, I say thank you very much.

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