

# FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

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**TITLE OF INFORMATION COLLECTION:** Perioperative Medication Safety Self-Assessment for Hospitals and Ambulatory Surgical Centers (ASCs) and Targeted Risk-Reduction Tool Development

## **DESCRIPTION OF THIS SPECIFIC COLLECTION**

### **1. Statement of need:**

Medication errors occur frequently in all phases of perioperative care, and patient harm has been linked to errors in this setting. Many best practices that would prevent these errors are known; yet, we do not know to what extent they have been implemented in healthcare organizations, as few rigorous assessments of medication systems and practices have been conducted in the perioperative setting. Nor has the healthcare community been effective in disseminating knowledge about best practices to perioperative practitioners or providing them with a detailed roadmap on how to assess medication systems for vulnerabilities.

A perioperative medication safety self-assessment will provide knowledge about best practices to healthcare providers and enable them to proactively identify and prioritize gaps in their medication systems and practices not currently recognized with voluntary medication error reporting and analysis, thus encouraging the development of action plans based on best practices. Reporting the results of organization-level assessments to a national database will result in baseline measurement of best practice efforts and allow identification of national perioperative medication safety priorities. This level of assessment is an essential first step toward improving medication safety in the perioperative setting. Please see draft perioperative self-assessment document and associated Frequently Asked Questions for additional information.

### **2. Intended use of information:**

The results of this study will be used to establish a baseline measurement of perioperative medication safety practices by using a self-assessment tool that can be used to guide tailored improvements in perioperative health outcomes (e.g., reduced medication errors) at medical institutions. The Institute for Safe Medication Practices (ISMP) will own the data and use it for analysis of baseline strategies for medication error reduction in perioperative settings, to identify national challenges, and to create a useful tool to promote perioperative medication safety (selected based on the survey results and identified needs). ISMP will be collecting data for FDA from January 2021 (following OMB approval) to April 2021, for baseline measurement of perioperative medication safety. However, the self-assessment tool will remain available from ISMP for organizations to use periodically to measure their own improvement in adopting the recommended best practices based on weighted responses. Previous ISMP Medication Safety Self Assessments® have been used in this manner by groups and individual healthcare providers to measure ongoing improvement. The associated tool (selected based on the survey results) will also be available for all organizations to reduce the risk of perioperative medication errors.

### 3. Description of respondents:

- ISMP is planning to invite all hospital and ambulatory surgery sites to participate. ISMP will not be selecting a discrete sample to take the survey. Instead, ISMP will be making the assessment available to all who provide perioperative care within the scope of the assessment. There is no cost to participate.
- Each respondent will comprise an interdisciplinary team of healthcare practitioners who work (or manage processes/technology) in the perioperative setting in hospitals, freestanding ambulatory surgery centers, and other facilities where perioperative services are offered.
- Teams may include representation from administration, medical staff (anesthesia practitioners, surgeons), perioperative nurses, pharmacists, technicians (surgical, pharmacy), risk/quality/safety, and information technology. Based on the pilot testing, ISMP recommends a team of 1 - 3 members for ASCs and 3 - 8 members for hospitals.

ISMP has a robust outreach plan for the perioperative assessment to get the word out to all hospitals and ambulatory surgery centers. This outreach plan is similar to the plan used to promote participation in previous ISMP Medication Safety Self-Assessments®, although the outreach vehicles in this plan are intended to reach a broader audience that includes both hospitals and ambulatory surgery centers. Therefore, we expect a similar response to our outreach plan for participation in the perioperative assessment.

Examples of the vehicles used for the perioperative assessment outreach plan include:

**Endorsements and supporters:** ISMP has requested endorsement of the perioperative assessment from 50 professional organizations, reaching out to join us in promoting this new evaluation tool and disseminating the findings. For the 2018 *Safety Self Assessment*, ISMP received endorsements from 20 organizations, including the American Nurses Association, American Society for Healthcare Risk Management, Anesthesia Patient Safety Foundation, Association of perioperative Nurses, American Society of Health-System Pharmacists, American Hospital Association, Institute for Healthcare Improvement, and The Joint Commission. We anticipate similar endorsements for the perioperative assessment, in addition to new endorsements from ambulatory surgery associations (e.g., Ambulatory Surgery Center Association, ASC Quality Collaboration) and accrediting organizations (e.g., Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities). Endorsing organizations are asked to let their members know about the assessment and to encourage participation. Many endorsers provide a link to the assessment on their professional websites.

Additionally, ISMP will be seeking support of the perioperative assessment from very large health systems (e.g., Kaiser, Ascension), group purchasing organizations, and government healthcare facilities (e.g., department of defense, veteran's administration), who will assist ISMP in awareness of the assessment while encouraging participation. Some of these large groups will analyze their aggregate data from the assessment to collectively work towards improvement.

**Email campaign:** ISMP has more than 50,000 email addresses and additional contact information for healthcare providers from both inpatient and outpatient settings who have specifically asked to receive important updates from ISMP about programs, projects, and medication safety. We will be sending information out to these healthcare providers to let them know the perioperative assessment is available and to actively encourage participation.

**ISMP newsletters:** ISMP has already begun an awareness campaign for the perioperative assessment via various ISMP newsletters. The acute care newsletter, the *ISMP Medication Safety Alert!* reaches practically every hospital in the US; the community/ambulatory edition reaches thousands of ambulatory sites; and the nursing edition reaches thousands of frontline nurses who work in various settings.

**ISMP speaking engagements/conferences:** ISMP has created slides about the perioperative assessment for ISMP staff to use during speaking engagements and conferences. To date, the slides have been used widely during speaking engagements, including at quarterly Medication Safety Officer Society (MSOS) presentations. ISMP has also planned a free webinar (to be scheduled after launch) to describe the value of participating in the perioperative assessment.

**ECRI marketing:** ISMP's parent organization, ECRI, will also be marketing the perioperative assessment to 50,000 members of ECRI and the ISMP Patient Safety Organization as well as to members of various other ECRI groups.

**4. Date(s) to be conducted:**

- January 2021 (after OMB approval) through April 2021
- Given the ongoing COVID-19 public health emergency, respondents will conduct this assessment using any mitigating steps required to protect participants, such as meeting remotely.

**5. How the information is being collected:**

- The assessment and directions will be obtained on the secure ISMP website.
- The assessment will be completed online or on paper, and the results will be submitted to ISMP online.
- Respondents will submit their findings anonymously to ISMP via a secure, password-protected website. Instructions for creating an account and for entering and submitting information to ISMP is included in the self-assessment form (page 10).
- Assessment questions describe current practices for safe use of medications in perioperative situations. Multiple choice answers in the assessment describe the practices and level of activity within the facility. By having multiple team members across multiple professional disciplines participate in answering the self-assessment questions, answers to the assessments and the levels of activity within the facility as identified in the assessments are more completely informed and offer more specific responses for the survey.

## 6. Confidentiality of respondents:

- Respondents will submit their findings anonymously to ISMP.
- ISMP will not be using the ISMP website to collect responses; Instead, ISMP has created a secure database for this purpose.
- Participating organizations will have access to their own data, including weighted scores. No participants will have access to any other individual data from other participating organizations. The anonymous, aggregate results will be provided by ISMP to participating organizations at the end of the data collection period via a workbook for comparison of individual scores to demographically similar organizations.
- It will not be possible for individual results to be linked to the facility that entered and/or submitted the data.
- The identity of participating organizations will not be known to the research team; however, participating organizations will have access to their own results through the password-protected website.
- Demographic questions will not result in the ability to identify the respondent.

## 7. Amount and justification for any proposed incentive:

- No monetary incentives
- Nonmonetary incentives
  - Data submission will be anonymous.
  - Receipt of the final perioperative medication safety self-assessment workbook and evaluation of the results in comparison to other organizations of similar size/business practice.
  - Numerically weighted scores that will help hospitals prioritize improvement opportunities and compare themselves to demographically similar hospitals will only be viewable in an organization-specific report after data submission to ISMP.
  - Only participating hospitals will have access to aggregate preliminary findings to compare themselves to demographically similar hospitals and ambulatory surgical centers, and to aid in prioritization and development of an organization-specific action plan.
  - Endorsement of the assessment by influential organizations.

## 8. Questions of a Sensitive Nature

- The assessment does not ask any questions of a sensitive nature.
- Assessment items will reflect best practices in perioperative medication safety against which an organization can determine its level of implementation.
- No questions will be asked about specific medication errors.
- Self-assessment items about potential at-risk behaviors will be included, but the organization's evaluation will reflect aggregate practices by the entire perioperative team, not a single practitioner.

Example: All medication/solution containers (including provider-prepared syringes, basins, or cups) prepared in the perioperative area are labeled immediately after filling, even if only one medication/solution is present in the sterile field.

## 9. Description of Statistical Methods

### Instrument

- To establish instrument construct and content validity, the ISMP team and expert advisory group will substantiate that the key constructs underpinning the content (e.g., key elements, core characteristics) are appropriate and included in the instrument, and that the content accurately assesses all the fundamental aspects of medication safety in the perioperative setting.
- Instrument criterion validity will be established for certain assessment items (e.g., implementation of technologies) by comparison to results published in professional surveys.
- To test internal reliability of the instrument, Cronbach's alpha or another meaningful psychometric evaluation will be computed for the key elements and core characteristics to assess correlations between the items within these sections.

### Assessment Data

- To identify the current state of perioperative medication safety systems and practices, make comparisons, and identify opportunities for improvement, mean percentages (and range) for each section (key element), subsection (core characteristic), and individual assessment item will be calculated by averaging the total numerical score from all respondents and calculating a percent score based on the maximum possible score.
- An Analysis of Covariance will be used to determine if there are statistically significant differences in the current state of perioperative medication safety systems and practices based on demographics.
- To understand the relationships between perioperative medication safety and demographics at a finer scale, multivariate canonical correlation will be used to relate the core characteristics response variables to the same set of demographic variables; additionally, both unadjusted and adjusted p-values will be calculated for each demographic comparison.

### **ANTICIPATED BURDEN HOUR COMPUTATION:**

To determine whether a healthcare facility is eligible to participate in the assessment, a practitioner will need to read either the Invitation to Participate or the Purpose, Audience, and Scope of the assessment. The time commitment anticipated to determine eligibility is about 2 minutes per person. Once eligibility has been determined, a small interdisciplinary team will be established.

ISMP has conducted pilot testing of the *ISMP Medication Safety Self Assessment for the Perioperative Setting*. Based on pilot testing results from 4 hospital/health systems and 4 ASCs, we estimate that it will take a team of 2-3 practitioners at ASCs a total of 8.54 hours to conduct the assessment, and it will take a team of 3-8 practitioners at hospitals a total of 25.67 hours to conduct the assessment. ASCs will have fewer self assessment items to evaluate given "Not Applicable" status, as well as fewer members on the team conducting the assessment, thus reducing the number of hours to complete the assessment compared to hospitals.

We also anticipate that 1,500 facilities will check their eligibility to participate in the assessment, which will take approximately 2 minutes each.

## **Pilot Testing Results**

### **Ambulatory Surgery Centers (ASCs)**

#### **ASCs: Demographics Section**

Facility	Number on Pilot Testing Team	Time to Complete (minutes)	Total Time Burden (minutes)
ASC 1	2	60	120
ASC 2	2	20	40
ASC 3	3	20	60
ASC 4	1	10	10

Average time to complete Demographics Section = 57.5 minutes = 0.96 hours

#### **ASCs: Assessment Section**

Facility	Number on Pilot Testing Team	Time to Complete (hours)	Portion Completed	Total Time Burden (hours)
ASC 1	2	3.5	Entire	7
ASC 2	2	2	First 50%	8
ASC 3	3	2	Second 50%	12
ASC 4	2	0.83	Second 50%	3.32

Average time to complete Assessment Section = 7.58 hours

**Total time (Demographics plus Assessment Sections) = 8.54 hours**

### **Hospitals**

#### **Hospitals: Demographics Section**

Facility	Number on Pilot Testing Team	Time to Complete (minutes)	Total Time Burden (minutes)
Hosp 1	1	40	40
Hosp 2	3	20	60
Hosp 3	3	30	90
Hosp 4	2	45	90

Average time to complete Demographics Section = 70 minutes = 1.17 hours

### Hospitals: Assessment Section

Facility	Number on Pilot Testing Team	Time to Complete (hours)	Portion completed	Total Time Burden (hours)
Hops 1	7	4	Entire	28
Hosp 2	3	3.5	First 50%	21
Hosp 3	3	3.5	Second 50%	21
Hosp 4	8	3.5	Entire	28

Average time to complete Assessment Section = 24.5 hours

**Total time for hospitals (Demographics plus Assessment sections) = 1.17 hours + 24.5 = 25.67 hours**

In 2018, ISMP conducted a similar assessment, during which 867 hospitals participated. Because the current ISMP Medication Safety Self Assessment for Perioperative Settings has been designed to allow both hospitals and ambulatory surgery centers (ASCs) to participate, we initially anticipated that 1,000 sites (both hospitals and ambulatory surgery centers) would conduct the assessment and submit their findings to ISMP. However, we have recently reduced our estimate for participation to 375 hospitals and 175 ASCs due to the significant impact of COVID-19 on US healthcare providers. Inevitably, the assessment will be launched during a time when there is considerable stress on the US healthcare system during this global pandemic. Realistically, we now believe that approximately 550 sites in total will actually conduct the assessment and submit their findings to ISMP. (ISMP also reduced the estimated number of facilities that will check their eligibility to participate in the assessment from 2,500 to 1,500 facilities, again due to the significant impact of COVID-19 on US healthcare providers.)

### Total Burden

Given that we anticipate participation by 375 US hospitals and 175 ASCs, we estimate that conducting this survey will consume approximately 11,120.75 hours in total (9,626.25 hours for 375 hospital teams, 1,494.50 hours for 175 ASC teams). Additionally, we anticipate that 1,500 healthcare facilities will take 2 minutes each to determine their eligibility to participate in the assessment, consuming approximately 50 hours. The burden in total for this assessment will be 11,170.75 hours.

### Totals

Facility Type	Participation Time	No. of Respondents	Total Burden (hours)
Time to determine eligibility	0.03	1,500	50
Ambulatory Surgery Centers	8.54	175	1,494.50
Hospitals	25.67	375	9,626.25
<b>Total</b>			<b>11,170.75</b>

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