

Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel

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The number of hospital discharges that included diabetes as a listed diagnosis increased from 2.8 million to nearly 5.5 million from 1998 to 2009.¹ The prevalence of elevated glycosylated hemoglobin (HbA_{1c}) values in inpatients without a known diabetes diagnosis has been reported to be 18%.² Mazurek et al.³ found that 24% of hospitalized patients without a known history of diabetes had an HbA_{1c} of at least 6.5%. In children the prevalence of diabetes is estimated to be approximately 0.18%, and the number of children who are diagnosed with type 2 diabetes is increasing at an alarming rate.⁴⁻⁶ In addition, hospitalized patients without diabetes may be at risk for hyperglycemia from underlying illnesses or hospital treatments.^{7,8} There is broad recognition that maintaining

Purpose. Consensus recommendations to help ensure safe insulin use in hospitalized patients are presented.

Summary. Insulin products are frequently involved in medication errors in hospitals, and insulin is classified as a high-alert medication when used in inpatient settings. In an initiative to promote safer insulin use, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation convened a 21-member panel representing the fields of pharmacy, medicine, and nursing and consumer advocacy groups for a three-stage consensus-building initiative. The panel's consensus recommendations include the following: development of protocol-driven insulin order sets, elimination of the routine use of correction/sliding-scale insulin doses for management of hyperglycemia, restrictions on the types of insulin products stored in patient care areas, and policies to restrict the preparation of insulin bolus doses and i.v. infusions to

the pharmacy department. In addition, the panelists recommended that hospitals better coordinate insulin use with meal intake and glucose testing, prospectively monitor the coordination of insulin delivery and rates of hypoglycemia and hyperglycemia, and provide standardized education and competency assessment for all hospital-based health care professionals responsible for insulin use.

Conclusion. A 21-member expert panel convened by the ASHP Foundation identified 10 recommendations for enhancing insulin-use safety across the medication-use process in hospitals. Professional organizations, accrediting bodies, and consumer groups can play a critical role in the translation of these recommendations into practice. Rigorous research studies and program evaluations are needed to study the impact of implementation of these recommendations.

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glycemic control with insulin improves patient outcomes in adults, and guidelines for inpatient glycemic control have been developed by several professional organizations.⁹⁻¹² For critically ill patients on insulin therapy, the American Association of Clinical Endocrinologists and the American Diabetes Association (ADA) recommend goal blood glucose concentrations between 140 and 180 mg/dL.^{10,12,13} For patients who are not critically ill, ADA recommends maintaining preprandial blood glucose concentrations at <140 mg/dL and randomly tested glucose concentrations at <180 mg/dL. ADA emphasizes the importance of safely maintaining desired blood glucose target concentrations and avoiding hypoglycemia.

The Institute for Safe Medication Practices (ISMP) identifies insulin as an inpatient high-alert medication.¹⁴ Insulin is frequently cited as one of the medications commonly implicated in medication errors in hospitals,¹⁵⁻²⁸ and insulin-related medication errors have the potential to result in serious harm, including death. The American Academy of Pediatrics, which has led pediatric patient safety efforts, has emphasized the importance of safe insu-

lin use in children.^{4,6} In a review of 16,600 patient safety incidents involving insulin, Cousins et al.¹⁸ determined that 24% resulted in patient harm. Hellman²⁹ reported that insulin was implicated in 33% of medication error-related deaths. Insulin errors have been reported across each step (i.e., prescribing, transcribing, storage and dispensing, administering, and monitoring) of the medication-use process, most frequently occurring during the prescribing and administering steps.^{18,30,31} Insulin-related medication errors occur in all hospital settings, including but not limited to the emergency department, critical care units, medical-surgical units, and the perioperative setting.^{11,25,32-35} In addition, insulin is frequently implicated in adverse drug events detected in patients who present to the emergency department.³⁶

Given the incidence of insulin-related medication errors in hospitals, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation convened a multidisciplinary expert panel to develop expert consensus recommendations to promote best practices to further enhance the safe use of insulin in the inpatient setting.

Methods

A 21-member expert panel composed of consumer advocates, nurses, pharmacists, and physicians was established; clinician panelists represented the fields of anesthesiology, critical care, emergency medicine, endocrinology, hospital medicine, hospital pharmacy, and pediatrics. Panel members received an honorarium and travel support for their participation. Consensus building occurred in three phases: a premeeting baseline survey, an expert panel discussion, and a follow-up survey modeled after the modified Delphi process.³⁷ The expert panel's work addressed the prevention of insulin-related errors and excluded therapeutic use of insulin (e.g., appropriate parameters for glycemic control).

In preparation for the expert panel meeting, the ASHP Foundation engaged ISMP to review the biomedical literature and the ISMP National Medication Error Reporting Program to identify insulin-use errors reported in hospitals. The results of the review were used to develop a 60-item survey that was distributed via an Internet-based tool (Survey Monkey, Palo Alto, CA) to the panel members and 118 other previously identified nurses, pharmacists, and

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physicians. Along with individual and institutional demographic data, questions focused on the steps in the medication-use process: (1) prescribing, (2) transcribing, (3) storage and dispensing, (4) administering, and (5) monitoring. For each step in the medication-use process, survey participants ranked their three highest-priority errors. Panelists also provided free-text comments after each of the five survey domains. Data were downloaded from Survey Monkey to Excel 2007 (Microsoft Corporation, Redmond, WA) for analysis.

Survey results then guided discussions during a 1.5-day facilitated expert panel meeting. During the meeting the panel was charged with developing strategies to reduce insulin-related errors and identify practice-based safety research questions. Through large-group discussion, panel members used the survey data to prioritize types of insulin-use errors and developed prevention strategies for these errors during small-group discussions. The panel then prioritized the prevention strategies as high, medium, or low priority.

Prevention strategies to which 50% or more of the panel members assigned a high-priority ranking were identified for inclusion in the next consensus-building round. The lead author edited the strategies and assigned them to the most appropriate area related to medication use: prescribing, storing and dispensing, administering, monitoring, evaluating, and planning.

In the final phase of consensus building, panel members participated in an iterative process, modeled after the modified Delphi method, that required panelists to indicate

their agreement with each of the nine prevention strategies using one of the following descriptors: strongly agree, agree, disagree, and strongly disagree. At this phase, panel members were provided with evidence supporting each of the prevention strategies. Panel members were required to do their own independent rating, and the use of substitute participants or discussion of the prevention strategies with other panelists was not permitted. Each member was required to vote on each strategy; no member was allowed to abstain from voting. Evidence was required to support dissenting opinions. All responses were submitted to ASHP Foundation staff representatives for compilation. Consensus was defined a priori as agreement by 17 of the 21 panel members (i.e., “agree” or “strongly agree” votes by 17 of 21 members, with no “strongly disagree” votes). If any panel member strongly disagreed with a recommendation or more than 4 panel members disagreed, revision of the recommendation was required.

The preliminary recommendations were submitted to several national stakeholder organizations (listed on page e22) for review and comment. A final modified Delphi round was used to address these organizations’ comments on revising the recommendations and possible additional recommendations; this resulted in revision of the correction dose/sliding-scale insulin recommendation and the inclusion of an insulin pen injector recommendation.

While this project was sponsored by Sanofi, the company did not influence panelist selection, manage meeting logistics, participate in the premeeting survey or panel discussions, or remunerate panelists, and it had no influence over the recommendations or development of the manuscript that summarizes the consensus-building process and recommendations. A sponsor representative observed the meeting for four hours on the first day.

Results

Ninety-five percent of expert panel members (20 of 21) and 24% of field experts (28 of 118) completed the premeeting survey that guided the expert panel discussions. Eight survey items were ranked by 50% or more of expert panel members or field experts as being among their three highest-priority errors. During large-group discussion, panel members used the survey data to prioritize 12 types of insulin-use errors (Table 1); they developed 24 prevention strategies targeting these errors during small-group discussions. Nine strategies for enhancing insulin-use safety in the inpatient setting were assigned a high priority during the expert panel meeting.

The initial modified Delphi process, in which all panel members participated, was conducted over a three-week period in August 2012. Consensus was reached on the nine recommendations during the first phase of the process. Two recommendations received a “disagree” vote from two panel members, and three received a “disagree” vote from one panel member. In the final prepublication modified Delphi round, the

panel added an additional recommendation on the use of insulin pens and revised the correction/sliding-scale insulin recommendation. Two panel members disagreed with each of these recommendations. No panel member strongly disagreed with any strategy. The strategies adopted by the panel are listed below and categorized by the phase of the medication-use process they affect.

Prescribing

Recommendation 1. Develop protocol-driven and evidence-based order sets for specific uses of insulin such as transition of administration route from intravenous to subcutaneous, administration via subcutaneous insulin pumps, postdischarge dosing, diabetic ketoacidosis, hyperosmolar states, hyperkalemia, and postcardiac surgery care. These order sets should include orders for glucose monitoring and decision-support capabilities that guide insulin use based on the patients’ nutrition status. In addition, protocol-driven and evidence-based order sets for the management of hypoglycemia should be developed and integrated into the care of all hospitalized patients who receive insulin.

Table 1.
Expert Panel-Identified High-Priority Insulin Errors, by Phase of Medication-Use Process

Phase	Error
Prescribing	Incorrect dosage/irrational insulin orders Nomenclature-related errors
Transcribing	Incorrect transcription of verbal or telephone orders Transcription of an incorrect dose
Dispensing and storage	Failure to double-check insulin products (i.e., preadministration) Look-alike containers Unsecure and/or non-segregated storage in patient care areas and/or pharmacy areas
Administering	Administration of incorrect doses Incorrect use of insulin pens Name confusion Relationship of insulin administration to nutrition
Monitoring	Failure to appropriately monitor for insulin effects and adjust dose accordingly

National Organization Reviewers

American Academy of Clinical Toxicology
 American Academy of Pediatrics
 American Association of Clinical Endocrinologists
 American College of Emergency Physicians
 American Diabetes Association
 American Society of Health-System Pharmacists
 Anesthesia Patient Safety Foundation
 The Endocrine Society
 Institute for Safe Medication Practices
 The Joint Commission
 National Consumers League
 National Quality Forum
 Society of Hospital Medicine

Recommendation 2. Eliminate the routine administration of correction/sliding scale insulin doses as a primary strategy to treat hyperglycemia.

Recommendation 3. Eliminate the use of “free text” insulin orders in electronic and paper medical records and replace them with protocol-driven and evidence-based order sets that allow for the prescribing of complex insulin regimens.

Storing and dispensing

Recommendation 4. Store only U-100 concentration insulin and U-100 administration devices (e.g., syringes, pens) in patient care areas and ensure that they are stored in a secure fashion and segregated from other medications.

Recommendation 5. Develop hospitalwide standard concentrations for insulin infusions to be adopted and used in all patient care areas.

Administering

Recommendation 6. Limit preparation, including for procedural areas, of all intravenous bolus insulin

doses and intravenous insulin infusions to the pharmacy department.

Recommendation 7. Hospitals must develop policies and procedures to ensure that insulin pens are used for individual patients only. In addition, hospitals must establish policies and educational programs to ensure the safe use of insulin pens and disposable needle tips.

Monitoring

Recommendation 8. Ensure that insulin use is linked directly to patients’ nutrition status. Meal delivery, point-of-care glucose testing, and insulin administration should be well coordinated and standardized. Patients and their family caregivers should be educated to request administration of rapid-acting insulin when the patient begins her/his meal. In patients with variable nutritional intake, prandial insulin administration should be delayed until completion of the meal. Protocol-driven and evidence-based order sets should be developed for insulin-use and blood glucose monitoring during planned and unplanned interruptions of enteral nutrition or total parenteral nutrition.

Evaluating

Recommendation 9. Every hospital should prospectively monitor/measure rates of hypoglycemia and hyperglycemia; insulin use; and coordination of insulin administration, glucose testing, and nutrition delivery. Real-time, institutionwide glucose reports should be provided to health care team members to ensure appropriate surveillance and management of patients with unexpected hypoglycemia and hyperglycemia.

Planning

Recommendation 10. Provide standardized education, including competency assessment, to all hospital-based health professionals who are responsible for the use (e.g., prescribing, compounding, dispens-

ing, administering, monitoring) of insulin.

Discussion

An expert panel composed of consumer representatives, nurses, pharmacists, and physicians reached consensus on 10 recommendations, spanning all aspects of the medication-use process, to enhance the safe use of insulin in hospitals. The panel’s recommendations align with components of an inpatient glycemic control program as described by the American College of Endocrinology, ADA, the Society for Critical Care Medicine (SCCM), and The Endocrine Society.^{13,38,39} The types of errors that these recommendations aim to prevent are consistent with those reported by others.^{14,16,18,23,30,31,34,40,41}

Since the release of the Institute of Medicine report “To Err Is Human: Building a Safer Health System” in 1999,⁴² health care providers, professional organizations, policymakers, and other stakeholders have worked to decrease medication errors in hospitals and throughout the health system. These steps traverse the medication-use process and include technology implementation (e.g., computerized prescriber order entry, bedside barcode-assisted medication administration systems, intelligent infusion devices), further integration of evidence-based guidelines in standardized order sets and clinical decision-support systems, establishment of patient safety and medication safety officer positions in hospitals, increased emphasis on the delivery of care through interdisciplinary team processes, emphasis on medication safety at transitions of care (e.g., medication reconciliation), and enhanced health professional education. Despite these efforts, medication errors continue to occur, and insulin is consistently identified as a high-alert medication that requires additional focus. This expert panel’s recommendations are meant to heighten awareness

and provide additional guidance to enhance insulin-use safety and are not intended to supplant existing safety procedures.^{11,41,43-46} Each of the recommendations identified by the panel is supported by existing evidence, and similar recommendations have been proposed by other organizations and researchers.^{13,14,31,40,44} The panel recommendations are consistent with the Joint Commission's medication management standards.⁴⁶

In their early discussions, the expert panelists decided to limit the total number of recommendations developed and to ensure that these recommendations are practical and easily actionable across all hospitals. The panel recognized that it is imperative that the recommendations can be implemented in all hospitals regardless of size, teaching status, or types of services provided. None of the recommendations, with the exception of the one related to clinical decision support, requires significant expenditures for technology to ensure implementation. As hospitals and health systems work to adopt these recommendations, nurses, pharmacists, and physicians must collaborate to develop systems that do not impede timely provision of patient care. The panel expected that the recommendations developed will not replace current practices that are geared toward increasing insulin-use safety.^{11,43-45,47,48} The expert panel identified high-risk situations that have not been previously addressed in a systematic way, such as the availability of U-500 concentration insulin in patient care areas, which pose great risks to patient safety and require new recommendations to decrease the potential for patient harm. In other cases, these recommendations are meant to place increased emphasis on already accepted best practices—such as coordination of meal delivery, point-of-care glucose testing, and insulin administration—to increase their rate of adoption.

Five of the 12 errors prioritized by the panel relate to administration of the wrong type of insulin due to name confusion. These include nomenclature-related errors, incorrect transcription of oral or telephone orders, look-alike containers, unsecure and/or nonsegregated insulin storage in patient care areas and/or pharmacy areas, and name confusion. This is consistent with other reports of insulin-related medication errors that result in the administration of the wrong drug due to name confusion and similarities in packaging.^{14,31} The panel directly addressed this potential source of insulin-related medication errors by developing six prevention strategies (recommendations 1, 3-6, and 10) spanning the medication-use process.

While the panel focused on new strategies for safe insulin use in hospitals, they also included a recommendation to eliminate the routine use of correction (i.e., sliding-scale) insulin doses. Although insulin administration with basal, nutritional, and correction components has been recommended in the inpatient setting for several years,^{9,49-51} it was the sense of the panel that these recommendations have not been uniformly adopted and that additional efforts are necessary to eliminate the routine use of correction doses of insulin. Given that sliding-scale insulin continues to be used routinely in some hospitals, these organizations must determine the root causes that are prohibiting the implementation of this critically important practice change.

Consistent with best practices that are being implemented throughout the health system to reduce prescribing errors, which are a leading cause of insulin-related errors, the panel concluded that it is imperative to use protocol-driven and evidence-based order sets that permit prescribing of complex insulin regimens and to eliminate the use of free-text insulin orders in electronic and paper medical records. In one published

study, an inpatient glycemic control program that included standardized insulin order sets, as called for in recommendation 3, resulted in a decrease in the ratio of short-acting insulin orders to basal insulin orders and a decrease in the proportion of sliding-scale insulin orders from 16% to 4%.⁵² Maynard and colleagues⁵³ demonstrated improved glycemic control, reduced hypoglycemia, and decreased the exclusive use of sliding-scale insulin following implementation of structured insulin orders and an insulin management algorithm. While the recommendations address clinical situations for which standardized order sets should be developed (e.g., diabetic ketoacidosis), these order sets should also address critical changes in care processes, such as the transitions from intravenous to subcutaneous insulin, that are prone to errors. The panel specifically identified the need for order sets for the management of subcutaneous insulin pumps to ensure that hospitals develop consistent approaches to their use across clinical settings and care providers.

The recommendation to store only U-100 insulin in patient care areas and to ensure that it is stored in a secure fashion and segregated from other medications resulted from numerous reports of errors with highly concentrated (i.e., U-500) insulin and errors in which insulin was confused with other medications such as heparin.^{14,31} ISMP has reported numerous cases in which U-500 insulin was inadvertently interchanged with U-100 insulin, resulting in fivefold dosing errors. Samaan and colleagues⁵⁴ reported on a U-500 insulin safety program that addresses the prescribing, storage, dispensing, and administration phases of the medication-use process; these authors specifically recommended not storing U-500 insulin in patient care areas and provided guidance on ensuring its safe storage within the pharmacy department.

Key Research Areas

- Role of bolus intravenous insulin in the treatment of hyperglycemia in the perioperative area
- Best practices (i.e., frequency of monitoring, route of insulin administration) to care for patients with diabetes during general anesthesia
- Comparative effectiveness of intravenous and subcutaneous insulin in the treatment of hyperkalemia
- Safest methods (e.g., pens, syringes) to provide and administer insulin in the hospital
- Use of alternative glucose testing methods (e.g., arterial blood gas sample analysis) versus point-of-care methods in the intensive care population and implementation of best practices given the need for fast turnaround
- Influence of improved insulin error reduction in the hospital on readmission rates
- Effects of health professional education, including simulation, on insulin error reduction
- Glycemic control and hypoglycemia rates (i.e., benchmarking to identify best-practice environments)
- Research on the use of daily reports to reduce hypoglycemia and hyperglycemia
- Prevalence of improper use of point-of-care glucose testing
- Influence of patient education at discharge on insulin management and subsequent impact on hospital readmission rates

The recommendation for development of hospitalwide standard concentrations for insulin infusions is consistent with guidelines from SCCM,¹¹ the Institute for Healthcare Improvement,⁴⁴ and the Anesthesia Patient Safety Foundation (APSF).⁵⁵ Another recommendation from the panel was to limit preparation of all intravenous bolus insulin doses and intravenous insulin infusions to the pharmacy department. This may pose implementation challenges for

some hospitals and in some clinical situations. For example, insulin infusions are frequently used in the care of critically ill children during interfacility transport; continuous perioperative insulin infusions are frequently used in patients undergoing vascular surgery; and administration of intravenous boluses of regular insulin is a common practice to treat hyperglycemia during general anesthesia and surgery.⁵⁶⁻⁵⁸ However, insulin infusions prepared by clinicians can potentially be diluted to incorrect or nonstandard concentrations, leading to medication errors. Wheeler and colleagues⁵⁹ found that the concentrations of insulin and other types of infusions prepared in patient care areas frequently differed from the expected concentrations by greater than 10%. APSF recommends that high-alert medications such as insulin should always be prepared by the pharmacy department rather than in the operating room.⁵⁵ The panel concluded that the potential patient safety risks posed by preparation of intravenous insulin outside of the pharmacy department (e.g., multiple clinicians calculating insulin doses, misreading of insulin vial concentrations, incorrect compounding of infusion concentrations) necessitated this recommendation. However, the panel also recognized that it is imperative for hospitals to establish systems to ensure rapid access to intravenous insulin in emergency situations, including access in procedural areas and during interfacility transport, and timely provision of insulin infusions in all other situations.

There have been numerous reports of risks associated with the use of the same pen device to administer insulin to multiple hospitalized patients. The Food and Drug Administration, the Centers for Disease Control and Prevention, and ISMP have warned hospitals not to share insulin pens among patients.^{60,61} It was the consensus of the panel that pens can be used safely if proper poli-

cies, procedures, and staff education are in place. In addition, technology solutions need to be developed to ensure that insulin pens are not used for more than one patient. If a hospital decides not to use pens routinely, exceptions are necessary under certain circumstances (e.g. preparation for patient discharge).

The panel recognized the importance of active patient and/or family caregiver involvement in safe insulin use through its recommendation that patients and their family caregivers should be educated to request administration of rapid-acting insulin when the patient begins a meal. This recommendation recognizes that patients and their caregivers play a fundamental role in diabetes management. Some patients' and caregivers' ability to participate in disease management at this level may be affected by their knowledge about diabetes, health literacy level, and/or degree of self-efficacy. It is important for health professionals to assess patient and caregiver knowledge of diabetes, as well as their ability to manage all aspects of their care, and to provide education as necessary. Along with the potential to affect safe use of insulin in the inpatient setting, enhanced patient and caregiver engagement in diabetes care will be beneficial as patients transition from hospital to home. As patient-centered medical home models are developed, inpatient education efforts should be coordinated with the medical home to ensure continuity of patient and caregiver education in the outpatient setting.

Hyperglycemia and hypoglycemia are both significant safety problems,^{12,13,16,38,62} and many medical centers are addressing inpatient glycemic control via the Surgical Care Improvement Project,⁶³ advanced certification programs from the Joint Commission,⁴⁸ the "Partnership for Patients" efforts,⁶⁴ and other collaborative efforts,⁵² yet many hospitals and health systems do not have reli-

able methods to monitor these initiatives in real time or retrospectively.⁶⁵ Voluntary reporting and monitoring of signal events (e.g., use of dextrose 50% for rescue therapy) are not reliable; as a result, insulin management and hypoglycemia protocols are often being implemented with marginal or no methods to gauge their impact. Real-time surveillance for glycemic excursions and patients who are “off protocol,” paired with proactive interventions to address lapses in care in real time, is necessary to optimize individual patient care. Ongoing retrospective analyses of hospitalwide data are critical to identification of system issues (i.e., root causes) that may affect the quality of care provided to inpatients with diabetes and others with labile blood glucose concentrations. Completion of root-cause analyses will enable hospitals and health systems to make system-level changes that aim to decrease rates of uncontrolled hyperglycemia and hypoglycemia.

The final recommendation calls for education of all hospital-based health professionals who are responsible for the use of insulin. These include physicians, pharmacists, and nurses who are responsible for ordering, dispensing, compounding, and administering insulin and monitoring its effects. In addition, this education must address unique delivery devices, including insulin pens and subcutaneous insulin pumps, given the safety and quality-of-care issues that can arise when they are not used properly. Educational programs specific to the use of insulin in hospitals are associated with decreased prescribing errors⁶⁶; however, these programs are not consistently integrated into hospitals’ approaches to the care of patients who require insulin. The panel recognized that educational programs must be tailored to the needs of the hospital or health system and the level of expertise of the health professional. For example, the educational needs of a physician will

differ from those of an entry-level nurse. The goal of this recommendation is to promote provision of quality education about insulin use that is current, tailored to the hospital or health system’s needs as well as the professional’s role, and uses regular assessments to evaluate competency.

Professional organizations, accrediting bodies, and other patient safety stakeholders are positioned to support translation of these recommendations into practice and should give strong consideration to incorporating them into their existing strategies for promoting insulin-use safety. Professional organizations can drive dissemination through member communications, provision of educational opportunities, revision of relevant professional policies to incorporate the recommendations, support of research, and publication in professional journals. The expert panel identified key research questions that can be used by professional organizations to develop grant programs (see box on page e24). Accrediting bodies should consider incorporating these recommendations into their accreditation standards. Consumer groups and patient safety organizations have an opportunity to increase patient and family caregiver awareness of steps they should take to participate in care and the importance of being fully engaged when insulin is administered in the hospital.

Conclusion

A 21-member expert panel convened by the ASHP Foundation identified 10 recommendations for enhancing insulin-use safety across the medication-use process in hospitals. Professional organizations, accrediting bodies, and consumer groups can play a critical role in the translation of these recommendations into practice. Rigorous research studies and program evaluations are needed to study the impact of implementation of these recommendations.

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