



The Office of the National Coordinator for
Health Information Technology



FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

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Office of the Chief Medical Officer,
Office of the National Coordinator for Health
Information Technology (ONC)

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Office of the National Coordinator for Health Information Technology (ONC)

- Support adoption of health information technology
- Create and maintain a certification program for EHRs
- Promote nationwide health information exchange

Office of the Chief Medical Officer (OCMO)

- Health IT safety and usability
- Clinical Quality
- Clinician Liaison

Meaningful Use (MU)

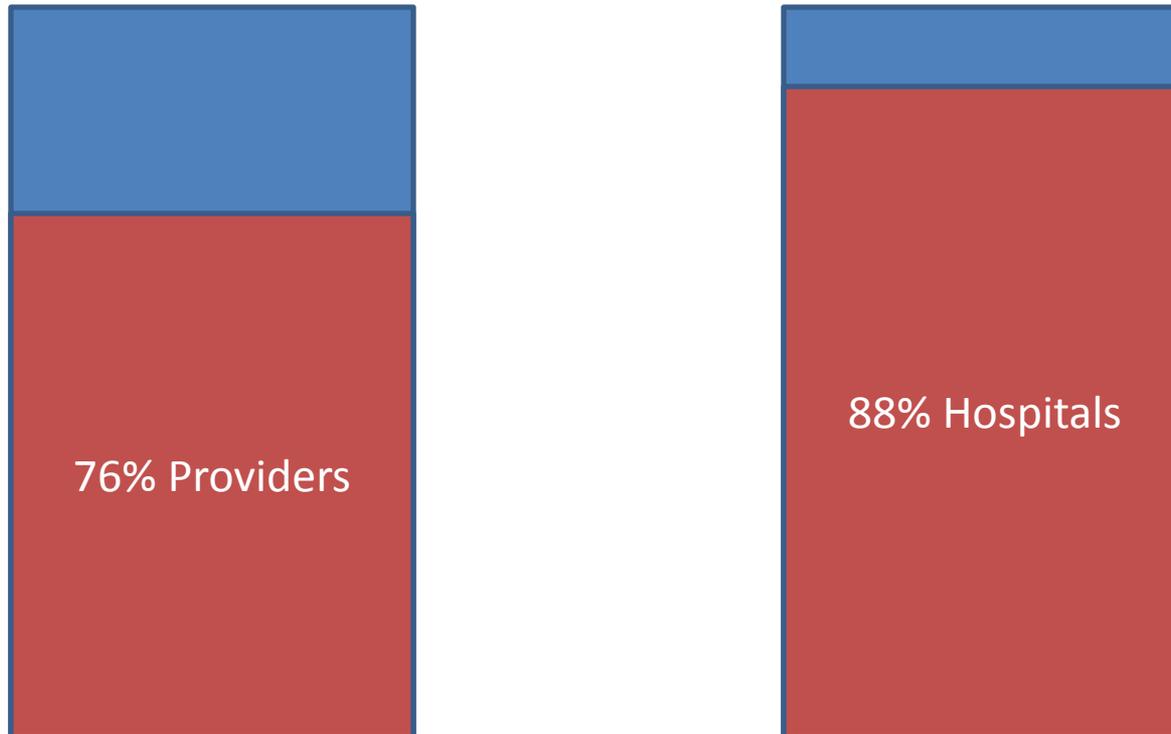
A CMS incentive Program under which hospitals and providers can earn payments for the Meaningful Use of Certified EHR technology.

Meaningful Use Stages

Stage 1 2011-2012: Meaningful use criteria focus on:	Stage 2 2014: Meaningful use criteria focus on:	Stage 3 : Meaningful use criteria focus on:
Electronically capturing health information in a standardized format	More rigorous health information exchange (HIE)	Improving quality, safety, and efficiency, leading to improved health outcomes
Using that information to track key clinical conditions	Increased requirements for e-prescribing and incorporating lab results	Decision support for national high-priority conditions
Communicating that information for care coordination processes	Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools
Initiating the reporting of clinical quality measures and public health information	More patient-controlled data	Access to comprehensive patient data through patient-centered HIE
Using information to engage patients and their families in their care		Improving population health

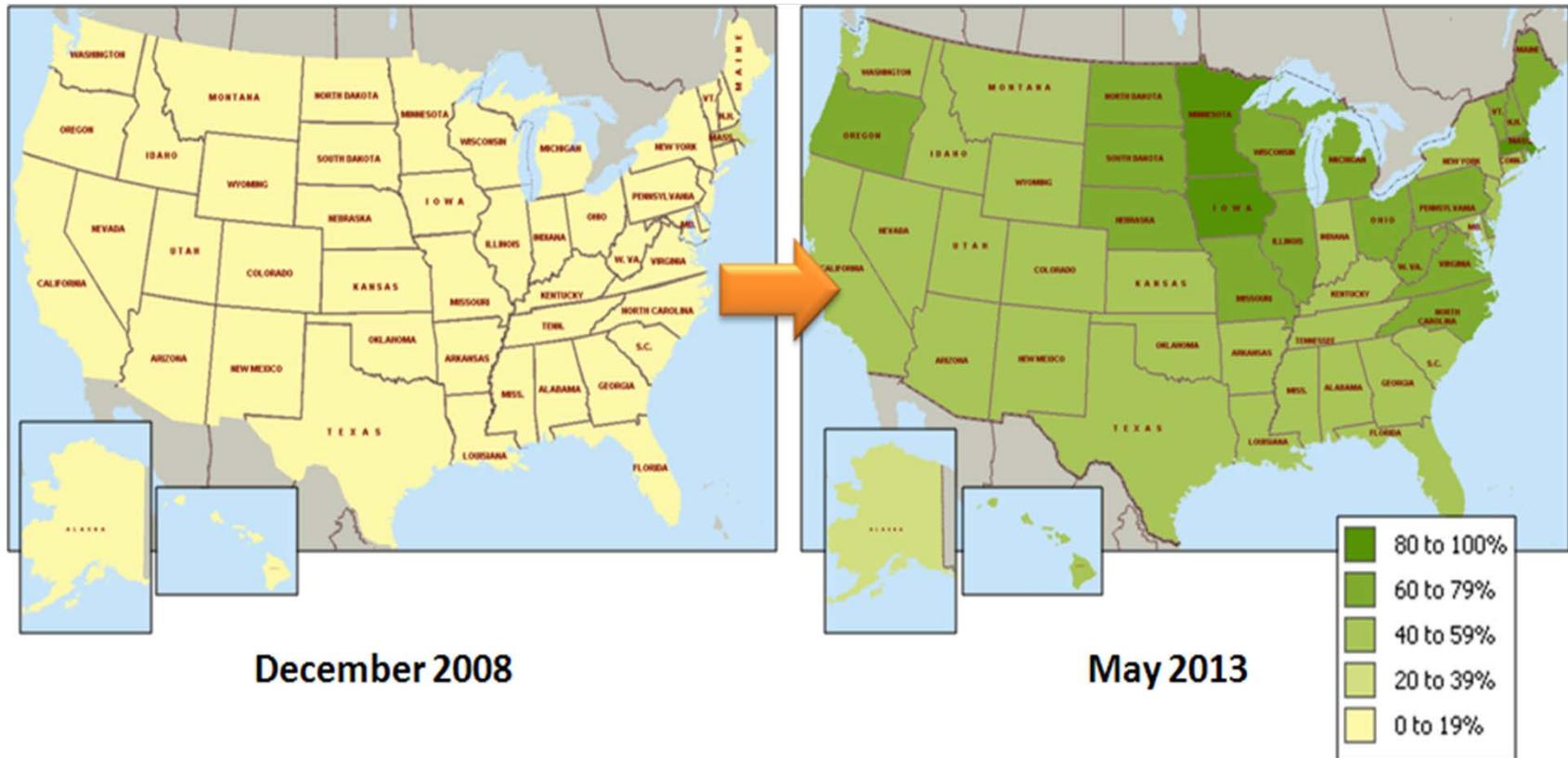
Meaningful Use Program Scope

As of June 2013, 76% of eligible providers and 88% of eligible hospitals in the United States are participating in the Meaningful Use EHR Incentive Program.



Increasing Opportunity for DDIs through EHR ERx

Percent of physicians e-prescribing using an EHR in 2008 and 2013



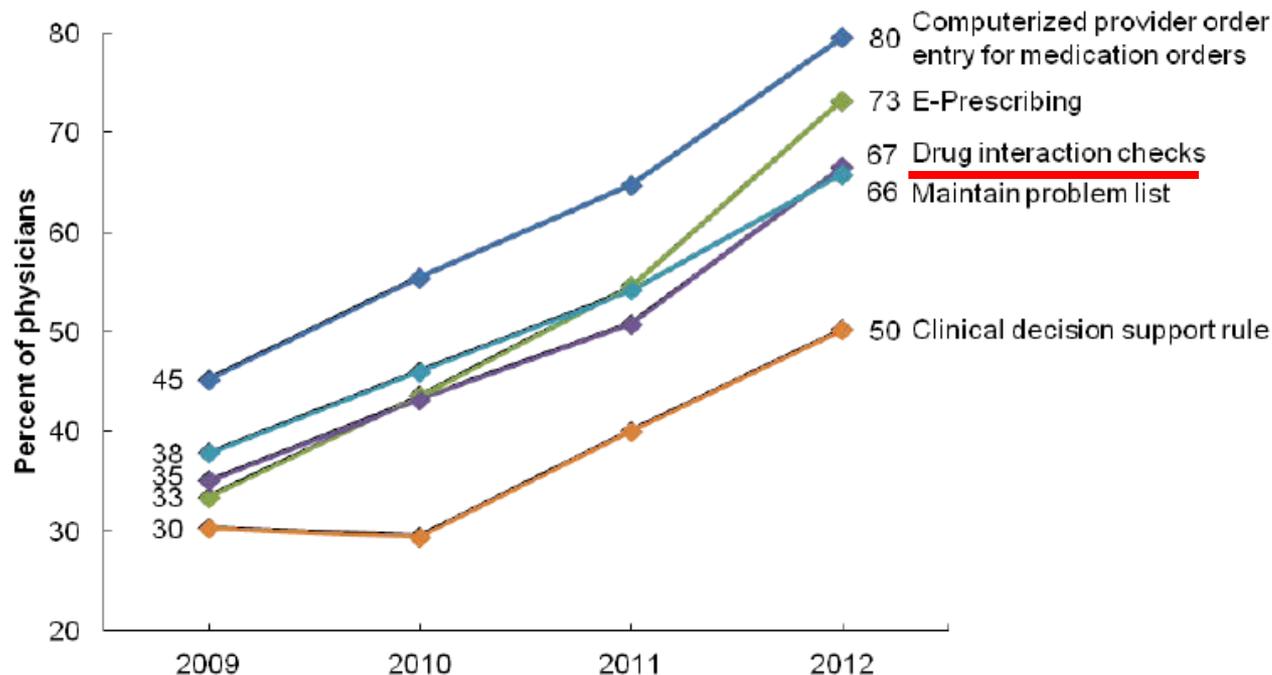
• In December 2008, 7% of physicians in the U.S. were e-prescribing using an EHR; by May 2013, over half (57%) of physicians were e-prescribing using an EHR on the Surescripts network.

• As of May 2013, forty-six states had more than half of their physicians e-prescribing using an EHR on the Surescripts Network.

Increasing Opportunity for DDIs through EHR ERx

Since HITECH started, physician adoption of EHR technology to meet five Meaningful Use Core objectives has increased by at least 66%.

Figure 1. Percent of physicians with computerized capabilities to meet selected Meaningful Use Core objectives: 2009-2012



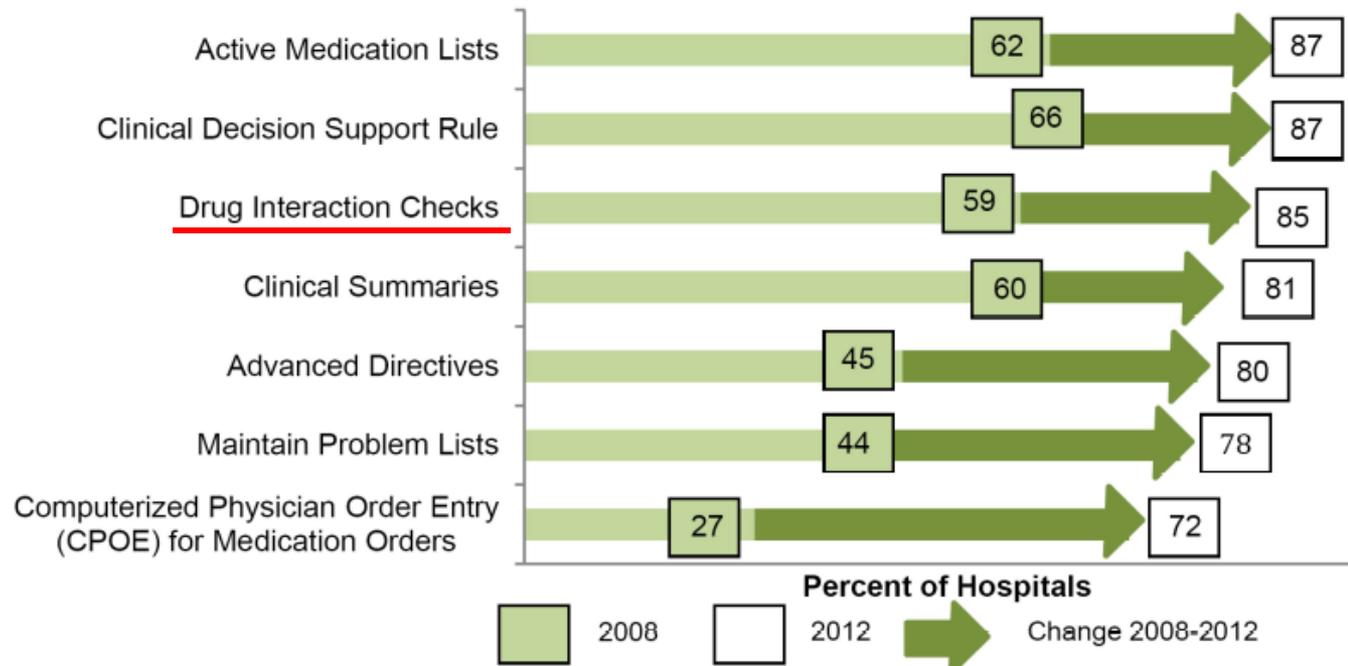
2012 is significantly different from 2009 for all computerized capabilities ($p < 0.01$).
SOURCE: ONC analysis of 2009-2012 National Electronic Health Records Surveys.

- ★ Since 2009, the percent of physicians with e-prescribing has more than doubled (119% increase).
- ★ Physicians' capability to meet four other Meaningful Use Core objectives related to improving quality, safety, and efficiency grew by 66% to 90%.

Increasing Opportunity for DDIs through EHR ERx

Since 2008, hospital adoption of EHR technology to meet Meaningful Use objectives has increased substantially.

Figure 1: Percent of non-federal acute care hospitals with computerized capabilities to meet selected Meaningful Use objectives: 2008-2012



All differences are statistically significant from the previous year ($p < 0.05$).
SOURCE: ONC/AHA, AHA Annual Survey Information Technology Supplement

- ★ From 2008 to 2012, hospitals' capability to meet each of seven Meaningful Use objectives grew significantly, with increases ranging from 32% to 167%. (Figure 1).
- ★ Hospital adoption of CPOE for medication orders showed the highest growth between 2008 and 2012, increasing by 167%.

EPs must meet 17 core objectives and 3 menu objectives that they select from a total list of 6, or a total of 20 core objectives.

EHs and CAHs must meet 16 core objectives and 3 menu objectives that they select from a total list of 6, or a total of 19 core objectives.

Sample Core Objectives

CPOE

Demographics (EP/ EH specific)

Vital Signs

Clinical Decision Support

Smoking Status

Generate Patient Lists

Patient Reminders (EP)

Patient Education

Electronic Med Admin Record (EH)

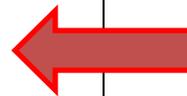
Transitions of Care

Electronic Prescribing

Medication Reconciliation

Clinical Labs as Structured Data

Securing Electronic Health Information



DDI's Included Here

		MEANINGFUL USE 42 CFR 495.6(j)-(m) Stage 2 Objective	MEANINGFUL USE 42 CFR 495.6(j)-(m) Stage 2 Measure	2014 Edition EHR CERTIFICATION CRITERIA 45 CFR 170.314	STA
CORE	EP EH	Use clinical decision support to improve performance on high-priority health conditions.	<p>1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's, EH's, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. Absent four clinical quality measures related to [an EP's scope of practice or patient population/an eligible hospital or CAH's patient population], the clinical decision support interventions must be related to high-priority health conditions.</p> <p>2. The EP, EH, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</p> <p>*Exclusions apply: see CMS rule for details</p>	<p>§170.314(a)(8) / §170.314(a)(2)</p> <p><u>Clinical decision support.</u></p> <p>(i) <u>Evidence-based decision support interventions.</u> Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:</p> <p>(A) Problem list;</p> <p>(B) Medication list;</p> <p>(C) Medication allergy list;</p> <p>(D) Demographics;</p> <p>(E) Laboratory tests and values/results; and</p> <p>(F) Vital signs.</p> <p>(ii) <u>Linked referential clinical decision support.</u></p> <p>(A) EHR technology must be able to:</p> <p>(1) Electronically identify for a user diagnostic and therapeutic reference information; or</p> <p>(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2).</p> <p>(B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.</p> <p>(iii) <u>Clinical decision support configuration.</u></p> <p>(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.</p> <p>(B) EHR technology must enable interventions to be electronically triggered:</p> <p>(1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.</p> <p>(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.</p> <p>(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section.</p> <p>(iv) <u>Automatically and electronically interact.</u> Interventions triggered in accordance with paragraphs (a)(8)(i)-(iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.</p> <p>(v) <u>Source attributes.</u> Enable a user to review the attributes as indicated for all clinical decision support resources:</p> <p>(A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section:</p> <p>(1) Bibliographic citation of the intervention (clinical research/guideline);</p> <p>(2) Developer of the intervention (translation from clinical research/guideline);</p> <p>(3) Funding source of the intervention development technical implementation; and</p> <p>(4) Release and, if applicable, revision date(s) of the intervention or reference source.</p> <p>(B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).</p> <p><u>Drug-drug, drug-allergy interaction checks.</u></p> <p>1. <u>Interventions.</u> Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.</p> <p>2. <u>Adjustments.</u></p> <p>(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.</p> <p>(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.</p>	<p>§ 170.204 Standard: (Retrieval A) (Infobutton) Implement § 170.204 URL-Based Context-Aware Retrieval (I) or § 170.204 IG: Context Retrieval (I) Oriented An Implement</p>

Drug-drug, drug-allergy interaction checks

1. Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

2. Adjustments.

- (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
- (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

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Research and applications

High-priority drug—drug interactions for use in electronic health records

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ABSTRACT

Objective To develop a set of high-severity, clinically significant drug—drug interactions (DDIs) for use in electronic health records (EHRs).

Methods A panel of experts was convened with the goal of identifying critical DDIs that should be used for generating medication-related decision support alerts in all EHRs. Panelists included medication knowledge base

described here was to identify a set of critical interactions that can be implemented in KBs for use in EHRs. A secondary goal was to identify the process and barriers that would be involved in successful implementation of such a list of critical drug—drug interactions (DDIs).

BACKGROUND AND SIGNIFICANCE

DDI pairs

Amphetamine and derivatives—MAO inhibitors

Atazanavir—PPIs

Febuxostat—azathioprine/mercaptopurine

SSRIs—MAO inhibitors

Irinotecan—CYP3A4 inhibitors

Linezolid—triptans

Narcotic analgesics—MAO inhibitors

TCAs—MAO inhibitors

QT prolonging agents—QT prolonging agents

Ramelteon—CYP 1A2 inhibitors

CYP 3A4 inducers—protease inhibitors

HMG Co-A reductase inhibitors—CYP 3A4 inhibitors

CYP 3A4 inhibitors—ergot alkaloids and derivatives

Tizanidine—CYP 1A2 inhibitors

Tranylcypromine—procarbazine

Triptans—MAO inhibitors

Drug–drug interactions that should be non-interruptive in order to reduce alert fatigue in electronic health records

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► An additional supplementary figure is published online only. To view this file please visit the journal online (<http://dx.doi.org/10.1136/amiajnl-2012-001089>).

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ABSTRACT

Objective Alert fatigue represents a common problem associated with the use of clinical decision support systems in electronic health records (EHR). This problem is particularly profound with drug–drug interaction (DDI) alerts for which studies have reported override rates of approximately 90%. The objective of this study is to report consensus-based recommendations of an expert panel on DDI that can be safely made non-interruptive to the provider's workflow, in EHR, in an attempt to reduce alert fatigue.

organizations.⁸ To help harness the benefits of medication-related CDS in EHR and improve the acceptance of medication-related CDS alerts, the Office of the National Coordinator sponsored an effort to decrease the burden of alert fatigue.⁹ Peterson and Bates¹⁰ described alert fatigue as the mental state resulting from receiving too many alerts that consume time and mental energy, which can cause important alerts to be ignored along with clinically unimportant ones. Consequently, alert fatigue may compromise patient safety by decreas-

Non-Interruptive DDI List

Table 1 List of low-priority DDI that the panel assessed as safe to suppress from interruptive alerting in EHR

Object drug/class	Precipitant drug/class
ACE inhibitors	Salicylates
Niacin	Statins
β-Adrenergic blockers	Serotonin reuptake blockers
Iron salts	Proton pump inhibitors
Thiazide-type diuretics	ACE inhibitors
Thyroid hormones	Calcium salts
Thyroid hormones	Statins
Thiazide-type diuretics	NSAID
β-Adrenergic blockers	Thyroid hormones
Macrolide immunosuppressives	Corticosteroids
Antacids	Corticosteroids (oral)
Bisphosphonates	Calcium salts
Vitamin B12	Omeprazole
Folic acid	Methotrexate
Sulfonylureas	ACE inhibitors
Iron salts	Thyroid hormones
Anticoagulants	Corticosteroids
Anticoagulants	Acetaminophen
Antacids	Iron salts (oral)

Table 1 List of low-priority DDI that the panel assessed as safe to suppress from interruptive alerting in EHR

Object drug/class	Precipitant drug/class
Anticoagulants	Corticosteroids
Anticoagulants	Acetaminophen
Antacids	Iron salts (oral)
Anticoagulants	Proton pump inhibitors
Proton pump inhibitors	Imidazoles
β-Adrenergic blockers	Calcium salts (oral)
ACE inhibitors	Angiotensin II receptor antagonists
Anticoagulants	Statins
Omeprazole	Benzodiazepines
Anticoagulants	Vitamin E
Zinc salts (oral)	Quinolones (oral)
NSAIDS	β-Adrenergic blockers
Clopidogrel	Salicylates
Oral contraceptives	Corticosteroids
β-Adrenergic blockers	Nifedipine and derivatives
Corticosteroids/corticotropin	Anticholinesterases
ACE inhibitors	NSAID

Policy Considerations for High Priority /Non-Interruptive DDI List



Priority/Non-Interruptive DDI List Considerations

- Adoption by key communities/stakeholders
- Membership of drugs to pharmacologic classes
- Certification v. Content
- Stewardship and Maintenance

Usability and Safety Considerations

- Provider Alert Fatigue
 - Sensitivity and Specificity
 - Applied human factors for EHR display design
- Legality of turning on/off DDIs

Opportunities for Federal Alignment

- AHRQ sponsored DDI Workgroups on evidence, content and usability.

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