



FACT SHEET: C.A.R.E.S. AllianceSM

New Patient Safety Alliance Launches Tools to Fight Pain Medication Misuse and Abuse

C.A.R.E.S. AllianceSM will partner with leading organizations to provide “safe-use” resources for patients, caregivers and healthcare professionals

Identifying the various risks associated with powerful pain medications called opioids is key to finding solutions that can stem misuse and abuse. For a new patient safety organization launched at the 2010 PAINWeek Conference, those solutions include a total of more than 60 resources, programs and tools available, all at no cost to patients, caregivers, healthcare professionals and communities.

Created with leading pain experts through a scientific process, the free resources offered through the C.A.R.E.S. (Collaborating & Acting Responsibly to Ensure Safety) Alliance will promote safe prescribing, dispensing, use, storage, and disposal of these medications.

About the C.A.R.E.S. Alliance

- The C.A.R.E.S. Alliance is a patient safety initiative which provides education and tools to healthcare professionals and patients to support responsible opioid prescribing and safe use.
- The goal of the C.A.R.E.S. Alliance is to increase patient safety through the appropriate use of pain medication, while reducing potential abuse, misuse, overdose and diversion.
- The C.A.R.E.S. Alliance is being developed by Covidien in collaboration with leaders in pain management, healthcare professionals, consumer health advocacy groups, policymakers and patients.
- The development of the C.A.R.E.S. Alliance began in 2009 as a safety and risk minimization program created to supplement and expand on the premise of the Risk Evaluation and Mitigation Strategy (REMS) required by the U.S. Food and Drug Administration (FDA) to assure that the benefits of certain prescription drug products outweigh the risks. The healthcare community, including regulators, prescribers and patient safety advocates, agree that opioids offer important benefits to many patients who suffer from pain – but they also have seen a rise in inappropriate and misuse of these medicines.
- The C.A.R.E.S. Alliance recognizes and promotes a collaborative approach that is not limited by congressional action, but driven instead by a concern for patients and their loved ones, a responsibility to provide support, and the belief that safe pain relief for legitimate patients is a cause we all can champion.

Benefits of participating in the C.A.R.E.S. Alliance

- Participants will have access to additional tools and resources that will facilitate responsible prescribing, dispensing and use of opioid pain medications.
- Grounded in science and research, a series of safe-use programs and voluntary tools were developed beyond the capabilities of REMS to further address the risks of opioid prescribing, dispensing and use. The science-based method of Failure Mode and Effect Analysis (FMEA) was employed to assist in the selection and design of risk-mitigation tools to help ensure safe use. Through the C.A.R.E.S. Alliance, these tools and resources are available free of charge to participants at www.caresalliance.org.

Who can participate in the C.A.R.E.S. Alliance

- The C.A.R.E.S. Alliance seeks participation and support from multiple groups including healthcare professionals, patients, pharmaceutical companies and other organizations focused on patient safety.



C.A.R.E.S. AllianceSM Tools and Resources

At the centerpiece of the C.A.R.E.S. Alliance is a variety of tools, programs and educational materials created for use by patients, caregivers, healthcare professionals and communities to combat the misuse and abuse of opioids. The tools have been developed with leading pain experts through a scientific process called Failure Mode and Effect Analysis (FMEA), a methodology to identify where problems occur in the use of pain medications and the underlying causes of those problems.

A new study on the FMEA research presented at PAINWeek 2010 identified 79 “failure modes” – or areas where problems occur – in the use of opioids and 290 potential underlying causes of those failures. Based on those causes, 929 potential interventions were identified, leading to the development of 37 initial tools, resources and programs out of the 60 total that are available through the C.A.R.E.S. Alliance.¹

Resources include clinical materials and risk assessments for physicians; safe-use guides for patients; and general education around safe and responsible opioid prescribing for all groups. These tools can be accessed at no cost via www.caresalliance.org.

PATIENT TOOLS

- Patient Safe Use and Handling Guide including wallet card
- Personal Medication Interaction Card
- Environmental Checklist for Safe Patient Storage, Use and Disposal
- Patient FAQ about methadone and general opioids
- How to Talk to Your Doctor Guide

PHYSICIAN TOOLS

- Ask An Expert Video Series
- *Opioid Prescribing Toolkit* (book by Nathaniel Katz, M.D., distributed exclusively through the C.A.R.E.S. Alliance)
- Opioid Clinical Management Guide
- General Opioid Physician Patient Medication Agreement (PPMA)
- Methadone PPMA
- Urine Drug Testing Brochure including tear-away reminder card
- Methadone Mini Reference Series
- Various Journal Reprints
- Pain assessment tools: Brief Pain Inventory, Numeric Rating Scale, Wong-Baker Faces Scale
- Risk assessment tools: Opioid Risk Tool, Pain Assessment and Documentation Tool, Screener and Opioid Assessment for Patients in Pain, Current Opioid Misuse Measure
- *Responsible Opioid Prescribing: A Physician's Guide* (book by Scott Fishman, M.D.)
- American Pain Society Treatment Guidelines (reprint)

PHARMACIST TOOLS

- U.S. Drug Enforcement Administration (DEA) Pharmacists' Manual
- Pharmacist Counseling Tool (includes best practices, tear-away card for print version and download)

As C.A.R.E.S. Alliance expands, it will seek input from participants and offer additional tools, programs and research aimed at improving the science of safety for opioids.

¹ Holman K, Mills S, Morelli A, et al. A Science-Based Approach to Responsible Risk Management for a Novel Long-Acting Opioid Analgesic [poster]. American Society of Pain Educators. September 2010.



C.A.R.E.S. AllianceSM Frequently Asked Questions

What is the C.A.R.E.S. Alliance?

The C.A.R.E.S. (Collaborating & Acting Responsibly to Ensure Safety) Alliance is a patient safety initiative, which provides science-based education and resources to healthcare professionals and patients at no cost to support responsible opioid prescribing and safe use. This initiative is being developed in collaboration with leaders in pain management, healthcare professionals, consumer health advocacy groups, regulatory bodies and patients. It is supported by Covidien.

What is an opioid?

An opioid is a powerful pharmaceutical prescribed to treat pain. Opioids work by bonding with opioid receptors in the central nervous system. The benefits of opioids can include decreased perception of pain and decreased reaction to pain, as well as increased pain tolerance. Opioids can cause moderate to serious side effects, which can lead to death. Because of the powerful properties of opioids, these drugs can be misused or abused.

Why was the C.A.R.E.S. Alliance formed?

The healthcare community, including regulators, physicians and patient safety advocates, agree that these medicines offer important benefits to many patients who suffer from pain. But they have also seen a rise in inappropriate and misuse of these medicines, and the C.A.R.E.S. Alliance was founded to help reverse this trend.

How were the C.A.R.E.S. Alliance tools and resources developed?

Grounded in science and research, a series of safe-use programs and voluntary tools were developed beyond the FDA Risk Evaluation and Mitigation Strategy (REMS) requirements for these medications to further address the risks of opioid prescribing, dispensing and use. The scientific process of Failure Mode and Effect Analysis (FMEA) was employed to assist in the selection and design of risk-mitigation tools to help ensure safer use. Through the C.A.R.E.S. Alliance, these tools are available free of charge to participants.

What tools are available?

Tools include clinical materials and risk assessments for physicians; safe-use guides for patients; and general education around safe and responsible opioid prescribing for all groups. More than 60 resources, programs and tools are available at no cost to participants. Tools and resources can be accessed via www.caresalliance.org. As C.A.R.E.S. Alliance expands, it will seek input from participants and offer additional tools and research aimed at improving the science of safety for opioids.

When was the C.A.R.E.S. Alliance formed?

The development of the C.A.R.E.S. Alliance began in 2009 as a safety and risk minimization program created to supplement and expand on the premise of the Risk Evaluation and Mitigation Strategy (REMS) required by the FDA to assure that the benefits of certain prescription drug products outweigh the risks. September 8, 2010 marks the official launch of the C.A.R.E.S. Alliance.

What is the goal of the C.A.R.E.S. Alliance?

The goal of the C.A.R.E.S. Alliance is to increase patient safety through the appropriate use of opioid pain medication while reducing potential abuse, misuse and overdose.

What are the benefits of participating in the C.A.R.E.S. Alliance?

Participants in the C.A.R.E.S. Alliance program will have access to tools and resources that will enable them to responsibly prescribe, dispense and use pain medication. These tools and resources are available free of charge to participants at www.caresalliance.org.

Who is currently participating in/involved with the C.A.R.E.S. Alliance?

The C.A.R.E.S. Alliance is seeking support from healthcare professionals, patient advocacy groups, industry organizations and others focused on patient safety.

Where can I find more information about the C.A.R.E.S. Alliance?

More information about the C.A.R.E.S. Alliance can be found at www.caresalliance.org.