How Alere™ CareAlerts Addresses and Successfully Closes Gaps in Care

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The Problem

Despite advances in medicine and technology, the U.S. healthcare system does not always produce optimal outcomes for people who have chronic diseases or who suffer from serious acute or episodic illnesses and injuries. Industry experts agree that healthcare costs will continue to escalate without a solution to address sub-optimal outcomes driven by a lack of consistency in the application of evidence-based guidelines to healthcare delivery. For instance:

- Research shows that only 55 percent of patients in the U.S. receive nationally recommended guidelines of care for their illnesses.[1]

- In a study that included a series of audio-taped physician-patient interactions during office visits, physicians inquired about adherence in 30% of the cases and made in-depth inquiries in only 4% of the cases.[2] The study included 100 patients who, between them, were supposed to be taking 410 prescribed medications. In focus groups as part of the study, a discrepancy was revealed between what physicians believe and what they actually do.[3] All physicians uniformly agreed that they see promoting adherence as part of their role as a physician, but admitted that they rarely ask detailed questions about adherence when seeing patients.

Physicians promoted adherence in 30% of audio-taped physician-patient interactions. The study included 28 physicians and 100 patients, who, between them, were supposed to be taking 410 medications.[2]

- Forty-seven percent of Americans have multiple chronic and other health conditions.[4] The average Medicare patient with one chronic condition sees four physicians a year while those with five or more chronic conditions see 14 physicians.[5] When surveyed, these patients report that they get conflicting advice, including directives for duplicative tests, inadequate care and poor coordination across providers.

- Medication errors are a substantial cause of death and injury in the United States. Approximately 1.3 million people are harmed annually in the United States due to medication errors.[6]

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[1] HealthLeaders Media, "Evidence-based Care Gaps Pervasive, Researchers Say," January 2011
[2] Journal of the American Geriatrics Society, "Provider Views About Responsibility for Medication Adherence and Content of Physician-Older Patient Discussions," Derjung M. Tarn et al, v.60, no. 6, June 2012
[3] Rand Fact Sheet, "When Patients Don't Take Their Medicine," June 2012
[4-5] Health Affairs, "Confronting the Growing Burden of Chronic Disease: Can the U.S. Workforce do the Job?" Jan/Feb 2009
[6] U.S. Food and Drug Administration, "Medication Error Reports," 04/30/2009

Variations in Adherence Cause "Care Gaps"

Care Gaps

- Over-utilization
  - Doctor visits
  - ER visits
  - Hospitalizations
- Under-utilization (not enough care)
- Unnecessary tests and procedures

Variations in adherence to national standards of care result in what the industry refers to as "care gaps". Care gaps can range from a simple lack of education about how to manage a chronic condition, to non-compliance with medications and the physician's prescribed treatment plan.

An example of a common care gap is poor drug compliance. This occurs when a participant under-utilizes a medication or is inconsistent in refilling prescriptions. Another example is early discontinuation of a treatment regimen. This might happen when a person with diabetes stops taking their insulin therapy. Missed screenings or preventive services, such as important lab tests or vaccinations, are also examples of care gaps.

Non-adherence is a serious issue in the U.S., and is associated with poor outcomes, higher utilization and higher mortality. Forty percent of older adults with chronic conditions, most of them with multiple chronic conditions, do not adhere to their treatment regimens.[7] The cost of non-adherence for all patients is estimated at $290 billion a year.[8]

Compliance Needs Improvement

Clinical guidelines, which are widely accepted by the medical community, exist for the management of the majority of chronic conditions. Although following the guideline recommendations has been shown to reduce mortality and morbidity in patients, compliance with the guidelines could be improved.

For example there are many scientific articles about drug safety related to medication errors, medication adherence, duplicate therapy and inappropriate medications for the elderly. One of these is the Beers Criteria, a list of medications that should not be used in the elderly.[9] Using the Beers Criteria, Fick noted that 29% of seniors required treatment for adverse drug reactions and an estimated 106,000 deaths were caused by medication-related issues.[10]

Figure 1

Examples of Clinical Guidelines

- American Diabetes Association - Standards of Medical Care in Diabetes
- American Heart Association – Secondary Prevention for Patients with Coronary Disease
- American Heart Association – Management of Heart Failure
- National Institutes of Health – Management of Asthma
- GOLD – Management of Chronic Obstructive Pulmonary Disease

[7-8] Rand Health Fact Sheet, "When Patients Don't Take Their Medicine: What Role Do Doctors Play in Promoting Prescription Adherence?" June 2012

[9] Archives of Internal Medicine, "Explicit criteria for determining potentially inappropriate medication use by the elderly," Beers MH (July 28, 1997). 157 (14): 1531–1536. doi:10.1001/archinte.1997.00440350031003. PMID 9236554

[10] Fick DM (Dec 8, 2003). "Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults," *Archives of Internal Medicine* 163: 2716-2724.

In Figure 1 is a list a few of the clinical guidelines that have been developed by expert consensus panels and are recognized as standards of practice among the medical community. These guidelines recommend screenings, specific medications, lab tests and procedures for patients with certain conditions and are based on evidence of effectiveness.

Adherence to recommended clinical guidelines can translate into overall lower health care costs. One example of this is the use of inhaled corticosteroids for patients with persistent asthma. A clinical study found that continuous use of an inhaled corticosteroid in patients with persistent asthma reduced the annual medical costs associated with their asthma by 24%.[11] Another good example focuses on the use of beta blockers after a heart attack. Not only does the use of beta blockers in patients who have recently suffered a myocardial infarction reduce the risk of a second heart attack, but the beta blocker also improves a patient's quality of life and provides significant savings over a three-year time period.[12]

Clinicians are looking for actionable information at the point when the patient is in the office. In most cases, clinicians are aware of the guidelines; however, some barriers prevent the patient from successfully meeting the guidelines. Other medical issues may take precedence during a short office visit; patients may not understand the importance of follow-up treatments; patients may stop medications due to side effects; patients may not be able to afford the medication; or the patient simply forgot what to do once they got home from the doctor's office.[13]

The Solution

Disease management programs provided either by health plans to multiple populations or by employers to their employees have done a good job at educating program participants about their conditions and how to live with them, teaching about the importance of and managing compliance, and increasing communication between patients and their healthcare providers. While these programs have succeeded in improving clinical and financial outcomes, there remains a challenge that could be a tipping point in care gap closure on a broad scale – engaging the physician. Without physician engagement and support, chronic care programs cannot live up to their full potential.

Clearly, the next step is to collaborate with the treating physicians, and more than half of them agree. In a Midwest Business Group on Health Survey of Physicians in 2010[14], 72% agreed that employers should have a role in improving and maintaining the health of their employees with chronic diseases, and 59% agreed that employers should inform physicians about their efforts to help patients manage their chronic diseases. In the survey, physicians were asked how employers can work with physicians to encourage participation in employer-sponsored health and wellness programs. Physicians were presented with a list of strategies, and here are the results:

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[11] Smith, Michael J., Karen L. Rascati, and Michael T. Johnsrud. "Costs and Utilization Patterns Associated With Persistent Asthma: A Comparison of Texas Medicaid Patients With and Without Continuous Inhaled Corticosteroid Treatment." *Journal of Managed Care Pharma cy* 7.6 (2001): 452-59.

[12] Peters, David H.; Benfield, Paul. "Metoprolol: A Pharmacoeconomic and Quality-of-Life Evaluation of its Use in Hypertension, Post-Myocardial Infarction and Dilated Cardiomyopathy." *Pharmacoeconomics.* 6(4):370-400, October 1994.

[13] JAMA. Why don't physicians follow clinical practice Guidelines? A framework for improvement. October 20, 1999. Vol 282, No 15.

[14] Midwest Business Group on Health, MBGH Physician Survey 2010

- 61% - Provide information about the program(s)
- 49% - Send patient clinical results to reduce redundancies
- 48% - Provide actionable reports to assist physicians with treatment
- 47% - Design programs to be an extension of physician's treatment regimen

Healthcare organizations are now developing communication programs to keep physicians and participants informed and in the loop regarding information shared in clinician-participant interactions, including the identification of care gaps via self-reported data. There are many different companies that offer this basic kind of service with varying features.

Alere has developed Alere™ CareAlerts – a messaging service provided as part of our Chronic Care program to keep physicians informed about their patient's progress, medication adherence and potential risk management issues, including care gaps. Messaging is developed to facilitate the closure of gaps before they escalate into high-risk or high-cost events.

What differentiates the Alere program is that it offers all of the functionality of an ideal care gap closure program, from a condition management perspective, which includes the following:

- Identifies issues that are based on nationally recognized evidence-based guidelines for management and prevention of health problems and generally accepted by the physician community.
- Communicates with both the patient and the treating doctor.
- Develops messages for each kind of clinical gap issue pertinent to the individual patient and/or doctor. For patients, the messages and action items are simple and easy to understand. For doctors, the messages are direct and concise.
- Encourages action and collaboration between the patient and doctor. The message delivered to the patient has specific action steps and a specific reason for contacting the doctor.
- Complements and enhances disease management programs by including more patients than are normally contacted by disease management programs and/or focused clinic-based programs; includes patients at all severity levels; and includes patients that do not want to participate in a phone-based program or who are unable to be reached via phone.
- Provides a program that is *relevant, concise and simple*.
- And for those participating in a disease management or case management program, ensures that the care manager can assess the care gaps and reinforce the messaging.

How Alere™ CareAlerts Works

Alere can provide its Alere™ CareAlerts solution together with other Alere services such as chronic care programs or as a standalone service. We have specially developed the Alere™ CareAlerts service so that it delivers results (gap closures) while providing a positive benefit for patients and their healthcare providers. Alere™ CareAlerts messages are *relevant, concise, and simple.* The service offers the following:

1) Identification of Relevant Issues for Individual Patients

Alere™ CareAlerts uses proprietary algorithms to identify clinical gaps in care. The algorithms are based on national evidence-based clinical guidelines from organizations such as the American Diabetes Association and the American Heart Association, as well as criteria used in determination of HEDIS® measures (Healthcare Effectiveness Data and Information Set). Administrative billing data, such as medical, pharmacy and lab claims, provide the patient's latest information for use in the algorithms. Alere™ CareAlerts addresses a variety of clinical issues: prevention awareness, medication adherence / utilization issues, medication safety and recommended treatment for various conditions.

2) Use of Concise Messages for Patients and Providers

On the right are graphic displays of Alere™ CareAlerts messages developed for patients. Figure 2 displays a message for patients who have endured a heart attack, to explain that beta blockers are effective in preventing and reducing the severity of future heart attacks. Figure 3 contains a message for patients who have either poor or no adherence with a prescribed maintenance medication. Both patient messages are concise, to the point and encourage collaboration with the physician. Alere developed the messages in collaboration with Alere physicians, pharmacists, nurses, a large health plan customer and HealthWise®, a consumer health communications company.

Figure 2

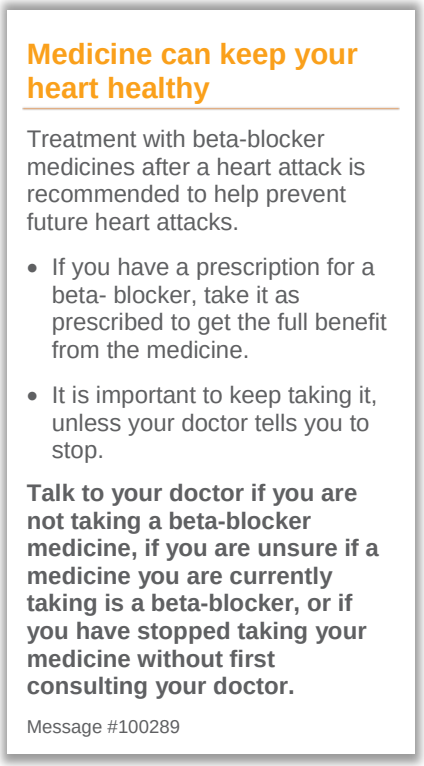
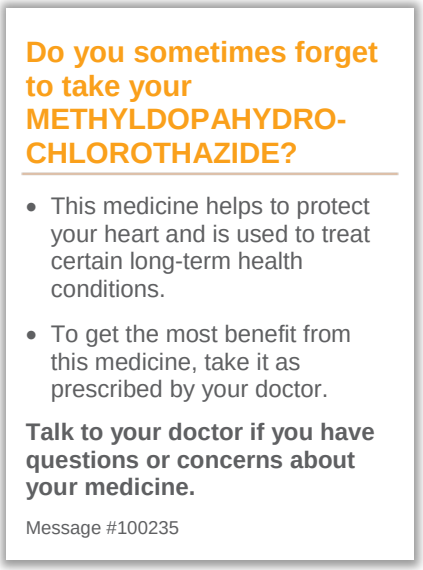


Figure 3



3) Simplification of Care Gap Closure

Participants of the Alere chronic care programs can receive Alere™ CareAlerts messages as often as monthly in the mail or electronically via the Alere secure confidential health portal. Participants receive care gap notifications first, before physicians, to give them time to address and close the gap or make an appointment with their physician. If a patient fails to address the care gap in three months, an alert is then sent to the physician. Physicians like this approach because it reduces the number of messages they receive.

If the care gap remains unresolved, a repeat message is sent to the participant and physician. The same message continues to be sent every four to six months until the care gap is resolved.

Physicians Get Two Reports in One

Physician reports include a cover letter that explains the program and two sections: 1) a summary report listing patients for each care gap issue and 2) a report for each patient on a single page to be placed on the patient's chart for discussion during the next office visit. This provides the physician with two ways to incorporate Alere™ CareAlerts into the office workflow. Alere sends these reports via mail or fax every three months.

On the right are two examples of physician Alere™ CareAlerts messages. (See Figures 4 & 5) As you can see, these messages to physicians are direct and to the point.

Figure 4

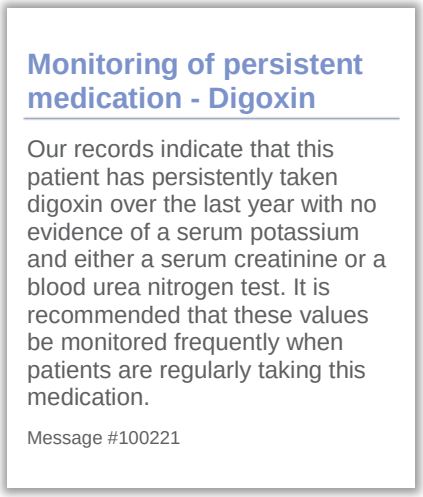
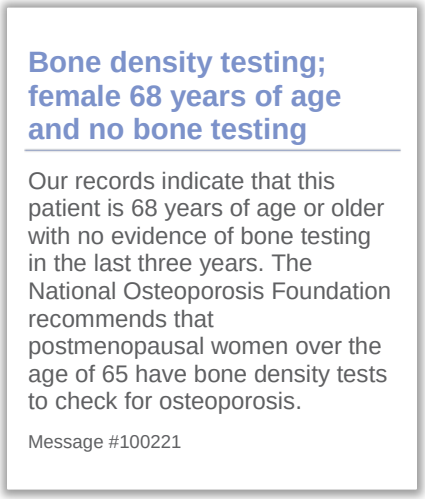


Figure 5



Alere™ CareAlerts Cover 100+ Rule Gaps

More than 100 different Alere™ CareAlerts rule gaps are grouped into four categories for reporting purposes. All categories contain some rules based on HEDIS criteria. The four categories comprise the following:

- **Rx Adherence Safety** – Adverse drug interactions, poor medication adherence and early discontinuation of maintenance medications.
- **Rx HEDIS –** Based on HEDIS criteria, such as inappropriate high-risk drugs used in the elderly, inappropriate use of antibiotics, and polypharmacy.
- **Care Gap** – Based on nationally recognized clinical guidelines. Examples include beta blocker use in heart attack patients and lack of A1C tests for diabetes patients.
- **Prevention** – Based on preventive criteria, such as breast, cervical or colorectal cancer screenings.

Since individual rules were constructed to contain several different drugs or even several classes of drugs, the 100-plus rules actually provide over 10,000 unique messages.

The Results

A clinical program is effective only if it can show that it results in closure of clinical gaps. *Alere considers that a gap has been closed if the patient has a claim for the recommended test or procedure after the Alere™ CareAlerts message was first sent to either the member or provider.* For instance, if an Alere™ CareAlerts letter was sent indicating that the patient should have an immunization, then a claim for that immunization received after the Alere™ CareAlerts mailing would indicate that the clinical gap has been closed.

The percent of clinical gap closures for each Alere™ CareAlerts category are calculated over four different time cohorts: 3 months, 6 months, 9 months and 12 months. Each cohort is the time period after Alere first delivered the Alere™ CareAlerts message to the patient or doctor. For instance, if the first time that a bone density alert was mailed to either the member or doctor was January, then the 3-month cohort would be February through April. The 6-month cohort from February would be July.

See Figure 6 for the Book of Business cohort conversion results for the Alere™ CareAlerts categories. As illustrated, the conversion rates increase over time and they vary from category to category. For instance, the alerts in the Rx Adherence Safety category were closed at a higher rate than the other alert categories. Twelve months after Alere sent the Rx Adherence Safety care alerts, 55.6% of the alerts were closed. The Prevention and Care Gap closure results were initially at a lower rate but increased over time to 21% and 27% respectively at 12 months.

Figure 6

Percentage of Clinical Gaps Closed by Alere™ CareAlerts[15]

	Number of months after alert is sent			
CareAlerts Category	**3 Months**	**6 Months**	**9 Months**	**12 Months**
Prevention Category Totals	4.9%	10.5%	16.0%	21.1%
Care Gap Category Totals	9.5%	17.6%	22.8%	27.2%
Rx HEDIS Category Totals	34.7%	47.1%	57.0%	63.4%
Rx Adherence Safety Totals	28.0%	42.0%	50.2%	55.6%
Total Results	11.4%	19.8%	26.0%	30.9%

Summary

As shown in the scientific literature, a substantial number of clinical care gaps still exist in the general population. Alere™ CareAlerts is an efficient and effective service that identifies relevant gaps in care and communicates those gaps in actionable messages to both patients and physicians.

Alere™ CareAlerts is effective at closing clinical gaps. The service has demonstrated total gap closure rates of about 31% at 12 months with rates over 50% and 60% with select gap categories. And the studies show that following clinical guidelines is associated with cost savings.[16,17]

[15] Results derived from CareAlerts clients with over one year of experience. Results for individual clients are dependent on many factors such as age of the population and medical benefit coverage. Subpopulations (i.e. total population, disease management subpopulation or other, will affect these representative results.

[16] Smith, Michael J., Karen L. Rascati, and Michael T. Johnsrud. "Costs and Utilization Patterns Associated With Persistent Asthma: A Comparison of Texas Medicaid Patients With and Without Continuous Inhaled Corticosteroid Treatment." *Journal of Managed Care Pharmacy* 7.6 (2001): 452-59.

[17] Peters, David H.; Benfield, Paul. "Metoprolol: A Pharmacoeconomic and Quality-of-Life Evaluation of its Use in Hypertension, Post-Myocardial Infarction and Dilated Cardiomyopathy." *Pharmacoeconomics.* 6(4):370-400, October 1994.

Another measure of effectiveness is member satisfaction. A recent survey[18] showed high satisfaction rates (95.6%) from individuals receiving Alere™ CareAlerts messages. The overall success and satisfaction are a result of messages that are well-crafted for the recipient with a focus on patient-physician collaboration in closure of care gaps.

The Alere™ CareAlerts service provides a cost-effective care gap messaging solution that results in reduced costs for employers and health plans, more informed decisions by health providers, and ultimately improved quality of life for participants. Future white papers pertaining to Alere™ CareAlerts will look at cost savings and gap closure rates by different segmented populations.

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[18] Alere Participant Satisfaction Survey internal documentation. June 2011.