The Value of a Wearable Personal Alert Device and Support System

Lessons Learned in a Pilot Study in a Medicare Advantage Population

Editor's Note:

Welcome to *Case In Point*'s inaugural peer review section. This issue presents the first in a continuing series of peer review articles brought to you through the collaboration of the Population Health Impact Institute and Dorland Health. The peer review series, to continue in future issues of *Case In Point*, will cover best practices in healthcare, health management and organizational improvement across the broad but interrelated continuum of care.

This peer review section is designed for rapid dissemination of concise peer-reviewed studies from cutting-edge programs aimed at measurably improving the health of defined populations. It focuses on populations and programs including wellness, case management, patient-centered medical home, healthcare information technology, remote monitoring devices, disease management, targeted benefit changes, consumer engagement strategies, organizational improvement and others.

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PART 1: INTERVENTION, TARGET POPULATION & PATHWAY

The Intervention: The intervention is a wearable personal alert device and call center support system. It is activated by a patient when they suspect they need help with a medical emergency.

The Target Population: Ambulatory members of a Medicare Advantage plan over the age of 65 with at least two claims for cardiovascular conditions based upon AHRQ's Clinical Classification Software (CCS) system, CCS groups 100-109. Continuously enrolled for six months prior to the wearable device install date, and six months after the install date. The install date was between April 1, 2008, and June 1, 2008. The eligible population was 1,221. All were called and 165 met eligibility requirements for the study (an additional 150 were provided the device but were excluded from the study as they did not have baseline evidence for cardiovascular disease). Any person with claims over $100,000 in any time period was excluded (this resulted in the exclusion of one patient from the referent group).

The Pathway: Use of the device/support system should decrease utilization of emergency rooms and inappropriate hospitalizations. This would happen for two reasons: 1) If the patient had any issue which they were concerned about, they could press the pendant and immediately speak to a professional who could advise them on the best alternative. It is believed, therefore, that this action will reduce unnecessary and inappropriate ER visits; 2) If the patient had a significant event and was unable to reach the phone or a loved one, they could press the pendant and either talk to a vendor representative or, if the user did not respond, the vendor would dispatch emergency personnel to the premises. This would lead to the patient presenting to the emergency room or inpatient facility earlier than without the advice and therefore would lead to an expected reduced use of acute care/inpatient services.

Operational Goals: Reduce inpatient and overall healthcare costs and inpatient costs compared to an equivalent referent. Assess impact of the plan's offer to make the device available to members without charge on member's satisfaction with the health plan compared to an equivalent referent Assess a nonfinancial benefit of the device (i.e., "peace of mind" and "satisfaction with the health plan").

PART 2: PATHWAY METRICS

Intervention Process Metric: Those with the device installed (the denominator) were instructed to test its functionality each month (the numerator, tracked each month). This was used as a proxy indicating the person was likely wearing the device and that it could be used in an emergency

For the study, the total test group *n* was 165 the total referent group *n* was 276.

Intermediate Outcomes: A telephone survey of all participants was designed and two questions were to be asked of all participants:

- "What has been your level of satisfaction with your health plan in 2008?"
  Possible answers: 1. Very high, 2. High, 3. Neutral, 4. Low, 5. Very Low.
- "I am likely to renew my membership to the health plan for next year."
  Possible answers: 1. Will definitely renew, 2. Will likely renew, 3. Have no opinion, 4. Will likely not renew, 5. Will definitely not renew.

One question was asked of test group only:

- "The device has given me and my family a 'peace of mind' that I did not have before."
  Possible answers: 1. Very high, 2. High, 3. Neutral, 4. Low, 5. Very Low.

Ultimate Outcomes: Average medical costs per person, costs associated with hospitalizations.

PART 3: CONFOUNDING FACTORS

Measured Confounders: The baseline equivalence between the two groups was

assessed by examining and comparing age, gender and the prevalence of the top 20 grouped conditions (based on AHRQ groupers cited before). In addition, the test and referent were compared on each of the following: mean age, percent male vs. female, HCC summary score, and number of the following HCC diagnoses: CAD, COPD, DIAB, and CHF. Risk score from Centers for Medicare and Medicaid Services' (CMS) Hierarchical Clinical Condition (HCC) score and the number of targeted HCC diagnoses. The HCC model is a "risk adjustment" (supplied by CMS) model used to adjust Medicare capitation payments to private healthcare plans for the health expenditure risk of their enrollees.

Unmeasured Confounders: One factor that may influence outcomes for which we do not have a metric is the patient's geographical proximity to emergency medical care. The patient may either choose not to travel to a distant facility for medical treatment, or may not arrive in time to get adequate treatment. Therefore, "proximity to medical care" should be classified as an unmeasured confounder.

PART 4: REFERENT

Referent cases were selected from the same geographic area based on evidence of cardiovascular disease at baseline plus matched criteria regarding age, gender, and the HCC score, and number of HCC diagnoses. A faux install start date was assigned to each referent case based upon the start date of each test person. The study was limited to those who had 12 time periods (28 days long) of continuous enrollment, six time periods prior to the assigned "start date" and six time periods after the assigned "start date."

PART 5: EQUIVALENCE/ COMPARISON

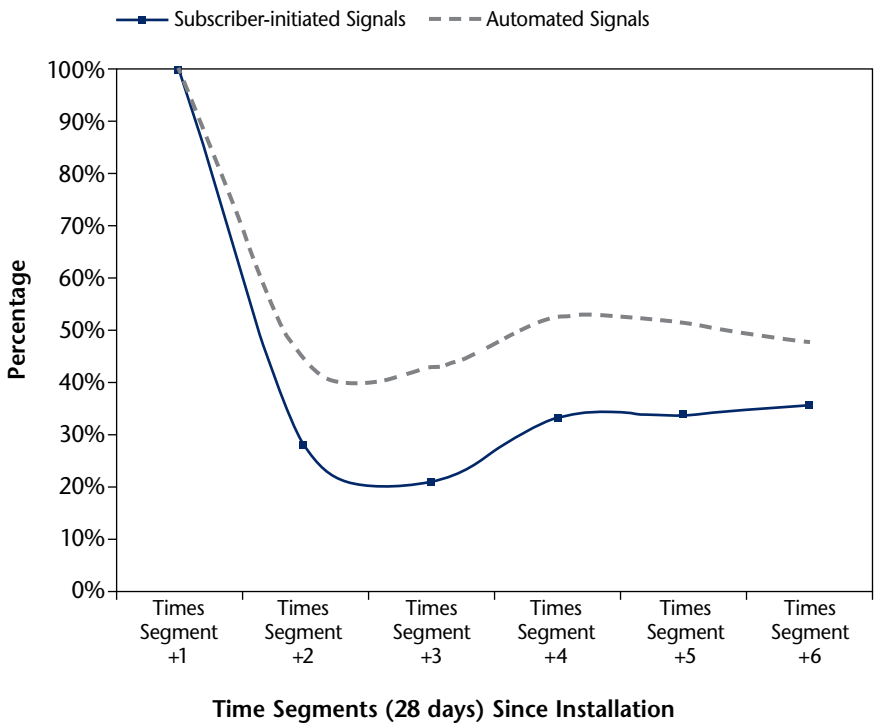
Confounding Factor Metrics Comparison (See Table 1): Age, gender, and distribution of diagnoses was similar in both the intervention and referent.

Intervention Process Metrics (See Figure 1): The testing of the wearable device, an intervention metric, dropped considerably after the first testing month.

Table 1: Baseline characteristics of the two groups

	TEST (n=165)	REFERENT (n=276)	Comparison (p-value)
Average Age (s.d.)	79.26 (4.78)	79.27 (4.77)	0.98
Percent Female	62.54	62.60	0.93
HCC Summary Mean Score (s.d.)	0.89 (0.81)	0.87(0.67)	0.78
Mean Number of unique HCC diagnoses (s.d.)	2.02 (1.13)	1.97 (1.07)	0.64
Average Cost per six baseline 28 days periods (s.d.)	1343.14 (4,213.01)	1,223.44 (3,606.56)	0.75
Average inpatient cost per six baseline 28 days periods	743.15 (3,691.46)	737.18 (3,094.56)	0.98
Coronary atherosclerosis and other heart disease	44%	39%	0.35
Essential hypertension	44%	46%	0.75
Nonspecific chest pain	36%	37%	0.91
Cardiac dysrhythmias	36%	37%	0.91
Other lower respiratory disease	28%	30%	0.74
Congestive heart failure, non-hypertensive	27%	26%	0.93
Diabetes mellitus without complication	24%	30%	0.21
Diabetes mellitus with complications	22%	20%	0.70
Medical examination/evaluation in the past 6 months	22%	19%	0.52
Chronic obstructive pulmonary disease and bronchiectasis	16%	17%	0.88

Figure 1: Personal Medical Alert Transmissions: All Alerts/Signals & Subscriber Initiated (n=165)



Intermediate Outcomes (See Tables 2, 3 and 4):

Table 2: What has been your level of satisfaction with your health plan in 2008?"

	TEST	REFERENT
1. Very high	65%	54%
2. High	30%	37%
3. Neutral	5%	8%
4. Low	0%	1%
5. Very Low.	1%	1%
Overall (mean)	1.44	1.57

Table 3: "I am likely to renew my membership to my health plan for next year."

	TEST	REFERENT
1. Will definitely renew	83%	77%
2. Will likely renew	12%	13%
3. Have no opinion.	3%	8%
4. Will likely not renew	1%	0%
5. Will definitely not renew.	1%	2%
Overall (mean)	1.25	1.37

Table 4: "The device has given me and my family a 'peace of mind' that I did not have before."

	TEST
1. Very high	44%
2. High	35%
3. Neutral	17%
4. Low	2%
5. Very Low.	2%
Overall (mean)	1.83

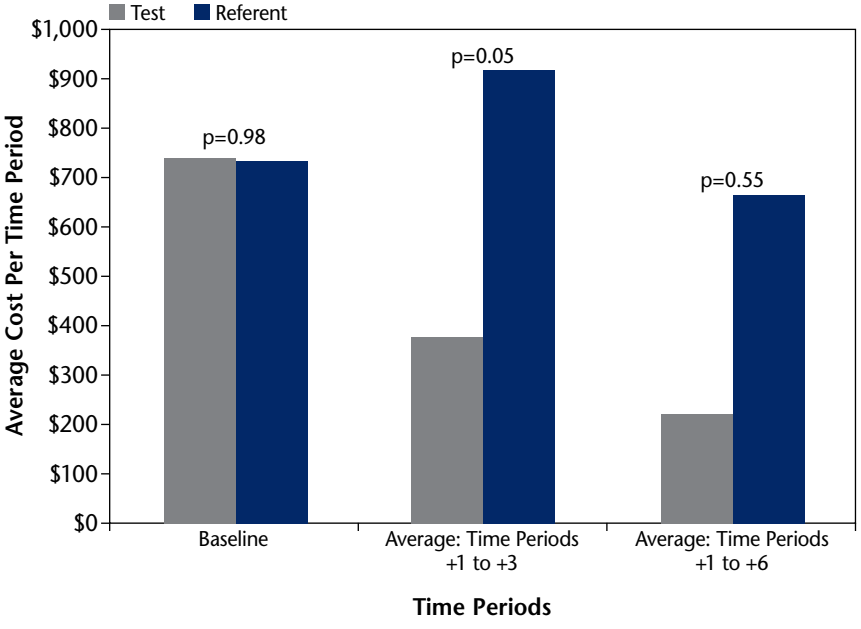
Level of satisfaction was higher in test group than in referent, these results were not statistically significant.

Outcome Metrics Comparison (See Table 5 and Figure 2): The baseline costs of both group were similar, the costs of the intervention group declined for the first the months, but for the second three months, the costs were approaching the referent group's costs.

Table 5: Average Costs in Baseline and Follow-up Periods

	TEST (mean)	TEST (SD)	REFERENT (mean)	REFERENT (SD)	TEST COMPARED TO REFERENT (p-value)
BASELINE					
Time Period-6	$1,234.43	$4,684.95	$759.28	$2,195.64	0.15
Time Period-5	$836.19	$2,039.63	$1,097.20	$3,649.71	0.40
Time Period-4	$1,742.51	$6,430.70	$1,280.79	$3,430.53	0.33
Time Period-3	$1,701.40	$4,241.94	$1,494.00	$3,944.76	0.59
Time Period-2	$1,251.57	$4,159.33	$1,287.68	$4,116.08	0.94
Time Period-1	$1,292.77	$3,721.52	$1,421.71	$4,284.64	0.75
Average: Time Periods -6 to -1	$1,343.14	$4,213.01	$1,223.44	$3,603.56	0.75
FOLLOW-UP					
Time Period+1	$648.23	$1,849.19	$1,142.32	$3,650.80	0.11
Time Period+2	$865.81	$2,478.13	$946.22	$2,845.53	0.76
Time Period+3	$676.26	$1,737.85	$1,045.60	$2,791.19	0.13
Time Period+4	$1,111.44	$3,763.74	$865.51	$3,947.48	0.52
Time Period+5	$713.65	$1,928.56	$720.15	$2,728.22	0.98
Time Period+6	$1,136.56	$6,194.52	$663.21	$2,911.05	0.28
Average: Time Periods +1 to +3	$730.10	$2,021.72	$1,044.71	$3,095.84	0.25
Average: Time Periods +1 to +6	$858.66	$2,992.00	$897.17	$3,145.71	0.90

Figure 2: Difference in Average Inpatient Costs at Baseline, Three Month and Six Month Follow-ip



PART 6: LEARNINGS

Conclusion/Next Steps: This was a pilot study to determine the value a health plan provided wearable alert device, and associated monitoring services, to a selected subset of a Medicare Advantage population. At the initiation of the pilot there was no literature or vendor data available to help determine the type of individual that would likely benefit from the device (and monitoring services), i.e., to help estimate expected results. Therefore, one purpose of this study was to provide some preliminary estimates

of results that could be used for a subsequent larger study. This pilot project did accomplish this. Projecting from these preliminary result, an alpha level of 0.10 and a Beta level of 0.20 (or an 80 percent power), one would need 550 individuals in the test group and another 550 individuals in the referent to adequately test this hypothesis. If we selected an alpha level of 0.05, the necessary number of people per group would expand to about 650.

The pilot also highlighted the need to have better measures of continued use of the device than the ones available for this study. The marked fall-off in subscriber initiated alerts after the first few months of use should be further explored to determine why this occurred. Simple interventions, like requiring a monthly subscriber initiated alert or an outbound call when such an alert fails to be transmitted, could help elucidate whether the member was still actively using (wearing) the device.

Intervention Learnings: The wearable alert device had mostly been marketed in commercial population where monthly fees were assessed; these fees, were, in essence, a marker of "use." We learned that giving a device for "free" negates this marker, thus we are considering charging in the future, or making testing mandatory.

The results of the claims-based study were encouraging for the first one to three months as both total costs and inpatient costs were lower in the test group than in the referent. However, the differences in total costs did not reach the level of statistical significance. Importantly, a summary of the first three time periods did reach statistical significance for inpatient costs.

In attempting to understand this apparent impact in the first few months but a falling off in the last three months, several explanations were considered:

1. Although the device was still in the home, participants did not use it appropriately, i.e., it was unavailable for emergency transmissions.
2. The apparent impact in the first three months was simply random.

Regarding the first point – there was a large drop in subscriber-initiated transmissions after the first month of operation. The test participants were told to test the device each month to make sure it was working. In lieu of monthly tests, the vendor has two methods of testing the system.

1. If the device was "not working" or power has been lost an automated transmission gets sent.
2. The monthly payment of the subscriber fee is a proxy for the member's continued use of the device.

Since the health plan provided the device free of charge, the second method of monitoring access to the device was not available. In addition, the vendor had informed the participants that the device would be "picked up" after six months, so it is possible that some of the members in the test group may have discontinued use of the device believing it would no longer be accessible to them. Indeed when the vendor did pick up the device they made the following observation:

- "The pilot was impacted greatly by Hurricane Ike (September 1-18, 2008). Members were forced to leave units in their homes severely damaged by the storm. Many were displaced for months afterwards, moving in with family in temporary quarters, changing their need for the unit from the original test parameters and their access to it."

Another possibility was that the novelty of having the device wore off after the initial months of use and participants simply "forgot" to or found it inconvenient to wear it. Discontinuation of use of monitoring devices (e.g., pedometers) in community settings after an initial period of use is a well known phenomenon.

Regarding the second point – the trends of cost were lower during the entire six-month period, even though they were not statistically significant. Thus random error could not be ruled out totally. A larger sample size may have led to a result that was statistically significant throughout the entire period. A prospective design with a well-defined study and referent group should also clarify the possibility of random error.

Intermediate Factors: The results of the survey were very encouraging. It appeared that the participants had greater satisfaction with the health plan than the referent; in addition, the participants were more likely to renew with the health plan. These results were not statistically significant. Moreover, nearly 80 percent of the participants stated they had "greater peace of mind" by having the device and monitoring services available. These results provide evidence of the value of wearable personal alert devices to the health plan, apart of the potential cost savings.

Confounding Factors: We were satisfied with the general equivalence of the two populations at baseline, but realize a lot of potential confounding factors were not considered. During the study a major hurricane impacted the area, an unexpected confounder, but it should have impacted both groups the same.

Outcomes: The fact that costs were lower for the first three months were encouraging, but the fact that then began to rise was not. This may be attributed to the potential lack of use of the device, or other factors. We hope to design a study in the future to solve this problem.

Overall: The alert device certainly has a lot of promise in the perceptual realm with improvement in quality of life and the sense that it may lead to a renewal of the contact with the health plan. The value to claims reduction is promising, but a larger study – with some administrative changes – will be necessary to show its value. The following steps are suggested:

1. Include a nominal monthly co-pay when the participant agrees to use the device.
2. State clearly that the co-pay is stable for the contract period.
3. Clearly select patients for the expanded pilot study as they were selected here: Limit to only those with baseline cardiovascular disease. Use non-participants as a reference, selected by matching criteria.

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What about any issues or problems from program?

Although the benefits far exceed the challenges, there are several things to keep in mind. The program will require resources to execute and manage versus having to do nothing with the employee sitting at home. But it is only marginally more time-consuming then, say, having a light-duty employee working on site. If you are self-insured or don't have a TPA then you will also have to manage the interactions with the nonprofit TPP, which will consume additional resources.

Not every situation will come up roses. We have had some injured employees who became more stressed out mentally in having to deal with others problems (e.g., hospice, depression, financial issues) and we had to spend additional time finding an alternative work scenario that was tolerable to the injured employee.

You may also get complaints regarding the pain of the injured employee or the tasks they are performing. But similar to if they are working onsite, you would indicate that the work was within the restrictions of your treating physician. Other challenges would be complaints of injured employee's having to travel a further distance then their normal work site or the hours available for working.

As you can see, the benefits far outweigh the negatives in the above scenario, and many other businesses are modeling programs to mirror the success achieved at Cheney Brothers. CIP

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When working with a complex care claimant, pressure map at home and ask a lot of questions about the environment, clothing and lifestyle and especially any recent changes. Use the test to educate or remind the claimant about maintaining posture, relieving pressure through pressure shifts and the independence-threatening danger of wounds.

Ideally, pressure mapping should be conducted once a year and after any significant illness, especially a hospitalization. Once a patient hits 55, it should be done twice a year because muscles and the immune systems break down and weaken as a person ages.

Sometimes it takes getting up close and personal to get to the bottom of a problem. Pressure mapping is a great tool, but it is only one tool and it needs to be combined with the knowledge of an experienced rehabilitation specialist who can dig through the layers of information and figure out the problem. CIP

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The need to evaluate services is extremely important, however the fact of an evaluation can alter the standard operating procedures. We have to balance the need to "get things done" with the need to evaluate "how we are doing." We realized the latter should always be considered, and were lucky to have a practical-minded evaluation expert advising the team from the beginning. Finally, this kind of "real world" study shows the value of a scientific approach to evaluating business decisions. It is a good example of moving toward a "learning culture" of continuous evaluation and refinement. CIP

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REFERENCES

Elixhauser A, Steiner C, Palmer L. Clinical Classifications Software (CCS), 2009. U.S. Agency for Healthcare Research and Quality.

Pope GC, Kautter K, Ellis RP, Ash AS, Ayanian JZ, Iezzoni LI, Ingber MJ, Levy JM, Robst J. Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model. Health Care Financing Review. Summer 2004/ Volume 25, Number 4: 119-141.

Harvey JT, Eime RM, Payne WR. Effectiveness of the 2006 Commonwealth Games 10,000 Steps Walking Challenge. Med Sci Sports Exerc. 2009 Aug;41(8):1673-80.