



**Sample MCO Healthcare Services, Inc. Colon Cancer Screening Initiative:**

**Medivo Program Protocols**

Client: Sample MCO Healthcare Services, Inc (MCO)

Test: Fecal Occult Blood (FOB) Home Test Kit, screening test for Colon Cancer

Dates: late 2009/early 2010

MCO contracted with a major U.S. laboratory and Medivo to conduct an FOB Test for a targeted list of its members, using a home test kit specimen collection method, with state by state physician oversight provided using Medivo's online platform and technology to facilitate lab test review/approval/results by Medivo's contracted physician network with a minimum of 1 credentialed physician in all 50 states.

**PROCESS**

Initially MCO sent information to a targeted list of members with a reply card for those who requested to participate in the program. MCO provided an eligibility file of this list of participants who sent back a reply card to the laboratory, which contained the following demographics:

First and Last Name

Address

Phone number

Date of Birth

Gender

The laboratory sent this file to Medivo via a secure data connection.

All individuals in the eligibility file are uploaded by Medivo into the vCare platform which allows each individual's lab test request to be reviewed by a Medivo physician licensed and residing in the individual participants' respective states of residence.

For all patients who meet the colon cancer screening protocol, the lab test requests are approved. For those patients who do not meet the lab test protocol, or for whom the Medivo physician has additional questions, the lab test requests are not approved, but sent back to the laboratory with an explanation and/or request for more information.



Medivo generates a unique requisition for each individual whose request is approved, and sends them back to the laboratory electronically, using our established API.

The laboratory sends out FOB home test kits which includes a printed copy of the unique requisition generated from vCare to the MCO patient from their local state's Medivo physician.

The patient collects the specimen at home and returns it to the laboratory for processing. Detailed instructions are provided in the test kit.

The laboratory analyzes the specimen and the results of the FOB test are sent electronically to vCare, using the validated API.

Using a set of protocols developed by Medivo physicians, the results are processed and filtered. Medivo physicians have full access to results of the members whose tests they approved.

If the result is normal - results are released and sent via standard US Mail to the patient.

If the results are abnormal – a trained Medivo staff member calls the patient and advises them of their abnormal result, requests that they follow up with their primary care physician, then sends a copy of the results and recommendations via standard US Mail.

- If there was no phone number given for the MCO patient, Medivo sends a certified letter with the above communication.

- If Medivo is unable to reach the MCO patient after 6 phone call attempts, Medivo sends a certified letter with the above communication.

All result communications are documented in the vCare database for regulatory, compliance, and audit purposes.

**RESULTS**

MCO sent 55,385 communications to the targeted list of members with risk factors for colon cancer. The algorithm for targeting this list is an essential component to assessing the program’s effectiveness, and will be requested for a collaborative analysis from MCO. Following are tables of response rates and outcomes broken out by gender, age, and state. Additional analyses are available as needed.

**Response Rates:**

Of those 55,385 letters sent out, 4,973 (8.65%) members returned the reply card with a request to participate in the screening program, and each received an FOB kit. Of the 4,973 kits that were delivered, 1,802 (37.06%) were returned with good quality specimens that the lab was able to process. Of the 1,802 processed specimens, 1,717 produced readable final results.

WI, MO, IL, KS were the highest volume target states and represented over 1,700 (>97%) of the 1,802 specimens received. Slightly more females than males returned kits, both because slightly more females received kits and because they returned them more consistently. Further MCO data is required to validate the genders of targeted members who received letters initially. There was a trend for older males to return the kits more frequently, though the trend was not observed for females. Missouri had the highest return rate of the 4 main states that were targeted (37.17%), whereas Florida, California and Texas all had higher return rates (~47%, ~54%, and ~54%) their total kits returned were quite low (8, 7, and 7).

**Overall Response Rates:**

Targeted Members	Reply Cards Received	Specimens Received	Overall Response Rate
55,385	4973 (8.65%)	1802 (37.06%)	3.25%

**Responses By Gender:**

Gender	Kits Mailed	Kits Returned	Response Rate (%)
Male	2479	889	35.86
Female	2494	913	36.60
<b>Totals</b>	<b>4973</b>	<b>1802</b>	<b>36.23</b>

**Responses By Age: (age ranged from 52-81, with average age of 59)**

Age	Kits Mailed	Kits Returned	Female	Male
>80	25	9	4	5
70-79	188	71	37	34
60-79	1865	721	353	368
50-59	2895	1001	519	482
<b>Totals</b>	<b>4973</b>	<b>1802</b>	<b>913</b>	<b>889</b>

**Responses By State (Top 8 States):** note that 25 other states had <10 responses each: IN MI OH AZ TN MN AR GA WA IA LA PA SC MD NE NM OK NJ AL CT KY MA NC OR SD and UT

State	Total Kits Mailed	Total Kits Returned	Total Return Rate (%)	Male Kits Returned	Male RR (%)	Female Kits Returned	Female RR (%)
WI	2338	825	35.28	421	18.00	404	17.27
MO	1945	723	37.17	328	16.86	395	20.30
IL	324	117	36.11	65	20.06	52	16.04
KS	233	81	34.76	43	18.45	38	16.30
FL	17	8	47.05	6	35.29	2	11.76
CA	13	7	53.84	3	23.07	4	30.76
TX	13	7	53.84	6	46.17	1	7.69
CO	10	3	30.00	2	20.00	1	10.00
<b>Totals:</b>	<b>4893</b>	<b>1771</b>	<b>36.19</b>	<b>874</b>	<b>17.86</b>	<b>897</b>	<b>18.33</b>

**Response Rate Map: White = 0, Red = 1-200, Green = 201+**

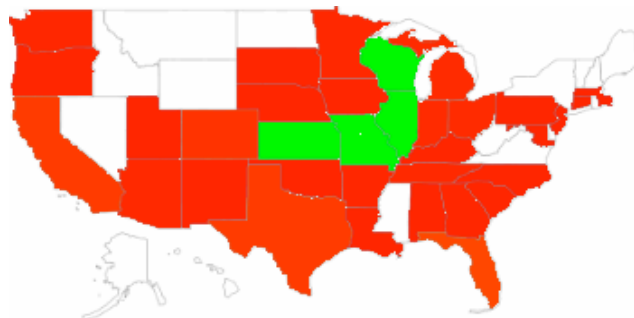


Table 1

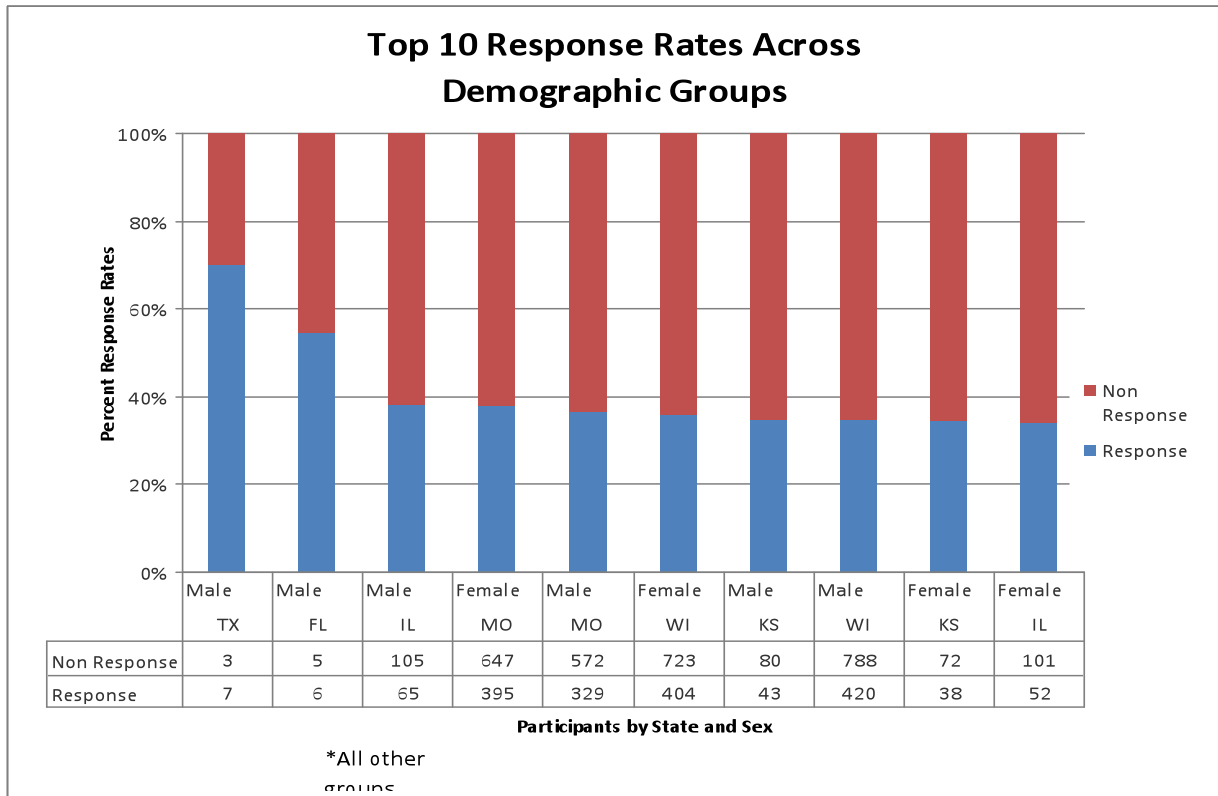
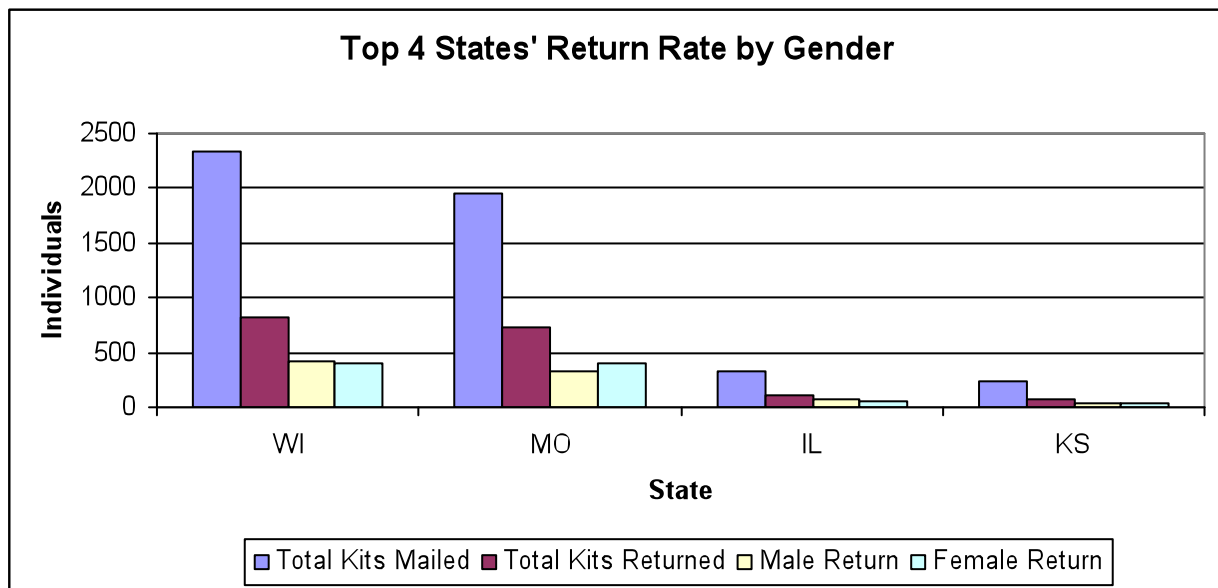


Table 2



**Outcomes:**

Overall 85 abnormal (4.71%) were observed, more males (50, or 5.62%) than females (35, or 3.83%) generated abnormal results. As expected among the top 4 targeted states, a trend was observed where older members had more abnormal results. The two states with the highest kits received volumes, Wisconsin (825) and Missouri (723) had lower than average abnormal results (3.8% and 4.7% respectively), whereas the two states with lower kits received volumes, Illinois (117) and Kansas (81) had higher than average abnormal results (10.2% and 7.4% respectively). Further analysis of the algorithm for targeting the members is critical to understand the apparently higher FOB prevalence in Illinois and Kansas.

As described above the members with abnormal results were contacted via protocols and the next typical step in managing the so-called "positive" FOB test outcome is to undergo colonoscopy to directly address the source of the blood.

**Outcomes By Gender:**

Gender	Normal results	Abnormal results	Total Results	Normal results (%)	Abnormal results (%)
Male	839	50	889	94.37	5.62
Female	878	35	913	96.16	3.83
<b>Totals:</b>	<b>1717</b>	<b>85</b>	<b>1802</b>	<b>95.28</b>	<b>4.71</b>

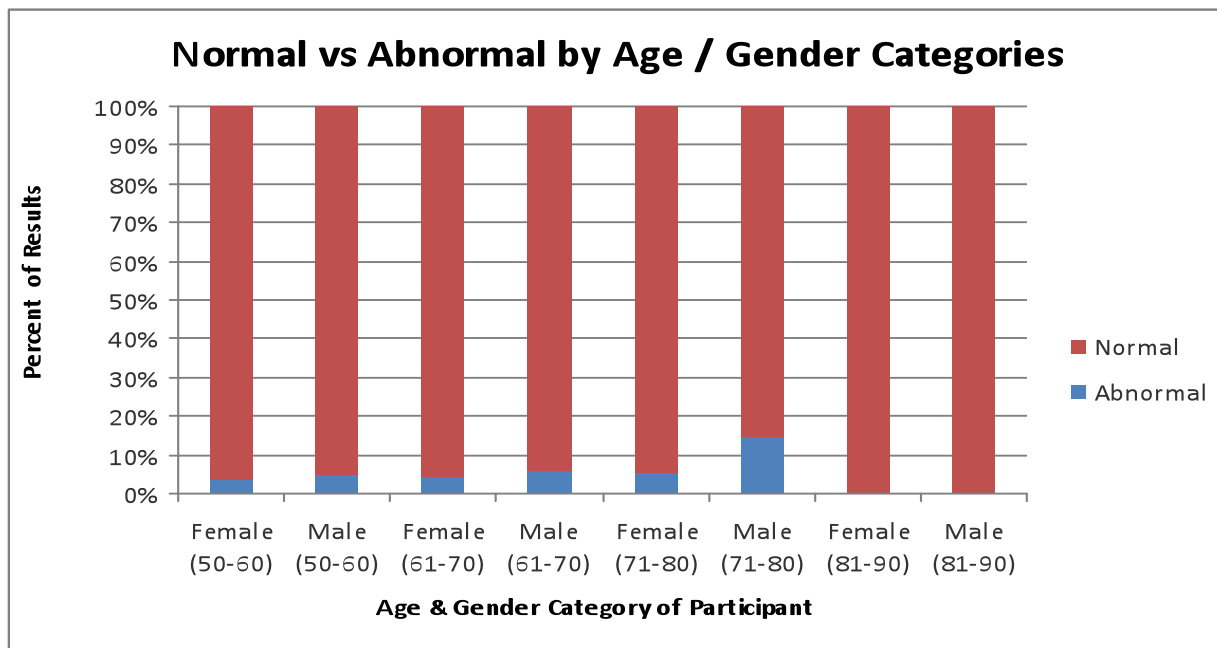
**Outcomes By Age:**

Age	Normal Results	Abnormal Results	Total Results	Male Abnormals	Female Abnormals
>80	9	0	9	0	0
70-79	67	4	71	2	2
60-69	685	36	721	22	14
50-59	959	42	1001	23	19
<b>Totals:</b>	<b>1717 (95.3%)</b>	<b>85 (4.7%)</b>	<b>1802</b>	<b>50</b>	<b>35</b>

**Outcomes By State:**

State	Normal Results	Abnormal Results	Total Results	Male Abnormals	Female Abnormals
WI	793	32	825	18 (2.2%)	14 (1.7%)
MO	689	34	723	19 (2.6%)	15 (2.1%)
IL	105	12	117	10 (8.5%)	2 (1.7 %)
KS	75	6	81	2 (2.5%)	4 (4.9%)
FL	8	0	8	0	0
CA	7	0	7	0	0
TX	7	0	7	0	0
CO	3	0	3	0	0
<b>Totals:</b>	<b>1687 (95.3%)</b>	<b>84 (4.7%)</b>	<b>1771</b>	<b>49 (2.8%)</b>	<b>35 (2.0%)</b>

Table 3



## Summary:

This MCO-Laboratory-Medivo program was highly successful in screening a large population for colon cancer. Nearly 5,000 MCO beneficiaries directly requested a home FOB kit, and over 1 in 3 returned the kit with valid samples for analysis. An overall rate of 4.71% of abnormal results were observed, and these individuals were provided communication to follow-up with their local physicians for further testing, including colonoscopy.

In reviewing the data, several interesting trends emerged. Males were more frequently abnormal than females (5.62% vs 3.83% respectively). In general higher age categories were associated with higher rates of abnormal results. Wisconsin and Missouri had lower abnormal rates than Illinois and Kansas (3.8%/4.7% vs 10.2%/7.4% respectively).

## Lessons for Future Screening Programs:

- The model of using virtual lab ordering/resulting with home testing kits was a very convenient one for the individuals who responded. They were able to get screened for colon cancer with physician oversight and outreach on their results without going to multiple doctor's appointments to get the screening completed and results released.
- Designing recruitment strategies using validated incentive systems may increase the response rates. While over 55,000 letters were sent out to a targeted group of beneficiaries, and a relatively robust 8.65% of the recipients requested the kits (better than typical direct mail campaign results by a factor of ~3), it seems that increasing this rate would be the most effective means of dramatically increasing the penetration rate of the screening effort.
- It would also be helpful to understand the targeting algorithm itself and why certain states had so many beneficiaries and others so few, because the demographics and/or job descriptions and/or other descriptive characteristics of these individuals could be correlated against the outcomes that were observed. Specifically the relative rates of abnormal results across the age ranges, genders, and states of residence will have different implications based on the algorithm of who was targeted, and for what reasons.