

Engaging Patients and their Stakeholders to Improve Oral Oncolytic Adherence.



“Patient and Stakeholders”



ABSTRACT

With rates of patient adherence to oral oncolytic therapy dipping as low as 20% in some studies,ⁱ care providers, patients and family members, and other patient stakeholders (such as health insurance payers and pharmacists) need to more closely work together to ensure the patient receives the full benefit of their prescribed treatment.

“Stakeholders” are those other people and organizations with reason to see the patient healthy and happy. Friends and family of the patient obviously want to see the patient productive and enjoying life as does the care provider whose mission is to support the health and well-being of their community. Other organizations have a similar interest in patients as well. Healthcare insurers face lower cost and reduced risk with patients properly taking their medications, and pharmaceutical manufacturers improve production forecast and lower cost when patients complete timely refills and don’t stop taking their meds early.

Anticancer medications account for the lion’s share of total global drug spending. Oral medications are reported to account for up to 35 percent of the current oncology pipeline.ⁱⁱ They are one of the fastest-growing areas of cancer treatment, comprising more than 25 percent of anti-cancer therapies.ⁱⁱⁱ

An estimated 15.5 million Americans are living with cancer, and 1.69 million Americans were expected to be diagnosed with some form of cancer over the past year. The historical mainstay of pharmacologic treatment has been ambulatory, infusion-based chemotherapy; typically involving many hours of stressful treatment such as intravenous chemotherapy sessions that are time consuming, costly, and emotionally draining. Significant investment by pharmacy research and development corporations and accelerated approvals by the Food and Drug Administration (FDA) have generated a new wave of major advancements in oral anticancer therapies in the U.S., and given patients an alternative to the traditional infusion-based treatment with medications that can be administered in the privacy and comfort of their home and perhaps continuing even to work throughout their treatment.

However, there are also significant downsides: self-administration of powerful toxic therapies in an unsupervised home setting can lead to sub-optimal drug adherence and poor management of side effects, and potential adverse reactions and unintended drug interactions. The self-administration of oral oncolytic requires patients to be “organized” and “disciplined” to properly take their meds, over both the short term and long term, without oversight and to promptly report side effects. And to seek consultation when they encounter impediments to taking their meds, as the potential wastage due to premature drug discontinuations is significant.

The use of oral oncolytic by cancer patients continues to grow, despite challenges of cost and self-administration. Healthcare professionals should anticipate operational system changes and needed strategies and procedures (e.g., communications, task flow, relationship building and team coordination) to



effectuate improved adherence, planned therapeutic outcomes, and high-value care. Increased oncology services with increased utilization of specially trained oncology pharmacists, nurses, nurse practitioners and physician assistants can help optimize cancer care and help address projected workforce needs in cancer management.

A 2016 survey by the Association of Community Cancer Centers showed that less than half of the cancer centers reported to have a formal oncolytic program or protocol established within their cancer program.

NotifiUs offers a solution to discuss how care providers, patients, and other patient “stakeholders” can coordinate through a program called the “Quality Improvement for Oral Oncolytic Adherence (QIOOA)” to leverage current clinical practices with ubiquitous and low cost mobile communications, data analytics and rewards, to measure real-time patient progress toward fulfilling their prescribed medication requirements.

Patient, Stakeholder and Standards

Despite the importance of medication, particularly for life threatening critical illnesses, research from the Quality Oncology Practice Initiative (QOPI®) found that 48% of certain oral oncolytic patients discontinue their medication within 12 months without consulting their physician.^{iv}

In addition to the challenge patients face with self-managing their adherence requirements, low adherence rates are also due to the complexity of the medication prescription^v and administration, demographics such as age and socio-economics, comorbidities and lack of follow up education and side effect identification^{vi} as well as the cost of the medication. It is well documented that non-adherence leads to disease progression, reduced functional abilities, a lower quality of life, wasted medication, and increased use of medical resources such as urgent care visits, hospital admissions and nursing home stays.^{vii}

Broadly we categorize the barriers to proper adherence to these four categories:

- (1) The patient's comprehension of the prescription requirements.
- (2) Impact from the cost and/or access to the medication.
- (3) Patient and patient stakeholder confidence in the care plan.
- (4) Patient understanding and "belief" in the efficacy – both benefit and risk-of the medication.

Many of these reasons overlap and of course within each category are contributing elements; like the complexity of one prescription over another and the total number of medications taken by the patient greatly impacts the patients understanding of the prescription requirements. And lack of educational material, training or feedback may make side effects difficult to recognize and eventually contribute to the patient's lack of confidence in both the care plan and the care provider.

Oral oncolytic is a particularly challenging medication as it is precise in its usage, meaning that the "time-to-take" is very narrow, and missing a dose or not taking a dose at the proper time can have dramatic impact to the patient's well-being and easily lead to further confusion.^{viii}

Both the Oregon Health and Science University (OH&SU) and the Hematology/Oncology Pharmacy Association conclude that quality improvement standards are key to achieving and sustaining the improved care of cancer patients with oral oncolytic.^{ix} Their research further recommends that the quality improvement standard include the patients' stakeholders (the patients' pharmacist, for example) as part of the on-going support team, and continuous education to address issues of recognizing and dealing with toxicity and reminders for when to take medications.^{xi}

The American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative (QOPI®) concludes that improving the care of cancer patients treated with oral oncolytic is best achieved with the use of objective measurements for patient satisfaction, and that these objective measures allow comparison between different procedures and policies.^{xii}

In summary, achievement goals measured within a framework of processes and procedures (standards) can provide continuous support to a patient to meet



their medication adherence requirements. In particular when the “standard” enables patient stakeholders to provide support through feedback, encouragement, and education to help resolve issues like cost or recognition of side effects.

And most importantly, such a standard must provide a process for patient and stakeholders to identify when changes to the care plan are needed, and a process to incorporate those changes to put the patient back on the proper care plan path. How this is accomplished will be explained in the next section of this paper.

QUALITY IMPROVEMENT FOR ORAL ONCOLOGY (QIOO)

Our proposed patient-provider engagement process is called the Quality Improvement for Oral Oncology Adherence (QIOOA), and it is designed to motivate, educate and measure each patient’s success toward self-managing their medication compliance requirements. It is completed within a communication structure that engages the patient and the patient stakeholders. In addition to tracking and reporting patient behavior the standards calculates rewards to the patient for meeting QIOOA objectives.

At the core of this recommendation is an initial patient-provider interview to determine specific level of patient attention for each of the four Achievement Goal categories specified below.

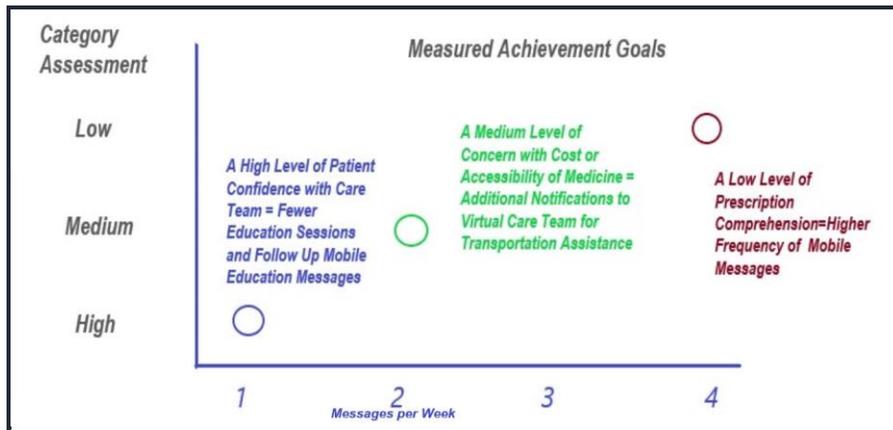
The Initial Patient-Provider Session Determines the Patients:

1. Comprehension of Prescription Requirements
2. Concerns with Cost or Access to Medication
3. Confidence in Care Plan
4. Understanding of Medicine Benefits and Risks

The patient completes a medication usage questionnaire to determine if they have a “high”, “medium” or “low” score within each achievement category. For example, a patient may receive a low score for comprehension of their prescription requirements due to their answer to a question such as, “do you always remember to take your medication at the proper time of day?”

The patient's answers are then used to equate the type, content and frequency of mobile communications administered between patient, provider and the patients virtual care team (stakeholders).

This is represented below in the purple text. The patient has a low level of comprehension of his/her prescription requirements so the number of reminder messages, text survey messages and involvement from the patients virtual care team is high.



In this example each of the text reminder messages, and text query messages is reported and analyzed as an achievement category objective. For example to make sure the patient continues to take their medications at the prescribed time of day, they will receive mobile reminder messages and/or query messages to confirm that they completed taking their meds as scheduled. The patient's stakeholders (acting as a virtual care team) will view copies of the reminders and the patient's response to the queries. And if the patient does not respond to the query, or responds with a "no" accomplishment, an immediate sequence of additional messages and phone calls from stakeholders will take place.

The stakeholders will determine the issues for not completing adherence and can provide feedback on care plan correction. For example, if the patient tires of text messages but continues to take their meds, then text messages can be reduced. Or if phone calls have a greater impact then text messages, that transition can be completed.

Over the longer term the patient's range of response to different care plan constructs can be studied for improvement or used by other patients with similar conditions.



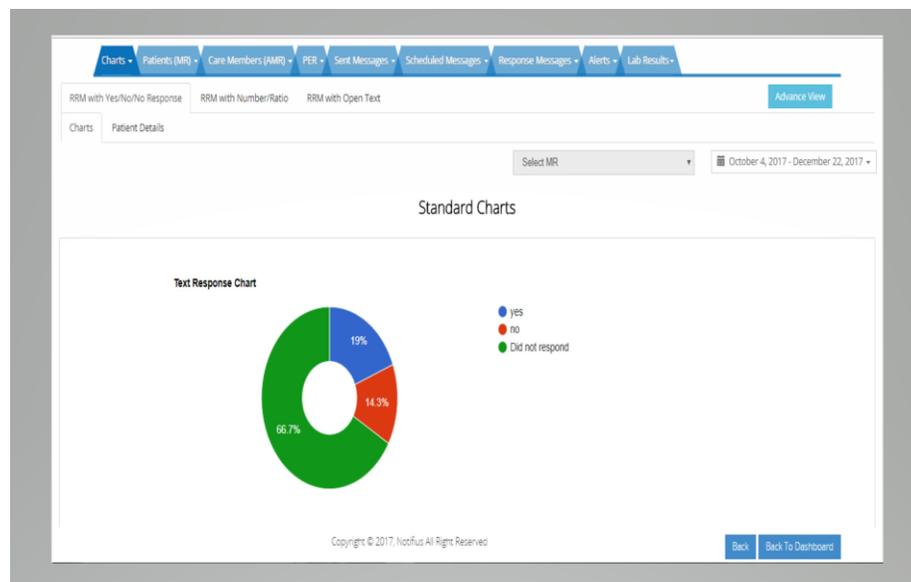
Once scheduled the communications program between patient, provider and virtual care team member's takes place in real time through a HIPAA compliant mobile communications service that collects patient data through a novel text message.



NotifiUs Mobile Communication Messages- Remind and Collect Patient Data

The NotifiUs Patient Engagement Software Platform securely collects (HIPAA secure) all the patient data and generates on-going reports, analysis, Notifications and Alerts to assist the patient provider to help maintain the patients' adherence objectives.

A range of reports and analysis are available to determine the patient's progress with their custom medication adherence care plan objectives. And if they are meeting their objectives and overall goals.



NotifiUs Patient Engagement Platform-Dashboard
Secure Message Service

Logged in as: Terry

Charts Patients (MR) Care Members (MR) PER Sent Messages Scheduled Messages Response Messages Alerts Lab Results

Total Number of Sent Messages for No Response: 8

#	Message Title	Content	Patient (MR)	Date	System Response	Message Type
1	test for 8 16 2017 2	no	Terry Wolters	Aug. 16 2017 7:48 PM	too bad, Pull Down Text: too expensive	Reply
2	RIM for Charles	no	Charles Winston	Aug. 21 2017 7:41 PM	what is up?, Pull Down Text: i am in class	Reply
3	test message	no	Terry Wolters	Aug. 29 2017 10:17 PM	we will call you to find out why, Pull Down Text: too expensive	Reply
4	test message	no	Terry Wolters	Sep. 05 2017 10:19 PM	we will call you to find out why, You Selected: too expensive	Reply
5	Test for Waltman	no	Terry Waltman	Oct. 15 2017 7:01 PM	Mary is calling you.	Reply
6	Hello Terry, did you take your meds today?	no	Terry Waltman	Oct. 23 2017 12:13 PM	Ok, sorry to hear. May is calling you. ,You Selected: forgot	Reply
7	test for demo	no	Janet Su	Oct. 31 2017 10:46 AM	sorry to hear, You Selected: i didnt feel well	Reply
8	Hydration	no	Janet Su	Nov. 05 2017 9:15 PM	we need to find out why, You Selected: 5 oz	Reply

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Tracking and Reporting Achievement Objectives and Goals toward Medication Adherence

A very important part of the program is the assistance or support quickly rendered to the patient from one of their care team members under certain conditions. For example, patient “Bob” may have reported that he did not take his medication because he forgot his refill. Or he does not respond to the text query about completing his refill pickup. His wife receives the Alert Message (in either case) and calls Bob to let him know that she will go by the pharmacy to pick-up his medication.

Again, all patient communications are recorded in the HIPAA secure NotifiUs Patient Engagement Platform from which integrated analytics and embedded algorithms track and respond to the patient data according to custom workflow configurations unique to each patient. For example, if Bob continues to respond with “Too Tired” or continues to cite “Forgets” as his reasons for noncompliance then changes to his current care plan need to be made to address these issues. More reminder messages, or perhaps a change to a different medicine to reduce his tiredness may be needed.

Along with the NotifiUs engagement platform are other services for Financial Advisory support, Train the Educators, and Pharmacy Program integration. The platform can support population health and management with compilation and reports for many patients across the community through approved and anonymized information.



NotifiUs Patient Engagement Platform-Dashboard
Secure Message Service

Logged in as: Terry

Charts Patients (MR) Care Members (AMR) PER Sent Messages Scheduled Messages Response Messages Alerts Lab Results

Total Number of Sent Messages for No Response: 8

#	Message Title	Content	Patient (MR)	Date	System Response	Message Type
1		no		Aug, 16 2017 7:48 PM	too bad, Pull Down Text: too expensive	Reply
2		no		Aug, 21 2017 7:41 PM	what is up/, Pull Down Text: I am in class	Reply
3		no		Aug, 29 2017 10:17 PM	we will call you to find out why, Pull Down Text: too expensive	Reply
4		no		Sep, 05 2017 10:19 PM	we will call you to find out why, You Selected: too expensive	Reply
5		no		Oct, 15 2017 7:01 PM	Mary is calling you.	Reply
6		no		Oct, 23 2017 12:13 PM	Ok, sorry to hear. May is calling you. , You Selected: forgot	Reply
7		no		Oct, 31 2017 10:46 AM	sorry to hear, You Selected: i didnt feel well	Reply
8		no		Nov, 05 2017 9:15 PM	we need to find out why, You Selected: 5 oz	Reply

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Example of NotifiUs Report for Population Health Adherence Data

The Quality Improvement for Oral Oncolytic Adherence (QIOOA) standard is formalize’s much of the healthcare industry recommendation to standardize support to help patients improve their medication adherence and leverage low cost, secure and ubiquitous message communications. And to extend additional support to cancer patients in the form of financial aid, and care professional training.

Additionally, each patient’s adherence strategy will encompass the full calendar term of the patient’s therapy, and exam potential patient concerns over medication cost, and continued confidence in the plan and medication on a continuous basis.

REWARDING PATIENTS FOR SUCCESSFUL BEHAVIOR

Integrated with the NotifiUs Patient Engagement Platform is a rewards program that is uniquely calibrated for each patient. Based on the patient’s success with achieving their objective and/or goals (or a percent) the patient can receive recognition in the form of a gift card or acknowledgement from the care team.

The NotifiUs Patient Engagement Platform formalizes current clinical operations with minimal disruption to the provider’s current resources. The collected patient data provides unique, real-time insight into the patient’s medication adherence behavior for all stakeholders: friends and family, pharma, insurer’s and care providers.



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