1. Title Page

Title: Use of Patient Buddy Application to Disseminate Knowledge & Prevent Readmission

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Inclusive dates: 4/1/2015-3/31/2017

AHRQ has been acknowledged in all outputs as the sole supporter of this project.

Grant number: 1 R21 HS024004-01

2. Structured Abstract

<u>Purpose</u>: Readmissions are a major burden in cirrhosis. A proportion of readmissions in cirrhosis, especially due to hepatic encephalopathy (HE) could be avoided through patient and caregiver engagement.

<u>Scope</u>: To define the feasibility of using the Patient Buddy App and its impact on 30-day readmissions by engaging and educating cirrhotic inpatients and caregivers in a pilot study. <u>Methods</u>: Cirrhotic inpatients with caregivers were enrolled and followed for 30 days post-discharge. On separately assigned devices loaded with Patient-Buddy, they were trained on entering medication adherence, daily sodium intake and weights, and weekly cognitive (EncephalApp_Stroop) and fall-risk assessment and were educated regarding cirrhosis-related symptoms. These were monitored daily through a Patient-Buddy loaded iPad by the clinical team. The App sent automatic alerts between patient/caregivers and clinical team regarding adherence and critical values. At 30 days, total, and HE-related admissions were analyzed as well as the feasibility and feedback regarding educational values.

<u>Results</u>: 40 patients and 40 caregivers were enrolled. Seventeen patients were readmitted within 30-days but none for HE. Eight potential HE-related readmissions were prevented through App-generated alerts that encouraged early outpatient interventions. Caregivers and patients were concordant in data entry but six did not complete data entries. Most respondents rated the App favorably for its educational value. In this proof-of-concept trial, the use of Patient-Buddy is feasible in recently discharged patients with cirrhosis and their caregivers. Eight HE-related readmissions were potentially avoided after the use of the App through dissemination of timely information.

Key Words: Cirrhosis, Readmissions, App, Hepatic Encephalopathy, Education, Dissemination

3. Purpose (Objectives of the study)

Specific aim 1: <u>To perform a pilot and feasibility study of disseminating current knowledge of</u> <u>readmission prevention in cirrhosis by using the Patient Buddy App with patient and caregiver</u> <u>interfaces.</u>

As part of this specific aim, 40 patient/caregiver dyads (total 80 subjects) of decompensated cirrhotics will be identified and enrolled at the day of discharge and followed for 30 days. They will be given iPhones loaded with the Patient Buddy app with caregiver and patient interfaces. They will be instructed extensively regarding the use of the App, which is preloaded with variables that associated with readmissions such as medications and adherence, issues with cognition and orientation and new symptoms. The patient and the caregiver will have separate devices linked to a device with the nurse manager through which daily communication will occur between patient/caregivers and the study team regarding previously identified risk factors associated with readmission. With this enhanced communication and educational value of the App, the study team will have greater access to events at patients' homes and the potential to prevent readmissions by intervening at that stage. The team will also engage the end-users (patients, caregivers and the nurse manager) by inquiring about their input in order to enhance the interface, user-friendliness and impact of the App. A detailed analysis of 30-day readmissions, including potential preventability with Patient Buddy will be performed. CITI will be responsible for establishing and monitoring the communication channels and implementation of the interfaces.

Specific aim 2: <u>To incorporate the opinion of key stakeholders (patients, caregivers and nurse</u> <u>managers) towards improving the Patient Buddy App in the prevention of readmission in</u> <u>cirrhosis</u>

The input of patients, caregivers and nurse manager and analysis of potential preventability of readmissions in specific aim 1 will be used to enhance the Patient Buddy App in collaboration with CITI. The updated App will then be available for future studies in larger populations of cirrhotic patients.

4. Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

1. Significance of the problem of cirrhosis and hospitalization

Cirrhosis affects more than 5 million patients in the United States. The natural history of cirrhosis involves a compensated and a decompensated phase. Decompensated patients develop complications of cirrhosis such as hepatic encephalopathy (HE), ascites, variceal bleeding, infections and spontaneous bacterial peritonitis (SBP). These complications led to more than 1.5 million hospitalizations and cost nearly \$4 billion yearly.

2. Readmissions in cirrhotic patients are an unresolved burden

Despite readmissions within 30 days being a quality improvement issue, there have been several federally-funded studies that have shown a relentless increase in this rate. The 30-day readmission rate for cirrhotic patients is as high as 37% in prior NIH-sponsored studies from multiple centers in North America. This was associated with a significantly higher 90-day mortality compared to subjects free of 30-day readmission.

Therefore readmissions are an unresolved burden on the patients and the medical system. **3. Factors associated with readmission can potentially be modified**

Studies from our group and several other groups have demonstrated that specific cirrhotic subgroups are particularly vulnerable to readmission. A large proportion of these factors are modifiable with poly-pharmacy, lack of understanding of medication use and their

adverse events being primary issues. Patients are often re-admitted for HE, falls, infections and ascites-related issues. *However despite the knowledge, there is poor dissemination of these findings into practice in order to prevent readmissions.*

4. Caregiver engagement in the prevention of readmission is poorly studied in cirrhosis Since most studies have concentrated on the individual patients' understanding of their disease process and their medications, the role of the caregiver/companion during this process has not been well studied. The involvement of the caregiver is a critical piece of the puzzle because patients with decompensated cirrhosis have cognitive dysfunction due to minimal or overt HE that can impair judgment and memory and are often unable to perform instrumental activities of daily living. This can impact their daily function, development of future complications and socioeconomic status from an individual, family and societal basis. Therefore, caregivers are essential to the understanding of the disease complications, prevention of medicationassociated issues and to alerting relevant clinicians earlier to manage problems as an outpatient, which if neglected could lead to readmission. Studies have shown that caregivers of cirrhotic patients are deeply affected by this disease from a psychosocial and financial perspective but they are often not involved while the disease severity, progression and complications are being explained to the patients.

The absence of caregiver involvement in the previous studies of readmission prevention is a major gap in our knowledge which requires investigation.

5. Current methods of preventing readmissions are inadequate and are reactive instead of pro-active

The current standard of care in cirrhosis currently is to schedule appointment follow-up and occasional telephone calls to the patients directly. There is little systematic investment into engaging the patient/caregiver dyad proactively and disseminating knowledge. The system thus is only geared towards evaluating patients when the problem requires emergent or urgent visits. *Therefore current knowledge that could prevent these readmissions is inadequately disseminated to the affected parties with the current standard of care.*

6. Mobile health applications are required to engage patients and caregivers with clinicians

The rapid dissemination of multiple studies that clearly define preventable reasons for readmissions in cirrhosis requires direct modes of communication between clinicians and the patient/caregiver dyads. Mobile health apps, which can communicate problems that can be handled before they need an emergent visit to the hospital are therefore a potential method to prevent these readmissions.

<u>5. Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)</u>

Patient Buddy is an App that provides HIPAA-compliant secure patient communications, adherence monitoring and real-time data analysis created through the Affordable Care Act. Its secure smartphone technology allows patients/caregivers to stay in close contact with the clinical team sustaining a "feedback loop" (Figure 1A). The Patient Buddy was customized for cirrhosis and focused on (a) medication and sodium intake adherence, (b) weight and (c) orientation and cognition (Table 1). The App automatically generates alerts for missed critical medications, missed measurements, significant changes to weight, or orientation/cognition scores, and for contacts with on-call physicians or emergency services.

Table 1: Area of interest	Specific entry in	To contact study team, physician on		
	Patient Buddy	call or emergency services(marked*)		
Medication adherence on	Enter each medicine entry	Questions regarding medications,		
each medicine on	time, date and dose	missing or increasing dose		
discharge				
New medications and	Enter new medicine and	Call when a new medicine/		
supplements	dose	supplement is initiated		
Dietary adherence	Enter grams of sodium eaten	Questions about diet		
Vitals (to be taken at	Daily weight	≥3 lb increase in 24 hours		
same time every day)	Daily Temperature	> 100.4 F or < 96.8 F		
Cognition (assessed	Orientation questions (5	Any question abnormal, coma*,		
every week or when	questions time/place/person)	confusion, or difficulty waking patient up*		
caregiver feels patient is	EncephalApp Score	>25 seconds over discharge score(17)		
not acting normally)	Daily bowel movements	<3 or >6 bowel movements day (if on		
		lactulose) and any change in those		
		without lactulose		
Timed up and go test	Time for get up and go test	Difficulty getting out of the chair/bed,		
(done every week with		Test time increased by >10 seconds(10),		
cognitive tests)		fall*		
Emergency/urgent/other	GI bleeding (detailed	Black stools, red blood in stools or		
symptoms	symptoms noted)	vomiting blood*		
	Infections (detailed	Fever, shortness of breath, burning in		
	symptoms noted)	urine, abdominal pain, nausea or		
		vomiting		

Data security: Patient Buddy is HIPAA (Health Insurance Portability and Accountability Act) compliant with federal regulations regarding HIPAA Privacy and Security. Given the sensitivity and need for security in managing and handling protected health information (PHI), no data is stored on either the clinical team's tablet or the patient/caregiver smartphone devices. Only after verification and authentication of login credentials is established with the server, is any data pushed out to the appropriate devices. All data is transmitted to the HIPAA-compliant server where it is controlled behind the network firewall. The data center provides several key security features that contribute to the safeguarding of PHI. These data safety and security features include physical security of the data center and infrastructure; perimeter security of IP reputation; network security for intrusion detection, firewall and vulnerability; server security for OS, anti-virus and log management; along with procedures and protocols for data backups. security audits, access control, change controls, and the maintenance of policies and procedures. From an application and program management standpoint, Patient Buddy offers further security safeguards to protect PHI to include secure data deletion upon termination of services; administrative security that provides for secure access and two-factor authentication; program access control; security policies and procedures, incidence response protocols, and risk assessments monitored and updated by CITI privacy and security officer, as well as data management and application management processes. With these security protocols in place, the VCU-CITI team met the intent of the HIPAA Security Rule as it relates to electronic protected health information (e-PHI) in ensuring the confidentiality, integrity, and availability of all e-PHI; identifying and protecting against reasonably anticipated threats; protecting against reasonably anticipated, impermissible uses or disclosures; and ensuring compliance by our workforce.

<u>Trial design</u>: We conducted a 30-day proof-of-concept trial of Patient Buddy, which included three visits and two phone calls (Figure 1B; www.clinicaltrials.gov number NCT02534805 and approved by the Virginia Commonwealth University IRB). We enrolled non-electively hospitalized cirrhotic patients and their caregivers who were both > 21 years. Cirrhosis was determined from biopsy, clinical decompensation, and/or radiological/Fibroscan evidence. Patients were excluded if they had active alcohol/substance abuse in the past month, lacked a willing adult caregiver, if patients were discharged to hospice/skilled nursing facilities, were unable to consent for themselves or were on hemodialysis.

Study design: All eligible and consented patient/caregiver dyads were consented and given an individual iPhone loaded with Patient Buddy. For the purpose of this study, a dyad was defined as a pair of patient and caregivers who were handed out the individual phones to input their information. The caregivers were trained to administer EncephalApp Stroop test(9), ask simple orientation questions, and to administer the Timed Up and Go (TUG) test(10). The EncephalApp was administered to measure cognitive processing and executive function for HE. Orientation was tested using with five questions asking the location/date/month/day/identification of caregiver, who judged the accuracy; if any question was incorrect, the caregiver would contact the clinical team. The TUG was done to determine the fall risk in a patient. Further, both patients/caregivers were taught to message the team via the App. They underwent a detailed educational session on prompt identification of GI bleeding, encephalopathy, and infections, including counseling about recognizing symptoms that require emergent attention. Directions for paging the physician-on-call, heading to the Emergency room or calling 911 as needed were also given (Table 1). They were instructed and also given a brochure (supplementary data), which outlined in detail the need to call emergency services or the on-call physician any time in

case they felt their problem was emergent or if they had not received a timely response via the App. Specifically they were counselled regarding emergencies (Table 1 marked with *).

At discharge, the medications (doses and administration times) were entered into the App and were divided into critical from a cirrhosis perspective (lactulose, rifaximin, antibiotics, non-selective beta-blockers, furosemide and spironolactone) versus others that were considered non-critical.

On the day of discharge, the patient had to record their weight, while the caregivers administered the EncephalApp, Orientation questions and TUG test to the patient in front of the medical team to record baseline data and to ensure that the caregiver was proficient in administering these measures. They were given a thermometer and weighing machine for the study and were required to record the patient's weight and medications daily and orientation/EncephalApp weekly taken into their separate devices. Patients were instructed to input medication intake, weight and sodium intake daily into the App.

If there were missed entries or alarm values per table 1, these generated alerts to the team via the App. Over the course of the study, alerts were monitored by the team using a central iPad with Patient Buddy to provide care as needed. If there were critical values or missing entries of critical medications, daily weights or sodium intake over 24 hours, automatic alerts were generated for the research team and to the patients and caregivers (Table 1). This alerted the teams and also the patients/caregivers to enter data and served as a reminder to clarify whether they missed the medications or simply did not enter their intake. All alerts were checked at least three times a day by the monitoring team and were followed upon via a text message through the App or via a phone call to the patients/caregivers. Specifically changes in EncephalApp values or orientation test questions were handled as impending HE episodes unless proven otherwise. The clinical team liaised with the outpatient clinics and the patients/caregivers to arrange for expedited outpatient follow-up if needed. Once a week, typically at Day 7 and 21 (+/- 2 days), the caregiver administered the EncephalApp, orientation questions, and TUG. These data were input into the App and generated alerts as necessary. At the day 15 and 30 visit, the patients did these tests/measurements with the study team.

At the end of the study, patients and caregivers completed a Likert scale questionnaire about the App and their feedback related to the ease of use and communication, connectivity and privacy, layout changes, suggested improvements and educational value along with an overall evaluation from 0-10 on a Likert scale. If they withdrew, the evaluations were sought within one week of withdrawal or at the time of readmission if they were readmitted.

Readmissions within 30 days were recorded via the App, with a thorough review of the record and discussion with the patients and caregivers. Examples of data entry and monitoring are shown in the supplementary information. All authors had access to the study data.

<u>Statistical analysis</u>: Total 30-day readmissions, HE-related readmissions and dropouts were measured. Analysis of feasibility and patient/caregiver/clinical team opinion regarding the App was also analyzed. A logistic regression using readmissions as dependent variables was performed. Variables from the following that had p value <0.10 were entered into the multi-variable model. The variables considered for univariate analysis were age, gender, alcoholic etiology, HE prior to admission, admission MELD (model for end-stage liver disease) score, length of stay, discharge MELD, discharge sodium, discharge albumin, discharge HE, discharge rifaximin use, discharge opioid use and discharge Proton pump inhibitor (PPI) use.

6. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Patient cohort:

Forty patients and forty caregivers were included and followed for 30 days post-discharge. The reason for hospitalization was anasarca in 10, HE in 10, GI bleeding in 9, infections in 3, hepatic hydrothorax in 2 and cirrhosis-unrelated conditions in 5 patients (Table 2). Of these, four did not complete App entries (one did not enter anything at all, three stopped entering at days 12, 15 and 21 post-enrollment) while two were unable to achieve adequate connectivity at home. These patients thought the App was too demanding and required too much information. At discharge, all patients were oriented (per the 5 orientation questions), EncephalApp Off+OnTime was 250.30±85.32 seconds (not done in three due to color-blindness) and TUG time was 20.96±11.82 seconds (not done in 12 patients because they were already on assistive walking devices and had counseling regarding falls before). Seventeen patients (42.5%) were readmitted within 30 days. The median duration of App use was 19 (IQR 8-28) days. The primary reason for readmission was infections (n=5), ascites (n=4), hepatic hydrothorax (n=1), upper GI bleeding (n=2), chest pain (n=1). None of the patients were readmitted for HE.

<u>Entry into the App</u>: Patients and caregivers were able to monitor the adherence to all medications, critical medications as well as daily weight (Figures 2 A-C). The patients and caregivers' analyses of these outcomes were similar indicating good agreement. Most patients and caregivers (n=24) were not able to adhere to daily sodium entries consistently because they thought them to be too cumbersome.

<u>Contact between study team, patients and caregivers</u>: There were a total of 899 alerts generated for missed critical medicines, 734 for missed sodium intake and 24 for rapid increase in weight from the App in response to patient/caregiver entries. There were 114 alerts initiated by the patients/caregivers via the App requesting medical input. These resulted in several phone calls between the patients, caregivers and the study team for technical, medical and other reasons; the contact was highest in those who were ultimately readmitted (Table 3). There was an average of 2±3 days of greater contact before the patients were ultimately readmitted compared to the rest.

Table 2 mean±SD unless indicated otherwise	Patient Group (n=40)				
Age	58±10				
Gender (men/women)	24/16				
MELD score on admission	19.5±5.2				
Etiology of cirrhosis (HCV /Alcohol/	9/7/5/13/7				
HCV+Alcohol/NASH/Others)					
History of hepatic encephalopathy (%)	29 (73%)				
History of ascites (%)	36 (90%)				
History of variceal bleed (%)	7 (18%)				
Length of stay index hospitalization (mean±SD)	6.5±3.5 Days				
Discharge Medications					
Lactulose alone n (%)	8 (20%)				
Lactulose+Rifaximin n (%)	21 (53%)				
Proton Pump Inhibitor use n (%)	25 (62%)				
Opioids n (%)	13 (33%)				
Discharge MELD score	18.6±8.5				
Discharge Sodium (meq/L)	134.9±4.5				
Discharge Albumin (g/dL)	2.9±0.64				

Table 3	Entire Group (day)		Those wi	Those without re-admissions(day)			Those with re-admissions (day)					
median	7	15	21	30	7	15	21	30	7	15	21	30
(IQR)												
Total	2	1	0	0.5	2.0	1	0	0.5	2.0	3	0.5	-
	(0-3.5)	(0-3.0)	(0-1.5)	(0-2)	(0.75-	(0-2)	(0-2)	(0-2)	(1-3.0)*	(0-4.25)*	(0-1.0)	
					3.25)							
Technical	0	0	0	0	1	0	0	0	0	0	0	-
issues	(0-1.5)	(0-1)	(0-0)	(0-0)	(0-2)	(0-1)	(0-0.5)	(0-0)	(0-1)	(0-0.5)	(0-0)	
Health-	0	0	0	0	0	0	0	0	1	2	0 (0-0)	-
care	(0-1)	(0-1)	(0-0)	(0-0)	(0-0.5)	(0-0)	(0-0)	(0-0)	(0-2)*	(0-3.5)*		
Reminder	0	1	0	0	0	1	0	0	1	1	0 (0-0)	-
	(0-1)	(0-2)	(0-1)	(0-1)	(0-2)	(0-1.25)	(0-1)	(0-1)	(0-1)	(0-2)		

The average TUG times got better in those without readmissions (day 7 21.1±11.1, day 15, 20.9±20.0, day 21 16.3±10.9 and day 30 15.1±5.9 seconds) but were similar in the readmitted group (day 7 23.6±15.7 day 15 20.0±10.6 and in two patients at day 15 50.0±0.0 seconds). The EncephalApp OffTime+OnTime values increased (worsened) from day 7 to day 15 in those who were readmitted but plateaued afterwards (day 7 242.9±74.8, day 15 296.4±179.2, day 21 223.6± 60.2 seconds) while these improved in those who remained without readmission (day 7 234.8±100.5, day 15 182.8±89.9, day 21 198.8±69.4 seconds). In eight patients alerts and subsequent calls were related to alteration in mental status after regular office hours. These were initiated by the caregiver who noted changes in the orientation exams (median 1 question was wrong) or a difficulty for the patient understanding the EncephalApp instructions. All these eight patients had prior HE with a median of 2 IQR (4) admissions. The last episode of HE was at least three months prior to the index admission and all had been prescribed on lactulose and rifaximin before this admission. Of the eight patients, the daily bowel movements in five patients showed constipation (range 0-2 bowel movements per day), while it was as prescribed in the remaining three (2-4 bowel movements/day). Due to attention from the clinical team, five patients were managed satisfactorily through App-related communications alone after adjusting the medication dosages and increasing the lactulose temporarily. The remaining three were seen in clinic within 24 hours to manage the HE using investigations without readmissions. Of the 17 readmissions, 12 contacted us via the App and 3 informed us via the App that they had directly contacted the physician-on-call or had gone to the ER. The remaining two patients/caregivers did not call us or alert us via the App. The readmissions for the last two patients were discovered when the alerts were not answered and the team directly contacted them. On subsequent questioning, they felt they needed attention sooner than awaiting the App response and actually were not able to inform us in time before we determined that they were hospitalized.

Of the 12 who contacted us via the App and who had not directly sought attention, outpatient management was tried for four for ascites/hepatic hydrothorax, and one patient with anemia

was arranged to have outpatient blood transfusions. These delayed the admission by 3±1 days but ultimately all were readmitted. The remaining seven patients were directly advised early clinic or ER visits, which resulted in readmissions.

On multi-variable analysis, predictors of all readmissions were discharge MELD score (OR 2.3, p=0.03) and discharge sodium (OR: -1.8, p=0.05).

<u>Evaluation of the App</u>: Most patients and caregivers had a favorable overall reaction to the App. The initial cohort of three patients/caregivers had problems connecting, which was corrected in subsequent builds. Most dyads (n= 35) gave it a score \geq 7 of 10 with a median score of 9.1 (IQR 8.3-10.0). Those who did not give it a favorable evaluation were the ones who stopped entering the data and withdrew. Their reasons were mainly technical because they found the App too demanding and thought it interfered with their daily activities. Most respondents thought positively about the App and appreciated its educational value (Table 4).

Table 4 Question (Likert scale values)	Caregiver	Patient
Is the application easy to use? Specifically the	10.0 (8.0-10.0)	10.0 (7.25-10.0)
graphics and process to record data.		
Were you able to communicate information	10.0 (8.0-10.0)	10.0 (7.5-10.0)
Did you experience any connectivity issues?	10.0 (7.5-10.0)	10.0 (8.25-10.0)
Did you experience any connectivity issues:	10.0 (7.3-10.0)	10.0 (0.25-10.0)
Do you or did you have any privacy concerns?	10.0 (10.0-10.0)	10.0 (10.0-10.0)
Are there areas that you think were important	10.0 (7.25-10.0)	10.0 (9.0-10.0)
that the application did not address sufficiently		
or at all?		
Are you satisfied with the layout as it is	10.0 (9.0-10.0)	10.0 (9.0-10.0)
currently?		
Do you think the application educates you	10.0 (7.25-10.0)	10.0 (7.25-10.0)
about your disease or the disease process of		
your loved one?		

Figure legends:

Fig 1A: Patient and data flow in Patient Buddy

Fig 1B: Design of the Patient Buddy Study

Fig 2: Individual data showing concordance between patients (blue) and caregivers (red). Missing values indicate dropouts.

Fig 2A: Adherence on all medications averaged over the study duration. Each column represents the average adherence on all medications for one individual patient followed by their caregiver's charting of the same in their own device. The charts with lower percentage charting are those who either got readmitted or stopped entering data.

Fig 2B: Daily weight average charted over the study duration. Each column represents the average daily weight for one individual patient followed by their caregiver's charting of the same in their own device. The charts with lower percentage charting are those who either got readmitted or stopped entering data.

Fig 2C: Medicine-wise charting of adherence on critical medicines for patients and caregiver throughout the study.



caregiver from Nurse manager

Figure 1B









percentage



Figure 2C: Total Proportion of Critical Medicines Charted (average per medication is shown for patients and caregivers separately)

7. List of Publications and Products (Bibliography of Outputs) from the study.

Products:

- Ganapathy, D., J. Lachar, C. Acharya, et al. "FRI-024-An Innovative app focused on patients and caregivers significantly decreases avoidable and HE-related readmissions in cirrhotic patients." Journal of Hepatology 2017 March; 66(1): S377-S378. Poster Presentation at International Liver Congress at EASL 2017 Amsterdam.
- Ganapathy, D., J. Lachar, C. Acharya, et al. "An Innovative app focused on patients and caregivers significantly decreases avoidable and HE-related readmissions in cirrhotic patients" Gastroenterology 2017 April; 152 (5) S1: S1048-S1049: Oral presentation at Digestive Disease Week 2017 in Chicago, IL.
- Accepted article in Liver International (accepted 6.7.17 no citation available as of today) *The Patient Buddy App Can Potentially Prevent Hepatic Encephalopathy-Related Readmissions* Dinesh Ganapathy, MD¹, Chathur Acharya, MD¹, Jatinder Lachar, MD¹, Kavish Patidar, MD¹, Richard K Sterling, MD¹, Melanie B White, RN¹, Catherine Ignudo, BS³, Swamy Bommidi, BS³, John DeSoto, BA³, Leroy R Thacker, PhD², Scott Matherly, MD¹, Jawaid Shaw, MD¹, Mohammad S Siddiqui, MD¹, Puneet Puri, MD¹, Arun J Sanyal, MD¹, Velimir Luketic, MD¹, Hannah Lee, MD¹, R Todd Stravitz, MD¹, Jasmohan S Bajaj, MD¹