AN ONLINE TOOLKIT TO IMPROVE PRIMARY CARE PROVIDER IDENTIFICATION OF NON-ALCOHOLIC FATTY LIVER DISEASE

By

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The DNP Project committee for Kelly Casler certifies that this is the approved version of the following DNP Project:

An Online Toolkit to Improve Primary Care Provider Identification of Non-Alcoholic Fatty Liver Disease

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Abstract

Non-alcoholic fatty liver disease (NAFLD) prevalence has reached epidemic proportions and the severe type, non-alcoholic steatohepatitis (NASH) is predicted to become the leading cause of liver transplant over the next two decades. The growing prevalence requires primary care (PC) providers to be adept at recognition and management. However, PC providers experience significant knowledge gaps which can result in delayed access to intervention that could improve outcomes. In response, the online NAFLD toolkit was developed, implemented, and evaluated using the Knowledge to Action framework in an effort to improve knowledge gaps and support evidenced-based practice among PC nurse practitioners (NPs) in a midwestern state. The success of the toolkit was evaluated by administering the NAFLD survey for general practitioners in a pre-post evaluation design. Responses (n=11) were compared for statistical significance using the Wilcoxin signed-rank test for matched pairs and showed improvement in overall knowledge score (p=0.011), perceived comfort scores (p=0.07), and intention to use the non-alcoholic fatty liver disease fibrosis score (NAFLD-FS) for patient monitoring and weight loss for management (p=0.008). The results of this project demonstrate successful implementation of a toolkit to support evidenced-based practice and support expanded use of the toolkit. Continued evaluation on a larger scale is needed.

Keywords: NAFLD-FS, NAFLD, NASH, toolkit, evidenced-based practice

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In 1980, a team from Mayo Clinic described what was at the time a new and previously unknown disease (Ludwig, Viggiano, McGill, & Oh, 1980). This chronic disease, non-alcoholic fatty liver disease (NAFLD), has reached epidemic proportions (Younossi et al., 2016), yet primary care providers (PCP) report knowledge gaps regarding the disease and its management. The purpose of this paper is to describe an evidenced-based practice (EBP) project that used a toolkit to increase PC Nurse Practitioner (NP) awareness and knowledge of NAFLD. This paper will define NAFLD and toolkits, describe the diagnosis and management of NAFLD, and describe the use of toolkits in quality improvement. It will also review the literature surrounding these concepts and knowledge gaps regarding NAFLD. Next, this paper will present the process for implementation and evaluation of the toolkit. Finally, conclusions from the project and implications for future scholarship will be discussed.

Background

NAFLD is a concerning epidemic. Nationally, it affects one third of adults and results in 103 billion dollars in healthcare costs annually. Its prevalence is rapidly increasing while infectious and alcoholic liver disease prevalence remains stable (Ruhl & Everhart, 2015; Younossi et al., 2011). For example, between 1998 and 2012, National Health and Nutrition Examination Survey data showed a 68% increase of NAFLD prevalence (Ruhl & Everhart, 2015). NAFLD is expected to become the leading reason for liver transplantation within the next two decades (Zezos & Renner, 2015). The global impact of NAFLD is similar to that of the United States (Pereira, Salsamendi, & Casillas, 2015)

NAFLD is characterized by excess fat storage, called steatosis, in the liver. There are two categories of NAFLD: NAFL and NASH. NAFL is defined by steatosis that occurs without inflammation whereas NASH is defined by steatosis, inflammation, and sometimes fibrosis

(Dharel & Fuchs, 2014). Fibrosis is graded using a four-point Kleiner scale as defined by liver biopsy results. One indicates mild fibrosis, two moderate fibrosis, and three severe fibrosis. A score of zero indicates no fibrosis; four identifies cirrhosis (Kleiner et al., 2005).

NASH is the more concerning form of NAFLD due to its severity. It occurs in an estimated 20% of patients with NAFLD (Spengler & Loomba, 2015). While the NAFL subset of NAFLD usually follows a benign course, NASH can progress along a continuum of severe liver fibrosis, cirrhosis, and liver failure. Hepatocellular carcinoma (HCC) is also possible. (Chalasani et al., 2017). Patients with NASH progress to severe fibrosis twice as fast as patients with NAFL and it is estimated that up to 20% of patients with NASH can develop cirrhosis and HCC (Nones et al., 2017; Stal, 2015).

NAFLD is considered the liver manifestation of metabolic syndrome. Likewise, rising incidence of two components of metabolic syndrome, obesity and impaired glucose tolerance (specifically, diabetes), are largely responsible for the increasing prevalence of NAFLD (Balesteri, 2014; Chalasani et al., 2017, Charlton et al., 2011; Lazo et al. 2013). Obese patients have the highest prevalence of NAFLD, with rates close to 90% (Chalasani et al., 2017), and are more at risk of NAFLD than their normal weight counterparts ($p=0.005$) (Portillo-Sanchez et al., 2015). Because obesity and diabetes rates continue to climb despite being key targets of Healthy People 2020, NAFLD will continue to be a pressing national health concern (Department of Health and Human Services, 2014; Trust for America's Health & Robert Wood Johnson Foundation, 2016).

Improving care of the patient with NAFLD presents many challenges. One challenge is improving PCPs ability to recognize the disease in its early stages early. Mild or absent symptoms make it challenging to recognize NAFLD and this is compounded by knowledge gaps

and limited training in the disease (Blais et al., 2015; Dharel & Fuchs, 2014; Polanco-Briceno, Glass, Stuntz, & Caze, 2016). Early identification by PCPs is especially important since NASH-induced cirrhosis confers an increased risk of HCC and liver failure and these complications have better prognosis with early identification. Unfortunately, PCPs often overlook patients at this increased risk (Angulo et al. 2007; Stal, 2015). Therefore, as the epidemic of NAFLD continues to grow, PCPs need education to recognize and manage patients with NAFLD (de Silva & Dassanayake, 2009)

The purpose of this evidenced-based project is, therefore, to design and evaluate an online toolkit for PCPs, specifically, PCNPs, to improve knowledge gaps regarding NAFLD. A toolkit is "a collection of related information, resources, or tools that together can guide users to develop a plan or organize efforts to follow evidence-based recommendations or meet evidence-based specific practice standards" (Agency for Healthcare Research and Quality [AHRQ], 2016, para 1). Toolkits can help speed the delivery of research into practice and are provided in two primary formats: written and web/electronic-based (Barac, Stein, Bruce & Barwick, 2016; Davis et al., 2017). Toolkits have been used to address provider knowledge gaps in a wide range of conditions such as autism (Bellando, Fussell, & Lopez, 2016), hypertension (Savarimuthi et al., 2013), and dementia (Graham et al., 2017). In 2016, the AHRQ developed guidance for and a checklist of best practices when designing toolkits.

This project was conducted in cooperation with the Association of Missouri Nurse Practitioners (AMNP). AMNP has over 500 active nurse practitioners (NP) and NP student members. Approximately 75% practice in primary care. AMNP was approached as a partner since the project matches the organization's purposes of promoting "excellence in practice, education, and research" and assisting professional growth and continuing education of nurse

practitioners (AMNP, 2017, para 1). An official letter of support for this project can be found in Appendix A.

Overview of NAFLD

NAFLD pathophysiology

Pathophysiology of NAFLD has been briefly reviewed in the introduction of this paper, introducing the concept that in some patients, liver steatosis progresses onto inflammation, fibrosis, and eventually, liver cirrhosis. It typically can take years to make this transition, averaging 7.7 years between progression of each fibrosis stage (Calzadilla-Bertot & Adams, 2016). Experts are still unclear how to predict which patients will develop NASH over remaining in the benign NAFL category and while the pathophysiology of NAFLD is known to be a predominantly inflammatory process, it is also complex and still incompletely understood. The most recognized pathogenic processes inducing the inflammatory mechanisms include poor diet, high caloric intake, high fructose/sucrose intake, and changes in intestinal flora (Byrne & Targher, 2015). Genetics is also a major contributor, with the patatin-like phospholipase domain containing (PNPLA3) gene mutation being the most recognized genetic variant (Eslam, Valenti, & Romeo, 2017). NAFLD is also associated with several other chronic conditions including cardiovascular disease (CVD) and chronic kidney disease. In fact, even though persons with NASH have an increased risk of liver-related mortality compared to non-NASH counterparts, CVD, not liver failure, is the leading cause of mortality in individuals with NAFLD (Byrne & Targher, 2015).

NAFLD Diagnosis

Lab work. NAFLD is rarely suspected until after laboratory testing reveals an elevated aspartate aminotransferase (AST) or alanine aminotransferase (ALT). Though the differential

diagnosis of patients with elevated AST/ALT can be vast, recent literature, including a systematic review, shows NAFLD is the most common reason for elevated AST/ALT; Alcoholic liver disease and viral hepatitis follow as the second and third (Lee, Kim, & Poterucha, 2012; Radcke, Dillon, & Murray, 2015). Since NAFLD is considered the liver manifestation of metabolic syndrome, clinicians can be relatively certain that patients with obesity or glucose intolerance have NAFLD. However, it is still important to consider other causes of elevated AST/ALT as obesity and glucose intolerance does not negate the chance of concurrent viral hepatitis infection or alcoholic liver disease (Younissi et al., 2004). Moreover, many patients with obesity or metabolic syndrome were born during years that meet the hepatitis C screening recommendation set by the Centers for Disease Control (Smith et al., 2012).

When patients present with elevated AST/ALT, the literature is not in complete agreement on exact steps and end points in the work-up. However, recurrent themes in the literature were noted as follows. First, patients should be screened for viral hepatitis. Next, patients should have screening for alcohol misuse. One available tool to exclude alcohol misuse is the AUDIT-C (appendix B). It has been used in studies of NAFLD to rule out alcoholic abuse as the cause of elevated ALT/AST (Blais et al., 2015). After alcohol misuse is excluded as a potential factor, medication induced liver injury, autoimmune hepatitis, and hemochromatosis are other, less common, possible diagnoses that should be considered. Finally, liver ultrasound should be conducted to evaluate for steatosis. A 2017 clinical guideline agrees with these themes **(**Kwo, Cohen, & Lim, 2017) and the literature findings and guidelines were incorporated into an algorithm (appendix C) developed for this project toolkit.

Two sources of contention in the literature regarding NAFLD diagnosis are screening and evaluation for NAFLD in the presence of normal ALT/AST. Screening for NAFLD can either

be done with ALT/AST, ultrasound or non-invasive calculations such as the NAFLD-FS. However, current United States NAFLD practice guidelines do not recommended screening in any form, even in patients with diabetes and metabolic syndrome (Chalasani et al., 2017). This argument is partly due to lack of proven cost-effectiveness (Corey et al., 2016). Rather than screening, experts recommend increased "vigilance" in monitoring for NAFLD, though little explanation is given. (Wong & Chalasani, 2016). Other literature counters this opinion stating there is an overreliance on normal ALT/AST to exclude NAFLD (Ratziu et al., 2012; Rinella, 2015). Additionally, the European Association for the Study of the Liver (EASL) guidelines call for screening with ultrasound or ALT/AST in those with metabolic syndrome, diabetes, and or obesity (Nascimbeni et al., 2013). It is likely that the recommendations against screening will change as newer research and treatments for NASH become available resulting in screening becoming more cost effective (Corey et al., 2016).

Liver biopsy. Liver biopsy has traditionally been the gold standard to identify NASH, the severe form of NAFLD (Chalasani et al., 2017; Spengler & Loomba, 2015), but multiple concerns over liver biopsy have driven the development of non-invasive diagnostic options like the NAFLD-FS. The vast prevalence of NAFLD makes it impossible to perform a liver biopsy on every patient with NAFLD and identify fibrosis in this manner (Dietrich & Hellerbrand, 2014). Further, liver biopsies are not without mortality, morbidity and expense concerns and are prone to sampling errors (Angulo et al., 2007; Chalasani et al., 2017)). Moreover, the accuracy of liver biopsy, measured by the area under receiver operating characteristic (AUROC), is only as high as 0.85 and many noninvasive options perform similarly or better (Musso et al., 2011).

Noninvasive diagnosis. Clinicians usually suspect NAFLD based on presence of metabolic syndrome and persistently elevated ALT or AST and/or steatosis detected on liver

ultrasound. The next step is then to determine whether NAFL or NASH is present. Traditionally, liver biopsy was used for diagnosis, but diagnosis is now being done with noninvasive diagnostic options. One challenge in diagnosing NASH with non-invasive diagnostic methods, is that unlike liver biopsy, the non-diagnostic methods cannot differentiate NAFL from NASH; they can only differentiate NASH with advanced fibrosis (Kleiner score three or higher) from more benign forms of NAFLD (NAFL or NASH with mild to moderate fibrosis). However, this concern is mitigated by the fact that patients with NASH and mild or moderate fibrosis can be managed in primary care and need not be managed by hepatology until severe fibrosis or cirrhosis is suspected (Chalasani et al., 2013; McPherson et al., 2013; Tapper et al., 2016).

The NAFLD-FS is the most popular non-invasive diagnostic option for detecting advanced fibrosis in NASH. NAFLD-FS is calculated using age, AST, ALT, platelet level, albumin level, presence of hyperglycemia, and Body Mass Index (BMI): all factors inversely related to severity of liver fibrosis in NASH (Chalasani et al., 2017). Although there are 12 other validated non-invasive diagnostic options, NAFLD-FS is the best studied, easily available in primary care, and most preferred by clinical experts (Chalasani et al, 2017). Therefore, it was selected as a tool in this project toolkit. Angulo et al. (2007) performed the seminal study that defined the NAFLD-FS for diagnosing advanced fibrosis in NASH. Using a cross-sectional design, the researchers sought to define a noninvasive scoring system that would allow stratification of NAFLD patients into two groups: those with and without advanced fibrosis. Angulo et al. identified the variables that were independently associated with advanced fibrosis (Kleiner scale three or four on liver biopsy) and created a calculation that was titled the NAFLD-FS. The NAFLD-FS was designed with three primary ranges. Scores below -1.455 are used to rule out severe liver fibrosis. Scores >0.676 presented concern for severe fibrosis and scores of -

1.455 to 0.676 were considered indeterminate and did not provide valuable information. AUROC was calculated at .82 and the authors concluded that the NAFLD-FS would have prevented the 60 percent of patients with scores below -1.455 from needing liver biopsy.

Since this seminal study, the NAFLD-FS has mostly been studied in specialty settings (Cichoz-Lach et al., 2012, McPherson et al., 2010, Lykiardopoulos et al., 2013, McPherson et al. 2013, Petta et al., 2013, & Ruffillo et al., 2011), but has been used in various other settings such as diabetic clinics (Armstrong et al., 2014), bariatric clinics (Pimentel et al., 2010) and primary care clinics (Armstrong et al., 2012 & Blais et al. 2015). Two recent meta-analyses demonstrate continued support for the NAFLD-FS (Musso et al., 2011; Xiao et al., 2017). Musso et al. compared noninvasive diagnosis of NASH induced liver fibrosis to liver biopsy and noted the NAFLD-FS performed at an AUROC of .85 (.80–.93). Performance of the NAFLD-FS in Xiao et al. (2017) also found an AUROC of .85.

Liver stiffness measurement (LSM), also known as elastography, is also being used in the non-invasive diagnosis of NAFLD and strengthens noninvasive diagnosis (Musso et a., 2011). LSM can be assessed through magnetic resonance imaging or ultrasound, but because of a more favorable cost profile, ultrasound is the more popular method. Available under the name brand Fibroscan, ultrasound LSM, was approved by the FDA in 2013 (Echosens, 2017). One drawback to Fibroscan is its limited availability, but access to the method is quickly expanding. Other drawbacks to Fibroscan include reduced accuracy in obese patients; however, this has been improved by development of an extra large (XL) probe. In a recent meta analysis (Tsochostakas et al., 2011), sensitivity and specificity of Fibroscan was 0.79 (95% CI 0.74–0.82) and 0.78 (95% CI 0.72–0.83) for moderate fibrosis and 0.83 (95% CI 0.79–0.86) and 0.89 (95% CI 0.87–0.91) for cirrhosis.

In addition to non-invasive scoring systems and transient elastography, there are several other non-invasive diagnostic options on the horizon. Discussion is beyond the scope of this paper, though one of the most promising is cytokeratin 18 (CK-18) (Kaswala, Lai, & Afdhal, 2016). CK-18 is still considered investigational, however, and not yet recommended by clinical guidelines (Chalasani et al., 2017).

NAFLD Management

Currently, there are no Federal Drug Administration (FDA) approved methods to specifically manage NAFLD. While FDA approved medications focused on treating related comorbidities such as obesity or diabetes are available, in the direct management of NAFL and NASH, lifestyle modifications are the predominate treatment modality. Caloric restriction, in the range of 500-750 kcal/day, and exercise, with a goal of 150 minutes per week, are the current recommendations (Younissi et al., 2017; Hannah & Harrison, 2016; Kenneally, Sier, & Moore, 2016). Strength training in addition to or as part of an exercise regimen can also be helpful (Hannah & Harrison). While the Mediterranean diet is a proven method for caloric restrictions in other chronic conditions and has been proposed for NAFLD (Trovato et al., 2015), patients should be encouraged to tailor caloric restrictions to personal preferences or use a combination of modalities since the focus should be more on amount of weight loss (Kenneally, Sier, & Moore, 2016). A weight loss of seven to ten percent of body weight results in regression of fibrosis in NASH, while even as little as five percent weight loss can stabilize NASH. However, maintenance of weight loss and improved lifestyle is challenging with less than half being able to maintain weight loss in the long term (Chalasani et al., 2017; Glass et al., 2015).

Because achieving weight loss and improved lifestyle is challenging, clinicians should consider using motivational interviewing (MI) with NAFLD patients. A mainstay of practice for

problems like substance abuse, MI is useful in helping patients achieve weight loss and other lifestyle changes (Barnes and Ivezaj, 2015; Hardcastle et al., 2013) and has been specifically proposed for NAFLD (Centis et al., 2012; Marchesini, Petta, & Dalle Grave, 2016; Stewart et al., 2015).

Bariatric surgery for weight loss is also effective in inducing and maintaining therapeutic weight loss in patients with NAFLD. More invasive surgical interventions (malabsorptive over restrictive procedures) produce better outcomes in terms of long-term maintenance of weight loss (Øvrebø, Strømmen, Kulseng, & Martins, 2017; Scheen et al., 2005).

Pharmaceutical treatments for NAFLD are of intense interest. Many trials are currently being conducted for novel treatments. As previously stated there are no FDA approved treatments. However, guidelines do offer a few recommendations for pharmaceutical treatment (Chalasani et al., 2017). One treatment is vitamin E. However, vitamin E is only recommended in non-diabetic patients, therefore missing a large proportion of patients with NAFLD. Guidelines also discuss treating NASH with thiazolidinediones and research has found pioglitazone improves liver histology, though weight gain side effects and contraindications in cardiac disease limit its use. Preliminary research on Glucagon-like-peptide (GLP-1) agonists in NAFLD is promising, but there is not enough research to recommended their use at this time. Probiotics and the role of intestinal health are another focus of current research, but guidelines await further research before offering recommendations (Lavekar et al., 2017).

Literature Review

As this project aims to produce a useful toolkit regarding NAFLD to deliver the aforementioned content for primary care providers, the literature describing NAFLD knowledge gaps of PCPs and how to improve them was evaluated. Additionally, literature was reviewed for

evidence of toolkit effectiveness in addressing knowledge gaps. After describing the methodology for this literature review, this section will first examine the literature exploring the knowledge gaps regarding NAFLD that sets the stage for the rationale of this project. Next, the literature regarding best practice in toolkit design and toolkit effectiveness in clinical practice is reviewed.

Methods

This literature review followed a standard review method. A research literature search map guided by the PICO question was used: Does the use of a NAFLD online toolkit (I), improve Primary Care Providers (P) awareness of NAFLD (O)? The Cumulative Index to Nursing and Allied Health Literature, Google Scholar, and PubMed search engines were queried using the terms "NAFLD", "NASH", "diagnosis", "treatment" and "awareness" and searches were conducted with both these abbreviations and the corresponding full written phrase. Other keywords used were "toolkits", "knowledge" and "primary care". Bibliographies from retrieved articles were used to look for other original research. Inclusion criteria limited studies to adult populations within the United States or Europe. Research in those under 18 years old was excluded. Grey literature was explored and systemic reviews on the topic were also reviewed. Because there were no articles discussing toolkits with NAFLD, literature exploring the use of toolkits regarding other diagnoses was performed as well as review of other NAFLD education programs. Initially, the literature search was limited to seven years, but even though there was much literature describing toolkits, there was limited literature on research regarding toolkit effectiveness. Therefore, the literature review for toolkit effectiveness was expanded as far back as 14 years.

NAFLD Knowledge gap

Defining the knowledge gap.

Health care providers. Several studies have identified a PCP knowledge gap regarding NAFLD. Three of these studies have been performed in the United States. Wieland et al. (2013) conducted a survey among 246 non-hepatology health care providers and was the only study to include NPs in their sample, though the sample was primarily physicians (92%). Only 31 % of the sample felt NAFLD was a clinically important issue while 83 % percent identified a need for education. Polanco-Briceno et al. (2016) used a nationwide online survey of physicians to analyze attitudes regarding NAFLD; one-half of the 302 physician only sample was primary care physicians (PCP). Half of these PCPs were unfamiliar with the differences between NAFL and NASH, yet they were managing patients with both diseases. Said et al. (2013) found similar findings in their survey of 119 physician only PCPs in Wisconsin. Eighty four percent of providers underestimated the prevalence of NAFLD even in obese and diabetic individuals. Fifty-eight percent reported a lack of confidence with disease treatment and reported this was a barrier to providing care for NAFLD patients. All three studies concluded a strong need for education among PCPs in the United States. A strength of the studies are the generalizability to the United States PCP population. A weakness is the low to absent representation of NP providers.

Five other studies looked at attitudes of providers outside the United States and found a similar impact of knowledge gaps. These studies included physician only samples. Two of these studies, focused on knowledge gaps in Australia among non-hepatology providers (Bergqvist et al., 2013 & Patel et al., 2017). While Bergqvist et al. (2013) studied hospitalists, Patel et al. (2017) studied PCPs. Both studies found a significant knowledge gap regarding the prevalence of NAFLD. Bergqvist et al. found that 75% of the 100 Australian hospitalists in the study

underestimated the prevalence of NAFLD while Patel et al. (2017) noted that among 108 PCPs, 58 % underestimated the prevalence of NAFLD. Patel et al. also found that nearly half of their sample erroneously thought that liver enzymes are sensitive enough to rule out NAFLD or were unsure of the role of liver enzymes in diagnosis. Additionally, the majority of the clinicians only used liver enzymes or abdominal ultrasound to diagnose NAFLD and failed to use recommended tools in guidelines such as the NAFLD-FS. Thirty one percent of the sample in Patel et al. volunteered that the survey made them realize they had an unrecognized knowledge gap. Both studies concluded a need for training of health care providers regarding NAFLD.

Ratziu et al. (2012) surveyed 352 French gastroenterologists to determine knowledge gaps in France. Only 22% of the sample would pursue a NAFLD diagnosis if AST/ALT were normal even if patients had metabolic risk factors or obesity. This finding is similar to previously discussed studies and important, given that AST/ALT has low sensitivity for ruling out NAFLD and specifically NASH. Ratziu et al. specifically highlighted a lack of collaboration among specialists and primary care providers in their study.

In a survey of 64 PCPs in the Netherlands, van Asten et al. (2017) noted 84% of the surveyed sample reported a need for more education and only one of the providers reported consulting clinical guidelines for NAFLD. Of concern, 24 % of those surveyed did not know the NAFLD acronym and 53% were unaware of the NASH acronym. Van Asten (2017) also noted a lack of collaboration stating that hepatology and primary care providers should work closely together to reduce the amount of undiagnosed NAFLD and that together they should "develop, validate, and communicate noninvasive tools and algorithms for the detection, referral, and (parallel) follow up" of patients (p. 1078).

Avery et al. (2017) used qualitative research methods to explore NAFLD knowledge and attitudes in the United Kingdom. The sample included 21 healthcare providers in hepatology, gastroenterology, diabetology, and primary care. A unique aspect of this study was that it also included 11 patients in the sample to provide this perspective. Findings included a need for clinical education for providers and patient education development. Several of the providers responded that coaching on motivational interviewing techniques would be helpful since lifestyle changes are the cornerstone of current management. Hepatology specialists in this sample did notice improvement in referring providers use of guidelines and scoring techniques such as the NAFLD-FS prior to referral, but also noted a general lack of comfort from PCPs who often requested referral to confirm treatment plan. Concerning findings in this study were the patient stated lack of education and support given to them by health care providers. Surprisingly, one patient was told to "google" NAFLD by her PCP, rather than the PCP providing her education. A weakness of this study was the lack of detailed description of the sample (physicians versus non-physician providers). A strength of the study is that it the only known qualitative study to illustrate knowledge gaps of NAFLD.

In summary, the literature above has illustrated a knowledge gap among mostly physician PCPs. It is unclear whether this knowledge gap extends to PCNPs since NPs were underrepresented in the study samples. The nature of this project design allowed an opportunity to address the underrepresentation of PCNPs. A total of 20 PCNPs completed the pre-survey portion of the project, but only eleven went on to view the toolkit and complete the post-survey. However, the 20 completing the pre-survey were compared in a separate analysis (phase one, see appendices @) and added data on PCNP NAFLD knowledge gaps to the general research

community. Further discussion of the findings are included in the data analysis and discussion sections of this paper.

Public Awareness. Recent studies have also demonstrated a NAFLD knowledge gap among the general public. Ghevariya et al (2014) interviewed 4000 patients in Brooklyn and found only sixteen percent knew the causes of NAFLD and 95% failed to realize that fatty liver was a problem. Further, 84 % of the patients were not aware of conditions that can cause NAFLD or cirrhosis. Wieland et al. (2015) conducted a survey of 302 patients in an United States endocrinology clinic and found that of patients at risk for NAFLD due to obesity or diabetes, only 18 % were aware of NAFLD. Another study by Goh et al. (2016) showed that 75% of patients with one or more metabolic risk factors did not believe they were at risk for NAFLD. However, despite this lack of awareness, patients desire education. For example, 75 % of surveyed patients in Wieland et al. were interested in education. Unfortunately, a previously discussed study in the United Kingdom noted that health care providers do a poor job of educating patients (Avery et al., 2017). Therefore, for this project several patient education tools were developed and provided as part of the toolkit.

Reasons for knowledge gaps. The literature was briefly explored to examine reasons that there might be a knowledge gap and lack of clinical guideline awareness and implementation. Literature specific to NAFLD guidelines and reasons for NAFLD knowledge gaps were not identified. However, several resources have described reasons for knowledge gaps and problems with adherence to clinical guidelines in general. In a landmark paper examining why physicians don't use clinical practice guidelines, Cabana et al. (1999) investigated 76 articles and found lack of awareness and familiarity with guidelines and recent research were among the top reasons. Confusion regarding guidelines and feeling guidelines

were cumbersome were also important factors influencing their use. Keiffer (2015) specifically examined the same themes among 17 non-physician providers in the United States and found the strongest reason was an inability to stay updated with the constantly evolving guidelines in ones field as well as lack of awareness of their availability.

Toolkits to address knowledge gaps.

The aforementioned literature demonstrates knowledge gaps regarding NAFLD and possible reasons for the gaps. Toolkits that provide education and resources for providers are one solution to this problem. While toolkits are wide spread in use and many examples are found, they are not always evaluated for effectiveness. The following literature review sought to examine evidence-based design of toolkits for use in NAFLD. During the literature review, only one research article on a NAFLD educational event targeting knowledge gaps was found, but no literature regarding a toolkit for NAFLD was available. Therefore, this literature review will discuss the sole article on addressing NAFLD knowledge gaps and then discuss literature regarding qualities that make an effective toolkit. Next, a review of success and failure of toolkits in other health problems outside of NAFLD is discussed.

Addressing NAFLD knowledge gaps. Only one study has tried to target provider lack of knowledge regarding NAFLD. Grattagliano et al. (2008) studied the Steatostop project, a full day teaching workshop in Italy and found positive results. An unique aspect of this study was that it collected data on referral and other practice patterns for a combined 212 NAFLD patients cared for by PCP participants for the two months preceding the educational event. It also surveyed the 56 PCP participants six months before and directly after the educational event and found statistically significant improvement in all knowledge areas which included screening for NAFLD, referral for liver biopsy, and management. The study noted that knowledge prior to the

education event was “barely adequate” (p. 391). Patient data showed the most common errors in NAFLD care were the failure to exclude alcohol use (only excluded in 7 out of 212 patients) and a failure to consider NAFLD in patients with both elevated ALT/AST and obesity/diabetes. After the educational event, 40% of the PCPs reported they would better investigate for NAFLD. This study’s weaknesses include the lack of validation of the questionnaire used to query PCPs and failing to assess for long-term knowledge gains by only surveying participants directly after the educational event. The research is also over 10 years old, which is another weakness. However, its strength is that this study is the only one to address NAFLD knowledge gaps among PCPs.

Components of a good clinical toolkit. In order to develop a clinically useful toolkit, it was important to review the available research for effective design. A recent qualitative study interviewed 96 primary care and community health leaders regarding opinions on effective toolkits (Davis et al., 2017). Fifty six percent of the sample included PCPs. Themes of the study included that toolkits should be easy to apply and tailor to specific situations and have a “quick start guide” (p. 5). They should also have a table of contents or index. Two other studies conducted systematic reviews of toolkits to illustrate overall effectiveness regarding toolkits. Barac et al. (2014) reviewed 83 toolkits (84% were healthcare related), but found only a little over one third reported on effectiveness. Of those reporting effectiveness, 21 found beneficial effects. A Canadian group led by Yamada et al. (2015) evaluated research on 39 patient and provider toolkits and concluded that 26 had too weak of study design methods to draw useful conclusions. Of the remaining 13 toolkits, eight studied the outcomes in a randomized controlled manner, and six of these eight toolkits were found to be effective.

These first three studies provide important themes. Among them are that toolkits should be based in evidence and studied in a formal fashion. Toolkits should also bridge research and practice to positively influence health outcomes and help with knowledge sharing and facilitate behavior and practice change (Barac et al., 2014). A last noted theme is that the internet is a popular and "fertile" ground for their implementation (Barac et al.). This was especially poignant given that past research has noted that printed educational toolkits for providers are often not effective (Giguère et al., 2012).

Two additional studies provide other insight to this project. Keiffer (2015) noted non-physician providers found toolkits more attractive if they were easy to use and evidence-based. The McDonnell Norms group (2016) findings agree noting that convenience and simplicity were most important to adoption of clinical practice guidelines into actual practice. Both studies emphasized the importance of easily retrievable guidelines and this may particularly support the usefulness of the internet as a host area for future toolkits.

Review of selected toolkits. Last, this literature review explored primary research articles demonstrating effectiveness of toolkits across a variety of clinical conditions. Eleven articles were found and are reviewed here. The first, a study in North Carolina, used a provider toolkit to help pediatric physicians in training (residents) coach 115 parents of children ranging from four to twelve years old regarding their children's obesity and lifestyle behaviors (Perrin et al., 2010). The toolkit included a stoplight colored BMI chart to educate parents/patients. It also included a physical activity and dietary patterns survey to trigger discussion among the physician and parent/patient. Results showed that up to one-half of patients improved their use of healthy lifestyle behaviors by the one month follow up. A weakness of this study is that data was only collected at one and three months post intervention. Other weaknesses of this study include the

exclusion of non-English speaking parents and a high attrition rate. Only 56% of parents completed the three month survey.

Two studies have examined the usefulness of toolkits in primary care management of depression. Starkey, Wiest, & Qaseem (2016) evaluated the use of an online depression toolkit in 18 United States physician-only practices. The study found statistically significant improvement in substance abuse screening, alcohol abuse screening, and suicide screening after using the toolkit ($p<0.001$). Additionally, providers relied less heavily on antidepressant prescriptions ($p<0.05$) after using the toolkit. Starkey, Wiest, & Qaseem also used Likert scale surveys and found more physicians reported feeling confident with depression management post-intervention than pre-intervention. Their results are limited in generalizability to this project in that although they used an online clinical toolkit, their intervention also incorporated practice improvement coaching calls. A strength of the study, however, is the measurement of patient outcomes as part of the evaluation of the toolkit. A second study on primary care toolkits for depression was conducted by Menchetti et al. (2013). Generalizability is also limited from this study as it included a dedicated psychiatry consultant as part of its intervention and the project was conducted in Italy. However, like Starkey, Wiest, & Qaseem , Menchetti et al. demonstrated statistically significant changes from a toolkit including decreased use of sedatives and hypnotics and more appropriate use of antidepressants. Treatment response rates were higher at three and six months in the intervention group.

One of the earliest studies of toolkit effectiveness was completed by Bysziewski et al. in 2003. In this study, 86 United Kingdom PCPs (physicians-only) used a printed toolkit to help discuss driving and dementia with their patients. The toolkit included clinical screening questions for safe driving, patient education, and algorithms for use of social resources. The

physicians completed pre-use and post-use surveys and demonstrated a 8.4/10 satisfaction rating with the toolkit. The toolkit was also effective ($p<=0.5$) for improvement in knowledge after use and intention to use in practice.

Three studies have examined toolkits to improve knowledge gaps and clinical care outcomes in patients with diabetes. Evans et al. (2017) used a mixed methods design to evaluate the use of the United Kingdom WAKEUP toolkit for pre-diabetes and additionally refined the written toolkit over two action research cycles. Results were primarily collected through focus groups and both patients (n=10) and PCPs (n=12) were part of the project sample. The PCP sample included five nurses but it was unclear whether the nurses were advanced practice or not. The toolkit was effective in helping educate and motivate patients. Ninety percent of patients had made changes suggested in the patient education part of the tool-kit and 80% of them could recite those changes. Positive findings were also reported by PCPs in the study. For example, PCPs reported being more clear on the need to schedule follow up for pre-diabetes patients. A useful finding of this study is that PCPs felt the toolkit would be better implemented with an educational introduction first rather than just delivering the toolkit to participants via postal mail.

The second study of toolkits for diabetic management was completed by Cavanaugh et al. (2009) in the eastern United States. This study was unique in that it was a randomized trial and focused on patient outcomes. It enrolled 198 patients, 99 in the intervention group and 99 in the control. Those patients in the intervention group received care for diabetes from diabetic providers (including nurse practitioners) who used the Diabetes Literacy and Numeracy Education Toolkit (DLNET) for three months. The patients in the control group received care from diabetic providers who did not use this toolkit. The DLNET toolkit included 24 modules that healthcare providers could use and modify for their patients regarding various self-care

activities. Data was collected at baseline, three months (intervention conclusion), and six months (three months after intervention conclusion). Statistically clinical improvement was demonstrated in glycohemoglobin A1C levels in the intervention group at three months ($p=0.03$) but not at six months. While the strength of this study was the addition of patient outcome data, a weakness was the short follow up period of six months.

The last study regarding toolkit use in diabetes was a Canadian intervention by Shah et al. (2014). This study showed that the toolkit, which incorporated a clinical guideline synopsis and patient education tools, was not effective in addressing two cardiovascular outcomes in diabetic patients. The primary outcomes studied were the use of a statin and occurrence of myocardial infarction. After implementation of the toolkit, no statistical difference was observed compared to before implementation. The authors speculated that since the high baseline rate of statin use was already high, this might account for the study finding. A follow up qualitative study with the 88 primary care providers in this cohort suggested other reasons. These included that the toolkit was too long (200 pages), in print form, and sent via postal mail, a more passive approach (Parsons et al., 2016). Strengths of Shah et al. included data collecting data on 933,789 patients and the randomization of physician practices to the intervention and control groups.

Peptic ulcer disease and fall prevention are two other areas where toolkits have been studied for their ability to improve quality of care. Two toolkits have been studied in a randomized controlled manner. Dykes et al. (2010) tested the effectiveness of a fall prevention toolkit while Majumdar et al. (2005) tested the usefulness of a toolkit to diagnose helicobacter pylori infection. The study by Dykes et al. (2010) differs from others in this literature review as it is the only study reviewed on inpatient management. The study used control ($n=4$) and intervention ($n=4$) units and used a toolkit delivered via computer software to evaluate fall risk

among 10, 264 patients. The toolkit then designed personalized prevention suggestions. The toolkit used a Morse fall score, posters, patient education and fall prevention plans. Although there was no significant difference between fall related injuries in the control and intervention units, the toolkit significantly reduced the number of falls on the intervention units. The study by Majumdar et al. randomized its primary care practice sample into three settings: high intensity intervention (n= 312 patients from 6 practices), low intensity intervention (n=147 patients from 3 practices) and usual care (n= 122 patients from 5 practices). The tested toolkit incorporated practice guidelines, pre-printed modifiable patient letters, and progress note templates. The toolkit was used in both high and low intensity intervention sites, with the high intensity intervention clinics also receiving pharmacist reminders, group performance details, and educational sessions. Only the high intensity intervention was found to be effective in improving the study outcomes, increased recognition of helicobacter pylori and reducing inappropriate proton pump inhibitor use. Strengths of these two studies are the randomized controlled designs. Weaknesses include the lack of generalizability to NAFLD care due to differing chronic conditions.

Knowledge gaps regarding Chronic Kidney Disease (CKD) have also been a target for toolkit intervention. Donald et al. (2016) used an online toolkit to increase adherence to CKD clinical practice guidelines and address a previously noted performance gap in Canada. The toolkit was evaluated with a mixed method design. PCPs liked the format of the online toolkit since "everything" was in one place. Eighty three percent of participants reported the toolkit increased their knowledge and confidence. Website analytics also showed that 33% of users returned to use the toolkit after the study period. Participants self-reported improved behavior

changes in diagnosis and management of CKD, but this was not statistically evaluated which was a weakness of the study.

Pediatric fracture management is the most recent quality improvement focus to be addressed by toolkits. Camp, Barnes, Damany, and Donnan (2017) designed a study to evaluate the use of a web based "fracture pathway" for pediatrics. The toolkit used a clinical pathway and algorithm to assist an emergency room in Canada to determine which fractures could be managed by primary care instead of orthopedic specialty clinics. Findings included a decreased utilization of resources with radiology use decreasing by 24% with use of the toolkit. Use of the specialty clinic was decreased by 12% and authors considered this important in that it reflected less parental time off work. However, the authors admitted an inability to confirm a causal relationship, however due to study design. This is a weakness of this study.

Literature Summary

This literature review was helpful in drawing important conclusions regarding toolkit design for this project. First, PCPs under recognize NAFLD and desire education regarding this topic. Second, while no toolkits have been specifically developed for NAFLD, toolkits have demonstrated their value in several other clinical problems . However, they are understudied. Therefore, this project's evaluation of the NAFLD toolkit incorporated inferential statistical methods and could be used as a pilot study for future research on the toolkit. Third, the majority of toolkits demonstrate usefulness, though one study in this review failed to show significant usefulness (Shah et al., 2014) and two studies noted high intensity support of a toolkit by experts was needed before outcomes improved (Majumdar et al., 2005; Menchetti et al., 2013). Fourth, all studies confirmed the toolkit will need incorporate evidence-based practice and best practice in terms of design and be easily accessible. Two last noted concepts were that the use of the

toolkit could be strengthened by pairing it with an educational session (Evans et al., 2007; Grattagliano et al., 2008) or pharmacist or other specialist support (Majumdar et al., 2005; Menchetti et al., 2013; Starkey, Wiest, & Qaseem, 2016). However, theses type of intervention are considered beyond the scope of this project, though they could be considered in future scholarship with the toolkit.

Theoretical frameworks

The Knowledge to Action conceptual framework (appendix N) was used to guide this project's development, implementation, and evaluation (Graham et al., 2006). This framework includes two cycles: the Knowledge creation cycle and the Application cycle. The Knowledge Creation Cycle begins with Knowledge Inquiry followed by Knowledge Synthesis. Last, knowledge products and tools are developed. This first cycle describes the process used in the development of the toolkit. Knowledge inquiry and synthesis was conducted through the literature review and the toolkit development (knowledge product) was developed. The Application, or Action, Cycle is the second cycle in the Knowledge to Action framework. In this cycle, the knowledge is implemented and adapted as needed to the context of various situations. The knowledge use is monitored and evaluated and refined in a continual, circular process for continued use. This cycle closely described the planned process for the implementation and evaluation portion of this project. The toolkit will be launched, feedback will be collected, and the toolkit refined.

Assumptions and Objectives

This project was based on two assumptions. First, PCNPs in Missouri experienced the same knowledge gaps and desired the same education as those noted in the literature review. Second, PCNPs will be open to a toolkit for NAFLD and be willing to use it in clinical practice.

This project was guided by three objectives. The first objective was to improve PCNP awareness and knowledge of NAFLD. Second, the project serves to help PCNPs apply clinical guidelines and EBP for care of primary care patients with NAFLD. Last, this project aims to evaluate the usefulness of the NAFLD toolkit in meeting objectives one and two.

Methodology

Project design

This project was designed as a Doctor of Nurse Practice (DNP) EBP and knowledge translation project to improve knowledge gaps and support EBP regarding NAFLD. The project focused on educating PCNPs on the management and diagnosis of NAFLD through an online provider toolkit. The toolkit was designed using toolkit development suggestions noted in the AHRQ (2016) guide for toolkit development. Additionally, the toolkit was designed using best practices identified in the literature review of this paper.

Specifically, project design involved three phases. The first phase involved gathering the necessary training on NAFLD to provide foundational knowledge of the disorder. To accomplish this, a systematic review of the literature for current knowledge and EBP in diagnosis and management of NAFLD was conducted. Much of this literature was reviewed in the Overview of NAFLD section of this paper. Additionally, the project director completed the American Association for the Study of Liver Disease (AASLD) Liver Learning, Fundamentals of Liver Disease: NAFLD and NASH module. This learning was complemented with a 40 hour clinical with the University of Kansas Medical Center (KUMC) hepatology NASH clinicians (doctor of medicine and adult nurse practitioner) to develop clinical expertise and identify patient preferences regarding the condition. Additionally, a 24 hour clinical was completed with a certified obesity medicine physician. Because clinical experience is one of the three feature of

EBP, the combination of this didactic and clinical learning was critical for the project director to obtain additional background knowledge and clinical experience to develop the online toolkit.

The second phase of the project involved development and pilot review of the online toolkit. The toolkit followed best practices in toolkit design by using toolkit development checklists from AHRQ (2016). The online provider toolkit is hosted on a free google website. A domain and web address for the toolkit was established at https://sites.google.com/view/nafldtoolkit/home (appendix D). Toolkit topics and content areas include diagnosis, epidemiology and pathophysiology, patient education, treatment, and bibliography. Pictures used on the toolkit were selected from creative commons licenses. Examples of selected tools that are provided in the tool-kit are included in appendix E through H. After the toolkit was developed, the toolkit was reviewed by the project director using the AHRQ (2016) checklist for toolkit best practices. Next, the patient education material was reviewed by the project director for literacy. The Suitability Assessment of Materials (SAM) checklist as described by Doak, Doak, and Root (1996) assured literacy. The SAM checklist is a tool to assure patient education materials are written at a level easy to understand by the lay public and focused on health literacy. The Flesh-Kinkead readability scale and Simple Measure of Gobbledygook (SMOG) was also calculated on the patient education material and assured the material was readable at a fifth grade reading level. This is important as one fifth of United States public reads at a fifth grade reading level or below (Doak, Doak, & Root, 1996). Third, a pilot review was conducted. One family nurse practitioner working with NASH patients assured content validity and the patient education material referencing dietary recommendations (appendix G) was expertly reviewed by a registered dietician working with NASH patients. Last, the toolkit was pilot tested by four doctorly prepared PCNPs in the University of Kansas

School of Nursing. Weaknesses and inconsistencies with the AHRQ toolkit development guidelines were identified through this review. For example, one pilot reviewer identified that the NAFLD acronym was used on the title page without first providing the full title. The issues were addressed and the toolkit was updated.

The last phase of this project included toolkit implementation and data collection. During this phase, the website was published, participants were invited to use the toolkit (Appendix M), and the project director evaluated the toolkit to see if it improved PCP knowledge gaps and comfort with NAFLD. This phase is further discussed in the data collection section of this proposal. It is important to note that prior to this last phase the project proposal was submitted to the University of Kansas Medical Center (KUMC) Internal Review Board (IRB) and was approved as an exempt study (Appendix O).

Project Sample and selection

Convenience sampling is a common method of sampling for quality improvement research and was considered appropriate for this project due to the similarities to quality improvement (Gray, Grove, & Sutherland, 2017). The planned convenience sample of 10 PCNPs was exceeded as 11 PCNPs completed both the pre- and post-survey. Inclusion criteria required that PCNPs be working in primary care part-time or full-time. Exclusion criteria included those NPs working in specialty care or urgent care and student NPs. An additional nine PCNPs meeting inclusion criteria completed the pre-survey in entirety, however, they did not continue on through the toolkit review and post-survey completion. These responses were still beneficial as they were combined with the eleven other pre-survey responses to provide a general overview of the state of PCNP knowledge regarding NAFLD (appendix Q, R, & S).

Data collection

Instruments. The data collection instrument for this project is found in appendix I. The instrument was selected in the following manner. Three study authors were contacted for use of their survey instrument: Said et al. (2013), Wieland et al. (2013), and Patel et al (2017). Patel et al. (2017) was the only team to respond and provide access to their instrument. Patel et al. previously conducted face and content validity of the instrument as described in their paper, however, test-retest reliability was deferred for unclear reasons. Because the survey by Patel et al. was developed for use in Australia, the instrument was updated and altered for use in the United States with guidance from the project committee director and clinical content experts (Melissa Laycock, MSN, FNP & Winston Dunn, M.D., personal communication April 4, 2018). Differences can be compared between appendix I (modified for this project) and J (original from Patel et al.) and also include the following changes. Question 2 was added to obtain a general idea of years of experience among participants. Question 20 (appendix I) was added after consultation with committee members. The question was added to assess for change in perceived comfort and preparedness regarding NAFLD diagnosis and management.

Procedure. The project director (DNP student) managed the data for this project. Participants were invited to participate in this project via 1) email invitation to active Association of Missouri Nurse Practitioners (AMNP) members 2) invitation posted on the webpage for AMNP and the Facebook page for AMNP and 3) email invitation to Nurse Practitioner members of the Missouri Nurses Association. This third invite was added after the initial two weeks of the data collection failed to produce a satisfactory amount of participants. Approval for this addition was separately requested and approved by KUMC IRB. Potential participants were informed via the email invitation of their rights as study participants and that completion of the surveys implied consent to participate in this project. Upon entering the website, participants were led

through three steps. First, participants completed the pre-survey. Next, the participants were asked to review the toolkit and work through the modules. Then, participants completed the post-survey to assess for change in response. REDCap was used to conduct the surveys and protect anonymity. No identifying information, including email, was collected from participants.

Data analysis

The data analysis plan consisted of descriptive and analytic statistics and occurred in two phases. In phase one, all PCNPs completing the pre-toolkit survey (n=20) were analyzed to gain an understanding of PCNP knowledge, approaches to care, and perceived comfort regarding NAFLD. As previously discussed this data analysis phase was conducted due to the underrepresentation of PCNPs in research exploring knowledge gaps among providers. Descriptive statistics were used for all analysis in this phase. Results can be found in appendix Q, R and S and are discussed in the results section.

Phase two data analysis was conducted with only the survey responses for those PCNPs who completed the pre-toolkit survey, reviewed the toolkit, AND completed the post-toolkit survey. There were 11 participants who met this criteria. Results of this analysis can be found in appendix P, T, U, V, and W. The survey tool was subdivided into three components for this phase of data analysis. 11 questions (Questions 3-13) assessed general knowledge regarding NAFLD and were pooled together and correct answers were added to produce a total score for each participant. Scores on the pre-survey were compared with scores on post-survey and the Wilcoxin signed-rank test for matched pairs was used to compare pre and post-scores for statistical differences. Four questions assessed general demographics of the sample and practice patterns/experiences (Question 2, 14,15, 17). Another four questions (16, 18-20) assessed for clinical approach behaviors. Question one was used to verify participants met inclusion criteria

and question two was used for demographic data collection. Participants were asked questions 3-13, 15-16, and 18-20 both pre- and post-exposure to toolkit. Questions 14, 17 were only asked in pre-survey to obtain general practice information and in retrospect, did not influence this project's findings and could have been deleted. Findings of the data analysis are discussed in the results section.

For all data, outliers were investigated for possible errors and cases with inconsistencies were assessed. Graphic representation of the data is included in the appendices. SPSS was used to conduct the inferential statistical analyses and Microsoft Excel was used to conduct descriptive statistical analyses. Analyses were conducted by the project director and checked for accuracy and appropriate statistical methods by two statisticians.

Timeline and Budget

The project budget and timeline details can be found in appendix K and L. The costs for the project were minimal due to volunteer hours of the project director and use of free pictures for the website via creative commons.

Results

Phase one descriptive data analysis provided a general exploration of PCNPs knowledge and approach to NAFLD as well as their comfort level regarding caring for NAFLD (appendices Q, R, & S). The range of years of experience of the participants was 1-43 years. Analysis of knowledge showed several knowledge gaps in some but not all areas (appendix R). This will be further discussed in the discussion section. Practice behaviors analysis (Appendix S) showed that while PCNPs knew about some guideline suggested interventions, few of them used them. For example, there was a high percentage of participants who knew that use of the NAFLD-FS was

recommended for use (question 11e and 13d in appendix R; 65 % and 70 %, respectively), yet only 15 % reported using it in clinical practice (question 16b, appendix S).

Phase one data analysis also included a correlational analysis which was conducted to see if PCNPs with more years of experience (question 2, appendix I) had higher perceived comfort with NAFLD (question 20, Appendix Q). Findings showed there was no correlation between these two variables (R=-0.06, p=.787)

Phase two data analysis showed four statistically significant findings (appendix X). First, there was statistically significant improvement in overall knowledge scores from pre-survey to post-survey (appendix X), Second there were statistically significant changes in report of two intended actions, use of the NAFLD-FS and referral to weight loss clinic for management. Last, PCNPs in this sample felt better prepared to take care of patients with NAFLD after using the toolkit (p=0.0156).

Phase two data analysis also allowed for qualitative comments. A summary is provided in appendix O. Comments of participants were positive including comments like "very helpful…" and "…good information". The qualitative data also highlighted the challenges of caring for this population. For example, one participant mentioned "Dietitian consult/Medical Nutrition Therapy is not covered by most insurers except for diagnosis of Diabetes or Chronic Kidney Disease. We can request consult but it is unlikely that patients will follow through after hearing the anticipated price." (Appendix P, ID22). Other qualitative findings during conduction of this project include that the project director was contacted by a NP from New Jersey for permission to use the algorithm in a continuing education talk on NAFLD. The NP found the toolkit website through a web search.

Discussion

Completion of this project provides important insights for EBP of NAFLD. Only 35% percent of this sample agreed (and none strongly agreed) that they had adequate knowledge to take care of patients with NAFLD. This demonstrates an important education need for PCNPs and combined with the objectively observed knowledge gaps from appendix Q, provides insight on the state of knowledge for PCNPs, a population underrepresented in current research. PCNPs experienced similar knowledge gaps as those described of their physician counterparts in the literature. For example, 65% of this project's sample were unlikely to refer to hepatology unless liver function tests were abnormal. This mirrored the findings of Patel et al. (2017) and Ratziu et al. (2012). Additionally, 65% of this sample underestimated the prevalence of NAFLD in the obese population and 45 % underestimated the prevalence in the general population which is similar to findings by Patel et al. and Said et al (2013).

Overall, the project findings provide an objective evaluation of an EBP toolkit for NAFLD and demonstrate positive outcomes. Moreover, the description of the process of development, implementation, and evaluation of this toolkit can be used by other clinicians to conduct similar EBP projects on other chronic care conditions.

Limitations.

There are a number of limitations to this project's results. First, The small sample size in both phase one and phase two analysis and the non-research design of a DNP project limits the generalizability of the results. Type two error is a potential limitation for the phase one correlational analysis of years of practice with perceived comfort due to the small sample size. Likewise, phase two analysis might suffer from type two error due to the small sample size and therefore other small, but significant improvements besides the four identified might have occurred. Another limitation of this project is that the survey used in evaluation was from

Australia, yet this project was conducted in the United States. This limitation was mitigated, however, by expert review of the survey with small changes made to reflect United States practice as discussed in the Instruments section. An additional limitation is that project participants completed the post-survey immediately after reviewing the toolkit and no conclusions can be drawn about the success of the toolkit in maintaining improvement in knowledge and actions. Future evaluation of this toolkit should, therefore, include post-survey evaluation a month or more after exposure to the toolkit in a longitudinal manner. Last, this project evaluation did not examine patient outcomes and therefore, no generalizations can be made as to whether the toolkit improved patient outcomes, though participants did report intentions to use more EBP strategies, such as the NAFLD-FS. Further, some studies such as Lucas et al. (2004) and Adorka et al. (2013) have shown that improved clinical knowledge led to better patient care decisions in physicians and this project did demonstrate strong clinical knowledge improvement.

Strengths.

Despite its limitations, this project has many strengths. First, the project was designed in an EBP manner after an exhaustive literature search to determine best practices in toolkit design. The project also followed best practices according to the highly respected AHRQ and used NAFLD national guidelines to guide content. Additionally, the evaluation section of this project provides objective, statistically sound data to the body of knowledge regarding effectiveness of toolkits to support EBP. This project also used a previously designed survey tool with previously proven content validity. Finally, this project's pre-survey allowed exploration of PCNP's baseline knowledge and approach to NAFLD, which is a population scantly represented in current literature of NAFLD knowledge gaps.

Implications

In this small sample, the NAFLD toolkit improved PCNPs knowledge, intended actions, and perceived preparedness. Results support expanding toolkit use nationwide and with other PC professions. Because of the limitations, evaluation of this toolkit should be continued with a larger sample and over a longer time frame in a longitudinal manner. Additionally, evaluation could be expanded to collect data on patient outcomes of providers that used the toolkit. Future study of this nature is planned in the project directors future scholarship plan. It is also felt that this project can serve as a pilot study for research on the NAFLD toolkit. Strengths and limitations identified during this project can be used to design a strong, large sample research study. A study of this nature is needed as there is some but not overwhelming evidential support on the success of toolkits in supporting EBP (and none on a NAFLD toolkit).

In conclusion, PCPs experience significant knowledge gaps regarding NAFLD. This leads to challenges in early recognition and management of NAFLD. Because NAFLD will continue to be a pressing concern over the following years, PCPs need education and support in caring for these patients. Provider toolkits are one solution to addressing knowledge gaps and providing support to PCPs. This project used the Knowledge to Action framework, national clinical practice guidelines, and AHRQ recommendations to design the NAFLD toolkit to support PCNPs in EBP. Early evaluation of the toolkit shows promise of the toolkit in improving the quality of primary care provided to patients with NAFLD and presents one viable option for PCPs to meet the increasing responsibilities placed on them.

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Appendix A: Letter of Support

Association of Missouri Nurse Practitioners
Delilah Pennington, DNP, APRN, FNP-BC, GNP-BC
President
8103 Deer Haven Rd.
Wardsville, MO 65101

January 8, 2018

The University of Kansas Medical Center
Institutional Review Board
3901 Rainbow Blvd MS 1032
Kansas City, KS 66160

To whom it may concern:

I am writing this letter in support of the DNP project entitled "An Online Toolkit to Improve Primary Care Provider Knowledge Gaps Regarding Non-Alcoholic Fatty Liver Disease " to be conducted by project director and doctoral student Kelly Casler, MSN, APRN, FNP-BC. The Association of Missouri Nurse Practitioners offers its support of this project and Kelly's proposal to collect the convenience sample from among our members who are practicing in primary care. We look forward to hearing about the outcomes of this project.

Sincerely,

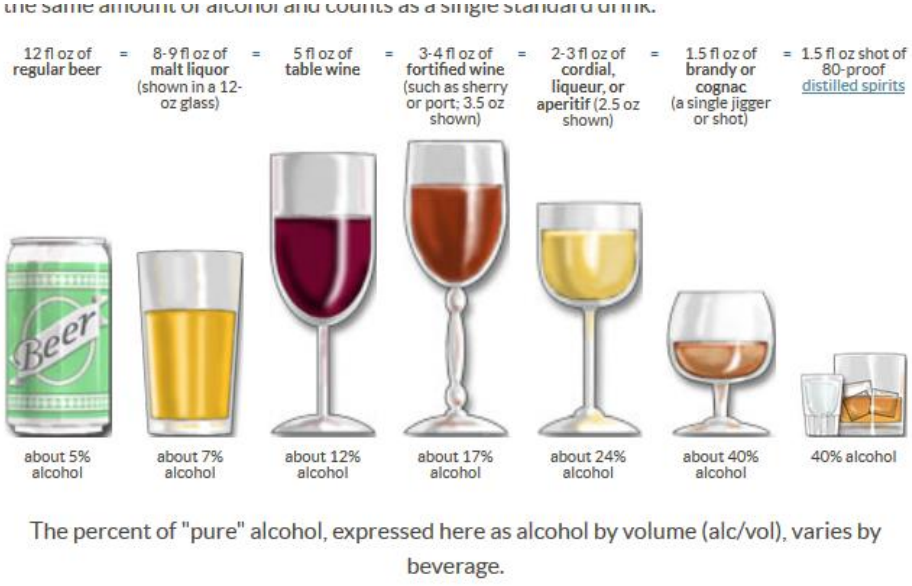
Delilah Pennington, DNP, APRN, FNP-BC, GNP-BC

Appendix B: AUDIT –C modified for this project from SAMHSA (2017)

Patient Name _____ Date of Visit _____

1. How often do you have a drink containing alcohol?
a. Never
b. Monthly or less
c. 2-4 times a month
d. 2-3 times a week
e. 4 or more times a week

2. **How many standard drinks containing alcohol do you have on a typical day?** * The picture below shows 1 standard drink *
a. 1 or 2
b. 3 or 4
c. 5 or 6
d. 7 to 9
e. 10 or more



*Picture from National Institutes of Health (2017)

3. How often do you have six or more drinks on one occasion?
a.Never
b. Less than monthly
c. Monthly
d. Weekly
e. Daily or almost daily

AUDIT-C - Overview

The AUDIT-C is a 3-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is a modified version of the 10 question AUDIT instrument.

Clinical Utility

The AUDIT-C is a brief alcohol screen that reliably identifies patients who are hazardous drinkers or have active alcohol use disorders.

Scoring

The AUDIT-C is scored on a scale of 0-12.

Each AUDIT-C question has 5 answer choices. Points allotted are:
a = 0 points, b = 1 point, c = 2 points, d = 3 points, e = 4 points

- **In men**, a score of 4 or more is considered positive, optimal for identifying hazardous drinking or active alcohol use disorders.
- **In women**, a score of 3 or more is considered positive (same as above).
- However, when the points are all from Question #1 alone (#2 & #3 are zero), it can be assumed that the patient is drinking below recommended limits and it is suggested that the provider review the patient's alcohol intake over the past few months to confirm accuracy.[3]
- Generally, the higher the score, the more likely it is that the patient's drinking is affecting his or her safety.

Psychometric Properties

For identifying patients with heavy/hazardous drinking and/or Active-DSM alcohol abuse or dependence

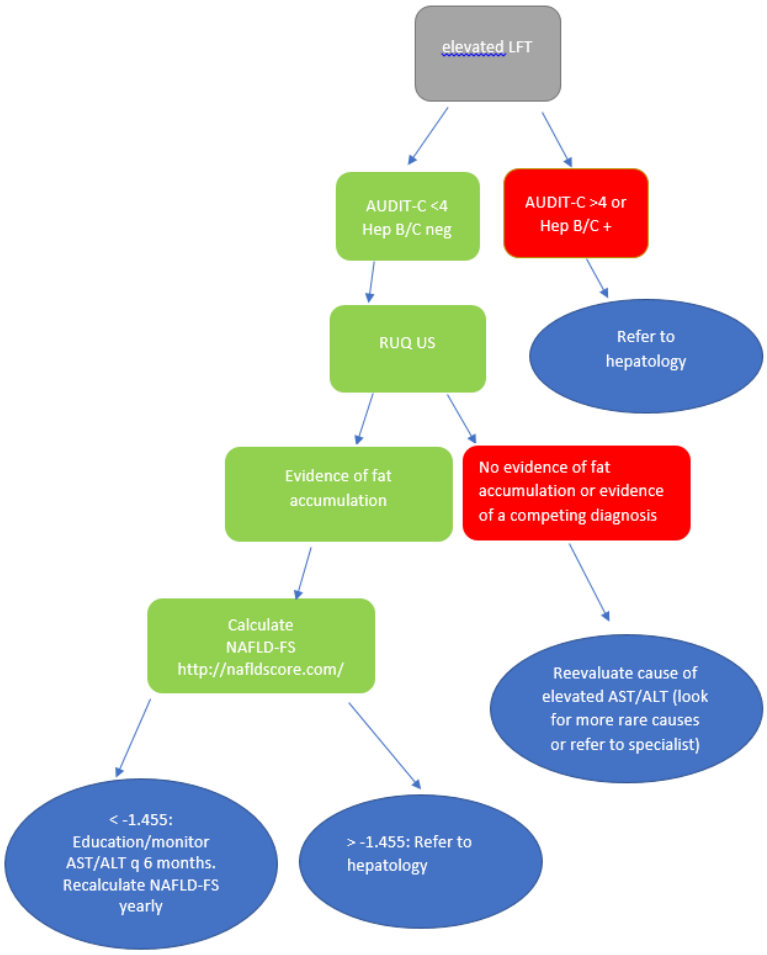
	Men[1]	Women[2]
≥3	Sens: 0.95 / Spec. 0.60	Sens: 0.66 / Spec. 0.94
≥4	Sens: 0.86 / Spec. 0.72	Sens: 0.48 / Spec. 0.99

For identifying patients with active alcohol abuse or dependence

≥ 3	Sens: 0.90 / Spec. 0.45	Sens: 0.80 / Spec. 0.87
≥ 4	Sens: 0.79 / Spec. 0.56	Sens: 0.67 / Spec. 0.94

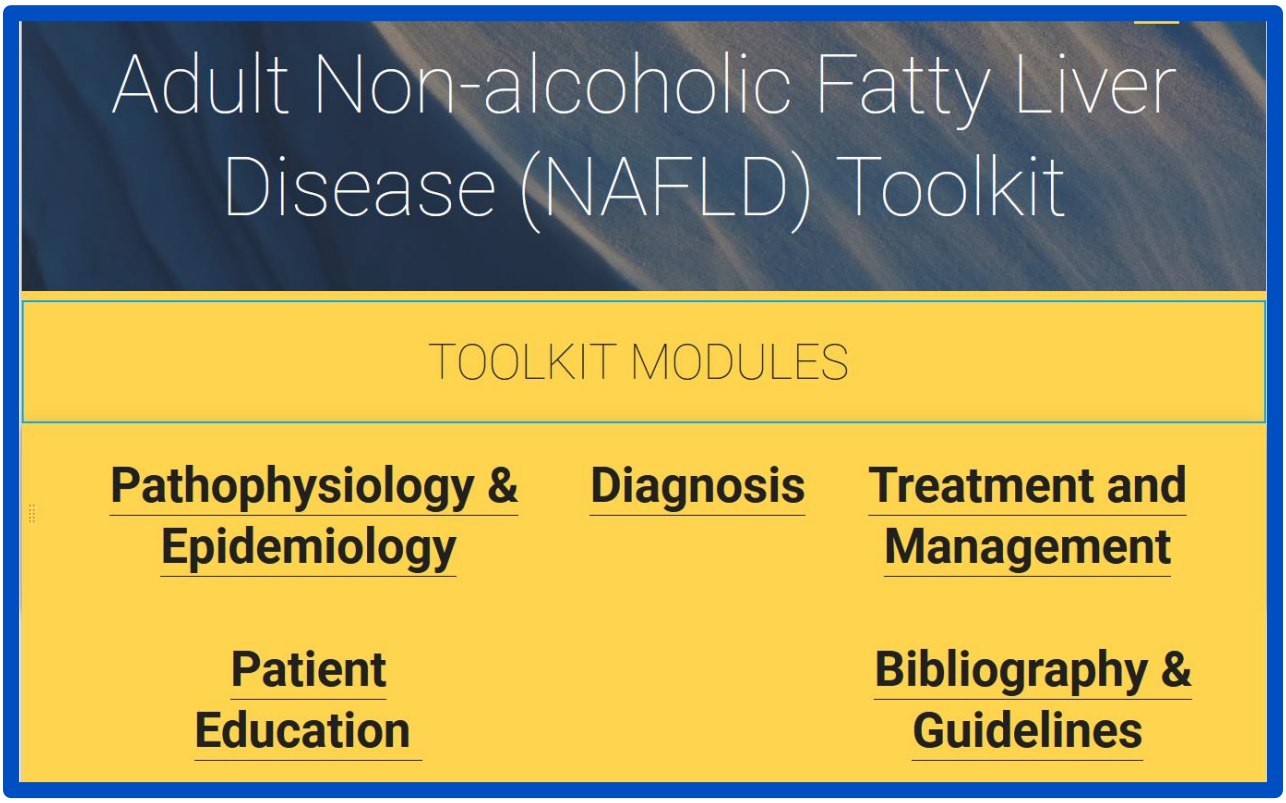
1. *Bush K, Kivlahan DR, McDonell MB, et al. The AUDIT Alcohol Consumption Questions (AUDIT-C): An effective brief screening test for problem drinking. Arch Internal Med. 1998 (3): 1789-1795.*
2. *Bradley KA, Bush KR, Epler AJ, et al. Two brief alcohol-screening tests from the Alcohol Use Disorders Identification Test (AUDIT): Validation in a female veterans affairs patient population. Arch Internal Med Vol 163, April 2003: 821-829.*
3. *Frequently Asked Questions guide to using the AUDIT-C can be found via the website: www.oqp.med.va.gov/general/uploads/FAQ%20AUDIT-C*

Appendix C: Algorithm for Diagnosis



1. Hepatitis C antibody, Hepatitis B antibody to rule out hepatitis
2. ceruloplasmin
3. ANA, IgG, & Antismooth muscle antibodies to rule out Autoimmune hepatitis
4. Anti mitochondrial antibody to rule out Primary biliary cholangitis
5. alpha-1 antitrypsin to rule out alpha-1 antitrypsin deficiency
6. IgA and tissue transglutaminase antibody to rule out celiac disease

Appendix D: Adult NAFLD Toolkit



Appendix E: NAFLD-FS Calculation: provider documentation form

patient _____

Age:
AST:
ALT:
Platelet:
Albumin:
BMI:
Insulin resistant: yes/no

NAFLD-FS = _____

Mark one:

- o Low range (provide action 1 & 2)
- o Indetermine range (provide action 1, 2 & 3)
- o High range (provide action 1, 2 & 3)

Action: [] 1. Provided education
[] 2. Recommended to recheck yearly.
[] 3. referred to hepatology. Appointment date and time:

If elevated AST/ALT

[] AUDIT-C score _____
[] Hepatitis C antibody result _____
[] Hepatitis B antibody result_____
[] liver ultrasound result _____

Appendix F : NAFLD-FS Calculation: Patient form

Patient name/number_____ Date _____

Non Alcoholic Fatty Liver Disease (NAFLD) is a disease where extra fat is stored in the liver. Obese people are especially at risk for this disease. When mild, NAFLD does not cause problems, but in some people NAFLD can turn into a more severe type of NAFLD, called Non Alcoholic Steatohepatitis (NASH) with advanced fibrosis. The Non-Alcoholic Fatty Liver Disease Fibrosis Score (NAFLD-FS) is a scoring system that is used to help determine if you are at risk of this severe type. We calculate the score using the data below.

Age:
AST:
ALT:
Platelet:
Albumin:
BMI:
Insulin resistant: yes/no

NAFLD-FS = _____

Your score is:

- Low range. Patients with a score in this range have a very low risk for complications from NAFLD and it is considered safe to manage and monitor the condition with us. Healthy eating and exercise are recommended to help treat NAFLD. The ideal timeframe for recalculating the NAFLD-FS is uncertain. We recommend you have this rechecked yearly.
- Indetermine range. Patients with a score in this range have a risk for complications from NAFLD, but the exact risk is hard to determine. We recommend that you see a hepatologist (liver doctor) who can determine your risk for complications from NAFLD. We have set this appointment up for you on _____ at _____. We also will help you learn more about NAFLD and eat healthy and exercise.
- High range. Patients with a score in this range have the highest risk for complications from NAFLD, but we cannot determine if you have complications of NAFLD from this calculation alone. We recommend that you see a hepatologist (liver doctor) who can determine your risk for complications from NAFLD. We have set this appointment up for you on _____ at _____. We also will help you learn more about NAFLD and eat healthy and exercise.

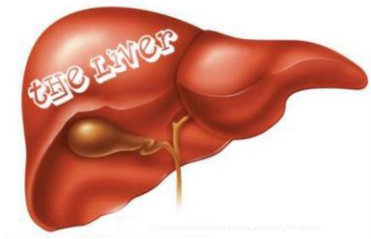
Appendix G: Patient education examples

MAKING CHANGES FOR A HEALTHIER YOU!

 TRY THIS:	 INSTEAD OF THIS:
Drink coffee, water, unsweetened tea. Eat whole fruits instead of drinking fruit juice.	Sugar sweetened drinks like fruit juices, soda, sweet tea, and sports drinks. They have too much sugar. This extra sugar is turned into fat by your body
Whole wheat pasta and grains. Vegetable pasta	White pasta, breads, and grains
Vegetables, Vegetables, and Vegetables	Potatoes and French fries
Lean protein like fish, chicken, turkey, 90% lean beef	Red meat.
Cooking at home and bringing your lunch to work	Fast food and eating out at restaurants since there is a lot of added fat and calories. When you do eat out pick steamed vegetables, fruits, or salads for sides!
Snack on Fruits, vegetables, cheese, nuts	Pre-packaged snacks
Eating protein for breakfast like eggs. The protein will keep you feeling fuller longer	Cereal, pancakes, waffles, donuts, and other carbohydrates
Low fat white milk	Chocolate milk
Whole fruits	Fruit juice or smoothies
Taking the stairs	Taking the elevator

Other thoughts.

- Journal about what you eat for 1 week. Then, review the journal and think about healthier changes you could make from the table above. Pick one change each week that you can make to get you to the healthier target.
- When grocery shopping: Spend most of your time in the produce section!
- Learn about a "Healthy Eating Plate". https://www.hsph.harvard.edu/nutritionsource/healthy-eating-plate/
- Learn more about carbohydrates. http://www.diabetes.org/food-and-fitness/food/what-can-i-eat/understanding-carbohydrates/types-of-carbohydrates.html



WHAT IS NON-ALCOHOLIC FATTY LIVER DISEASE?

The liver is on the right side of your body and sits underneath the right lung at the bottom of your ribs. The liver has many jobs. It cleans your blood and helps remove harmful things from your body. It also helps to make sure your blood cells do their job. It also helps turn the food you eat into energy.

Non-alcoholic fatty liver disease (NAFLD) is a liver problem that happens when fat builds up in the liver. There are two types of NAFLD. Non-alcoholic fatty liver (NAFL) and Non-alcoholic steatohepatitis (NASH). NAFL means that there is only extra fat in the liver but it is not causing any problems. NASH means that the extra fat has irritated and damaged the liver (also called inflammation). Sometimes this irritation causes scars in the liver that make it stiff. This is called fibrosis. The liver can still do its job even with the scars. But, sometimes the scars can get worse and take up too much space in the liver for the healthy parts to work right. This is called cirrhosis. In some patients the liver can stop working because of cirrhosis. When this happens it is called liver failure.

In NAFLD, the extra fat in the liver comes from eating too much unhealthy food, drinking too many sugary drinks, and carrying extra body weight. Eating healthy foods, drinking less sugary drinks, exercise, and losing weight will help the liver heal and get rid of the extra fat that is irritating the liver.

Appendix H: Diary

Week of:						**Notes: (exercise, total calories, etc.**
Breakfast: -drink: -meal:	**snack:**	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Monday						
Breakfast: -drink: -meal:	snack:	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Tuesday						
Breakfast: -drink: -meal:	snack:	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Wednesday						
Breakfast: -drink: -meal:	snack:	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Thursday						
Breakfast: -drink: -meal:	snack:	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Friday						
Breakfast: -drink: -meal:	snack:	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Saturday						
Breakfast: -drink: -meal:	snack:	Lunch -drink: -meal:	snack:	Dinner -drink: -meal:	snack:	
Areas I can improve for next week:						

Appendix I - Survey from Patel et al. (2017) (edited for this project)

The highlighted answers are the correct answers

Please mark the appropriate answer for each question.

<u>More than one answer</u> may be appropriate for some questions.

3. In the United States, the prevalence of NAFLD in the general population is:

☐ Less than 5% ☐ Approx. 10% ☐ Approx. 30% ☐ Approx. 50% ☐ Unsure

4. In the United States, the prevalence of NAFLD in the obese population (BMI >30 kg/m^2) is:

☐ Less than 10% ☐ Approx. 25% ☐ Approx. 50% ☐ Approx. 70% ☐ Unsure

5. The following conditions are strongly associated with NAFLD:

a)	Overweight / obesity	☐ True	☐ False	☐ Unsure
b)	Type 2 diabetes	☐ True	☐ False	☐ Unsure
c)	Metabolic syndrome	☐ True	☐ False	☐ Unsure
d)	Chronic obstructive pulmonary disease	☐ True	☐ False	☐ Unsure
e)	Hypertriglyceridemia	☐ True	☐ False	☐ Unsure
f)	Alcohol consumption	☐ True	☐ False	☐ Unsure
g)	Hypertension	☐ True	☐ False	☐ Unsure
h)	Renal impairment	☐ True	☐ False	☐ Unsure

6. For healthy men and women, the lifetime risk of harm from alcohol-related disease is reduced by drinking:

☐ ≤ 2 standard drinks per day in men/≤1 standard drinks per day in women

☐ Related to number of binge drinking sessions

☐ ≤ 4men/≤3 women standard drinks per day ☐ Unsure

☐ ≤ 6men/≤5 women standard drinks per day

7. Isolated (simple) steatosis is associated with:

a) Liver fibrosis in many cases	☐ True	☐ False	☐ Unsure
b) Increased incidence of cardiovascular disease	☐ True	☐ False	☐ Unsure
c) Cirrhosis	☐ True	☐ False	☐ Unsure
d) Future development of type 2 diabetes	☐ True	☐ False	☐ Unsure
e) Increased liver-related mortality	☐ True	☐ False	☐ Unsure

8. NASH is associated with:

a) Liver fibrosis in many cases	☐ True ☐ False ☐ Unsure
b) Increased incidence of cardiovascular disease	☐ True ☐ False ☐ Unsure
c) Cirrhosis	☐ True ☐ False ☐ Unsure
d) Future development of type 2 diabetes	☐ True ☐ False ☐ Unsure
e) Increased liver-related mortality	☐ True ☐ False ☐ Unsure

9. A diagnosis of NASH can be made using:

a) Serum liver enzymes	☐ True ☐ False ☐ Unsure
b) Liver imaging (ultrasound, CT or MRI)	☐ True ☐ False ☐ Unsure
c) Liver biopsy	☐ True ☐ False ☐ Unsure
d) Fibroscan	☐ True ☐ False ☐ Unsure

10. Liver enzymes (ALT and AST) are sufficiently sensitive to detect underlying NAFLD-NASH? ☐

True ☐ False ☐ Unsure

11. What tests/scores can help to identify NAFLD patients with advanced fibrosis/cirrhosis:

a) Liver enzymes (ALT, AST)	☐ True ☐ False ☐ Unsure
b) Platelet count	☐ True ☐ False ☐ Unsure
c) Serum albumin	☐ True ☐ False ☐ Unsure
d) Prothrombin time	☐ True ☐ False ☐ Unsure
e) NAFLD Fibrosis Score	☐ True ☐ False ☐ Unsure
f) Fib-4 Score	☐ True ☐ False ☐ Unsure
g) Abdominal ultrasound	☐ True ☐ False ☐ Unsure
h) ELF score	☐ True ☐ False ☐ Unsure

12. Current therapeutic management of NAFLD involves:

a) Specific liver-directed pharmacologic therapy	☐ True ☐ False ☐ Unsure
b) Weight loss	☐ True ☐ False ☐ Unsure
c) Physical exercise	☐ True ☐ False ☐ Unsure
d) Pharmacologic therapy directed at weight loss	☐ True ☐ False ☐ Unsure
e) Bariatric surgery	☐ True ☐ False ☐ Unsure
f) Medical treatment of concurrent metabolic disorders	☐ True ☐ False ☐ Unsure

13. What tests/scores can help to monitor patients with NAFLD for disease progression:

a) liver enzymes (ALT, AST)	☐ True ☐ False ☐ Unsure
b) platelet count	☐ True ☐ False ☐ Unsure
c) Fibroscan	☐ True ☐ False ☐ Unsure
d) NAFLD Fibrosis Score	☐ True ☐ False ☐ Unsure
e) liver ultrasound	☐ True ☐ False ☐ Unsure
f) ELF test	☐ True ☐ False ☐ Unsure

14. In my clinic, the percentage of patients with the following factors is:

a) Type 2 diabetes	_____%

b)	Dyslipidaemia or hypertriglyceridaemia	_____%
c)	Hypertension	_____%
d)	Overweight or obesity (BMI > 28-30 kg/m^2)	_____%
e)	Alcohol excess	_____%

15. The proportion of <u>my patients</u> that are likely to have NAFLD is:

☐ None ☐≤ 5% ☐5-10% ☐10-20% ☐ 20-30% ☐ 30-40% ☐40-50% ☐>50%

16. In my clinical practice I utilize the following tools to assess my patients with NAFLD:

a)	FibroScan	☐ Yes	☐ No
b)	NAFLD Fibrosis Score	☐ Yes	☐ No
c)	Fib4 Score	☐ Yes	☐ No
d)	Abdominal ultrasound	☐ Yes	☐ No
e)	Liver enzymes	☐ Yes	☐ No
f)	APRI Score	☐ Yes	☐ No
g)	ELF test	☐ Yes	☐ No

17. The number of referrals I make to Hepatology <u>each month</u> for an opinion regarding suspected

NAFLD-NASH is: ☐ None ☐ 1-2 ☐ 3-5 ☐ 6-10 ☐ 11-20 ☐ 21-30 ☐ >30

If your answer is none

I do not refer many patients to Hepatology for NAFLD / NASH because:
- ☐ The patients do not want referral
- ☐ There is no specific pharmacotherapy available
- ☐ I manage them myself by optimising lifestyle

18. If I suspect one of my patients has NAFLD, I would:

a)	Provide information on optimising diet & exercise	☐ Yes	☐ No
b)	Provide management plan involving team approach	☐ Yes	☐ No
c)	Refer to exercise/ physical activity	☐ Yes	☐ No
d)	Refer to weight loss clinic	☐ Yes	☐ No
e)	Refer to dietician	☐ Yes	☐ No
f)	Refer to Gastroenterologist / Hepatologist	☐ Yes	☐ No
g)	Refer to Endocrinologist	☐ Yes	☐ No

19. I am unlikely to refer a patient to Hepatology unless liver function tests are abnormal: ☐ True ☐ False

20. I have the needed knowledge regarding NAFLD to diagnose, manage, and refer (when necessary) these patients

☐Strongly Disagree ☐ Disagree ☐Neutral ☐ Agree ☐ Strongly Agree

21. Comments:

Appendix J: Survey, original from Patel et al. (2017) (unedited)

Non-Alcoholic Fatty Liver Disease (NAFLD) Survey

Aim: To assess opinions of non-alcoholic fatty liver disease (NAFLD) by General Practitioners. It is anticipated that this information will help to guide appropriate referral, approaches to specialist care, resource allocation and the development of educational strategies.

Method: Conduct a cross-sectional survey of ~ one hundred General Practitioners and clinicians via a structured questionnaire. By completing the questionnaire your consent to participate is implied.

Things to know before commencing this survey:

- We are interested in your honest and genuine responses to a number of issues regarding non-alcoholic fatty liver disease.
- Your responses will not be re-identifiable.
- This is a survey of current opinions and is not designed to be a test of your knowledge of the literature.
- This questionnaire should take no more than 5-10 minutes to complete.
- Please feel free to make comments during the questionnaire (in the margin) or after the questionnaire (in the space provided) if you have any concerns or suggestions.
- A surveyor may be present during your questionnaire to facilitate the process.

Please note: All of your responses will be de-identified immediately and collated with other respondents without facility for re-identification.

Background Information

- Non-alcoholic fatty liver disease (NAFLD) is a condition characterised by excessive fat accumulation in the liver ("steatosis") in the presence of metabolic risk factors and the absence of significant alcohol intake, systemic illness or medication use known to cause fatty liver disease. (APASL guidelines 2007).
- Steatosis may occur in the absence of significant inflammation or fibrosis and is often referred to as "simple steatosis". Non-alcoholic steatohepatitis (NASH) defines a subgroup of NAFLD where steatosis is accompanied by liver cell injury and inflammation.

My Practice postcode is: ✍

My appointment is: ✍

(*e.g. GP , Adv Trainee*)

✍

Per week, the average number of <u>different</u> patients I see in clinic is:

Please tick the appropriate answer for each question.

<u>More than one answer</u> may be appropriate for some questions.

1. In Australia, the prevalence of NAFLD in the general population is:

☐ Less than 5% ☐ Approx. 10% ☐ Approx. 30% ☐ Approx. 50% ☐ Unsure

2. In Australia, the prevalence of NAFLD in the obese population (BMI >30 kg/m^2) is:

☐ Less than 10% ☐ Approx. 25% ☐ Approx. 50% ☐ Approx. 70% ☐ Unsure

3. The proportion of <u>my patients</u> that are likely to have NAFLD is:

☐ None ☐≤ 5% ☐5-10% ☐10-20% ☐ 20-30% ☐ 30-40% ☐40-50% ☐>50%

4. The following conditions are strongly associated with NAFLD:

i)	Overweight / obesity	☐ True ☐ False ☐ Unsure
j)	Type 2 diabetes	☐ True ☐ False ☐ Unsure
k)	Metabolic syndrome	☐ True ☐ False ☐ Unsure
l)	Chronic obstructive airways disease	☐ True ☐ False ☐ Unsure
m)	Hypertriglyceridaemia	☐ True ☐ False ☐ Unsure
n)	Alcohol consumption	☐ True ☐ False ☐ Unsure
o)	Hypertension	☐ True ☐ False ☐ Unsure
p)	Renal impairment	☐ True ☐ False ☐ Unsure

5. For healthy men and women, the lifetime risk of harm from alcohol-related disease is reduced by drinking:

☐ ≤ 2 standard drinks per day ☐ Related to number of binge drinking sessions

☐ ≤ 4 standard drinks per day ☐ Unsure

☐ ≤ 6 standard drinks per day

6. Isolated (simple) steatosis is associated with:

a) Liver fibrosis in many cases	☐ True ☐ False ☐ Unsure

b) Increased incidence of cardiovascular disease ☐ True ☐ False ☐ Unsure

c) Cirrhosis ☐ True ☐ False ☐ Unsure

d) Future development of type 2 diabetes ☐ True ☐ False ☐ Unsure

e) Increased liver-related mortality ☐ True ☐ False ☐ Unsure

7. NASH is associated with:

a) Liver fibrosis in many cases ☐ True ☐ False ☐ Unsure

b) Increased incidence of cardiovascular disease ☐ True ☐ False ☐ Unsure

c) Cirrhosis ☐ True ☐ False ☐ Unsure

d) Future development of type 2 diabetes ☐ True ☐ False ☐ Unsure

e) Increased liver-related mortality ☐ True ☐ False ☐ Unsure

8. A diagnosis of NASH can be made using:

a) Serum liver enzymes ☐ True ☐ False ☐ Unsure
b) Liver imaging (ultrasound, CT or MRI) ☐ True ☐ False ☐ Unsure
c) Liver biopsy ☐ True ☐ False ☐ Unsure
d) Fibroscan ☐ True ☐ False ☐ Unsure

9. Liver enzymes (ALT and AST) are sufficiently sensitive to detect underlying NAFLD-NASH? ☐

True ☐ False ☐ Unsure

10. What tests/scores can help to identify NAFLD patients with advanced fibrosis/cirrhosis:

i) Liver enzymes (ALT, AST) ☐ True ☐ False ☐ Unsure
j) Platelet count ☐ True ☐ False ☐ Unsure
k) Serum albumin ☐ True ☐ False ☐ Unsure
l) Prothrombin time ☐ True ☐ False ☐ Unsure
m) NAFLD Fibrosis Score ☐ True ☐ False ☐ Unsure
n) Fib-4 Score ☐ True ☐ False ☐ Unsure
o) Abdominal ultrasound ☐ True ☐ False ☐ Unsure
p) ELF score ☐ True ☐ False ☐ Unsure
q) Fibroscan ☐ True ☐ False ☐ Unsure

11. Current therapeutic management of NAFLD involves:

g) Specific liver-directed pharmacologic therapy ☐ True ☐ False ☐ Unsure
h) Weight loss ☐ True ☐ False ☐ Unsure
i) Physical exercise ☐ True ☐ False ☐ Unsure
j) Pharmacologic therapy directed at weight loss ☐ True ☐ False ☐ Unsure
k) Bariatric surgery ☐ True ☐ False ☐ Unsure
l) Medical treatment of concurrent metabolic disorders ☐ True ☐ False ☐ Unsure

12. What tests/scores can help to monitor patients with NAFLD for disease progression:

g)	6 monthly liver enzymes (ALT, AST)	☐ True ☐ False ☐ Unsure
h)	6 monthly platelet count	☐ True ☐ False ☐ Unsure
i)	Annual Fibroscan	☐ True ☐ False ☐ Unsure
j)	6 monthly NAFLD Fibrosis Score and/or Fib-4 Score	☐ True ☐ False ☐ Unsure
k)	Annual liver ultrasound	☐ True ☐ False ☐ Unsure
l)	Annual ELF test	☐ True ☐ False ☐ Unsure

13. In my clinic, the percentage of patients with the following factors is:

17.	Type 2 diabetes	_____%
18.	Dyslipidaemia or hypertriglyceridaemia	_____%
19.	Hypertension	_____%
20.	Overweight or obesity (BMI > 28-30 kg/m^2)	_____%
21.	Alcohol excess	_____%

14. In my clinical practice I utilise the following tools to assess my patients with NAFLD:

h)	FibroScan	☐ Yes	☐ No
i)	NAFLD Fibrosis Score	☐ Yes	☐ No
j)	Fib4 Score	☐ Yes	☐ No
k)	Abdominal ultrasound	☐ Yes	☐ No
l)	Liver enzymes	☐ Yes	☐ No
m)	APRI Score	☐ Yes	☐ No
n)	ELF test	☐ Yes	☐ No

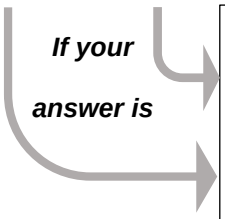
15. The centre in Metro South Heath District that I usually refer to for Hepatology is:

☐ Logan Hospital ☐ Princess Alexandra Hospital ☐ QEII Hospital

☐ Mater Hospital ☐ Private Hospitals

16. The number of referrals I make to Hepatology <u>each month</u> for an opinion regarding suspected NAFLD-NASH is:

☐ None ☐ 1-2 ☐ 3-5 ☐ 6-10 ☐ 11-20 ☐ 21-30 ☐ >30



I do not refer many patients to Hepatology for NAFLD / NASH because:
☐ The patients do not want referral
☐ There is no specific pharmacotherapy available
☐ I manage them myself by optimising lifestyle

17. If I suspect one of my patients has NAFLD, I would:

22. Provide information on optimising diet & exercise	☐ Yes	☐ No
23. Provide GP management plan & Team care arrangements	☐ Yes	☐ No
24. Refer to exercise physiologist	☐ Yes	☐ No
25. Refer to weight loss clinic	☐ Yes	☐ No
26. Refer to dietician	☐ Yes	☐ No
27. Refer to Gastroenterologist / Hepatologist	☐ Yes	☐ No
28. Refer to Endocrinologist	☐ Yes	☐ No

18. I am unlikely to refer a patient to Hepatology unless liver function tests are abnormal: ☐ True ☐ False

Any comments:

✍

Further information and who to contact

Clinical contact person	**Study Coordinator**
Professor Elizabeth Powell	Ms Leigh Horsfall
Chief Principal Investigator; Hepatologist	Clinical Research Coordinator
Tel +61 7 3443 8015	Tel +61 7 3176 1055
elizabeth.powell@health.qld.gov.au	leigh.horsfall@health.qld.gov.au

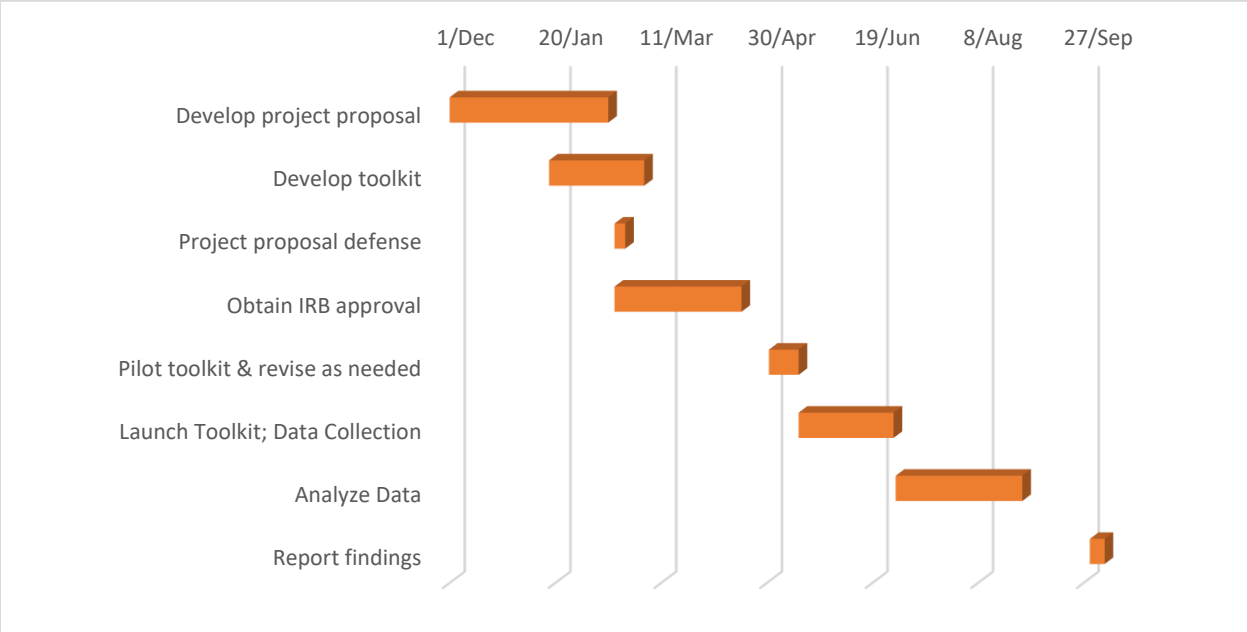
If you have any complaints about any aspect of the project, the way it is being conducted or any questions about participating in general, then you may contact the HREC approving this research and HREC Executive Officer:

Human Research Ethics Committee Coordinator, Metro South HHS HREC

Tel: +61 7 3443 8049

Patient Liaison Officer – Princess Alexandra Hospital

Appendix K: Project timeline



Task	Start Date	# Days Required
Develop project proposal	1-Dec	75
Develop toolkit	17-Jan	45
Project proposal defense	17-Feb	5
Obtain IRB approval	17-Feb	60
Pilot toolkit & revise as needed	1-May	14
Launch Toolkit; Data Collection	15-May	45
Analyze Data	30-Jun	60
Report findings	15-Sep	7

Appendix L: Project Budget

Use of google sites = free website
Development of website = volunteer hours from project director

Appendix M: Letter to participants

Dear Colleague,

As a fellow member of the Association of Missouri Nurse Practitioners, I would like to invite you to participate in a project I am conducting as a doctoral student at the University of Kansas Medical Center (KUMC) School of Nursing.

Title: An Online Toolkit to Improve Primary Care Nurse Practitioner Awareness of Non-Alcoholic Fatty Liver disease in Adults

If you choose to participate, we will ask you to take a survey, review an online tool-kit for NAFLD and repeat the survey at the end.

There are no personal risks to participating in this study beyond the usual risks associated with operating a computer and answering questions about identification and treatment of liver disease. Taking part in this project is voluntary and you may choose to start or end participation at any time over the six week study period. Therefore, you may leave and come back to the project survey/site at a later time. **Completing both the surveys will be interpreted as your consent to participate in this project**. Any data that is collected during your participation in the project will be collected anonymously and stored on a secure KUMC server.

The benefit of this study is that you may gain new knowledge on NAFLD and contribute to the findings of this study, which will be used to improve toolkits for use in primary care. Participation or not will have no impact on you and your relationship with this organization or KUMC.

Contact Kelly Casler, project director, at kcasler@kumc.edu if you have any questions about the project or the KUMC Institutional Review Board (IRB) at 3901 Rainbow Blvd., MS 1032, Kansas City, KS, 66160, (913) 588-1240, or email humansubjects@kumc.edu.

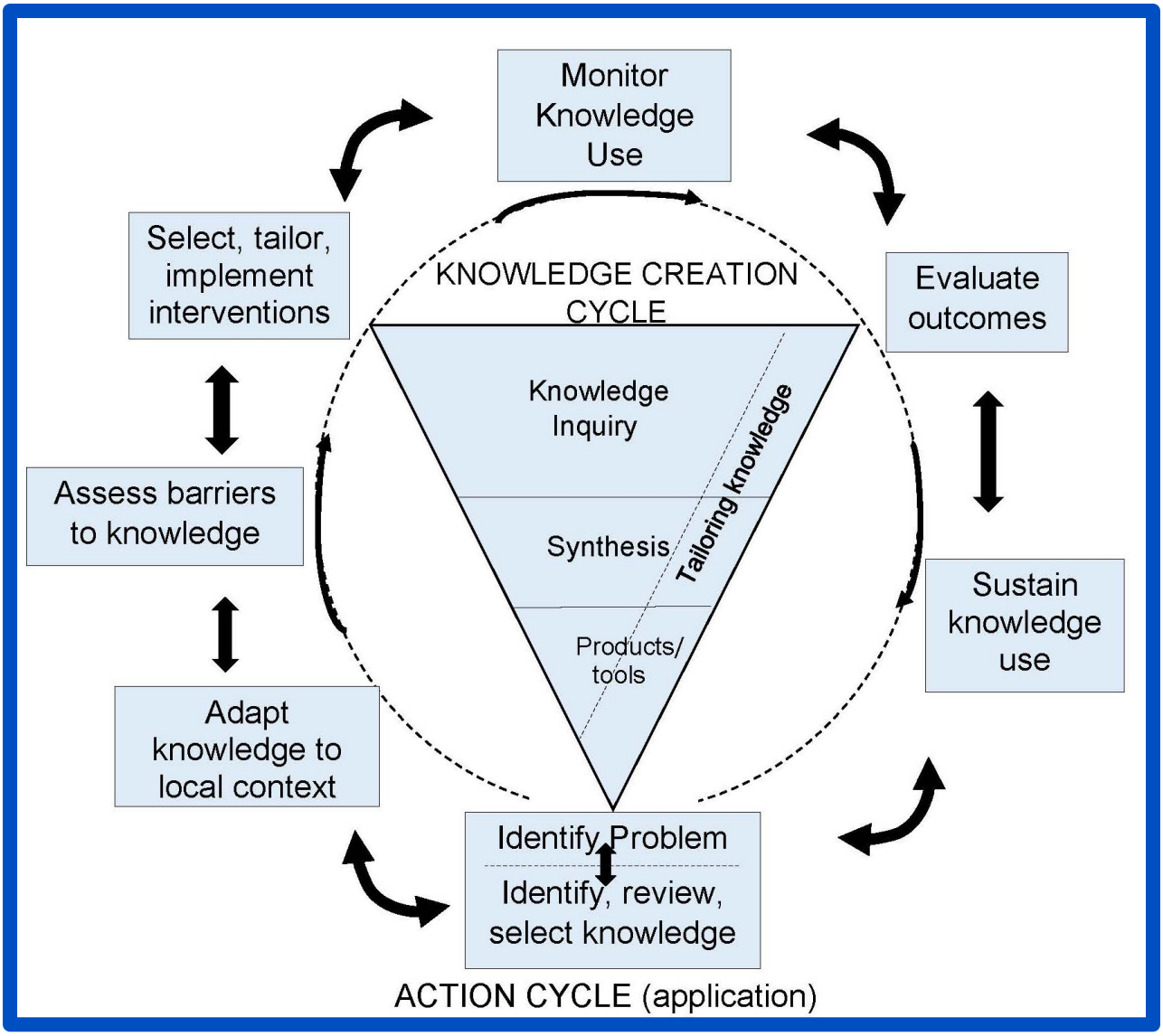
If you agree to be a participant in the project please visit the toolkit at:

https://sites.google.com/view/nafldtoolkit

Kelly Casler, MSN, FNP-BC
Family Nurse Practitioner
Doctor of Nursing Practice student
University of Kansas School of Nursing

Kelly Bosak, PhD, ANP-BC
Associate Professor
University of Kansas School of Nursing

Appendix N: Knowledge To Action Framework (Graham et al., 2006, p. 11)



Appendix O: IRB approval

The University of Kansas Medical Center

Human Research Protection Program

APPROVAL OF SUBMISSION

April 27, 2018

Kelly Bosak
kbosak@kumc.edu

Dear Kelly Bosak:

On 4/27/2018, the IRB reviewed the following submission:

Type of Review:	Initial Study
FWA#:	00003411
IRB#:	STUDY00142332
Title:	AN ONLINE TOOLKIT TO IMPROVE PRIMARY CARE NURSE PRACTITIONER AWARENESS OF NON-ALCOHOLIC FATTY LIVER DISEASE IN ADULTS
Investigator:	Kelly Bosak
IRB ID:	STUDY00142332
Funding:	None
Exemption Category:	(2) Tests, surveys, interviews, or observation
Documents submitted for the above review:	• Survey Use LOS • AHRQ Checklist for Toolkit Development • Expedited Project Description • Protocol • Online Consent Document • Toolkit Homepage • NAFLD Survey

The IRB approved this submission as of 4/27/2018.

This "exempt" approval is based upon the assurance that you will notify the HSC prior to implementing any revisions to the project. The HSC must determine whether or not the revisions impact the risks to human subjects, thus affecting the project's "exempt" status. Projects that do not meet the "exempt" criteria must comply with all federal regulations regarding research.

For more information on Human Subjects Research Policies or using the eCompliance system, please see our website at: http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board.html

Mail-Stop 1032, 3901 Rainbow Blvd., Kansas City, KS 66160
Phone: (913) 588-1240 Fax: (913) 588-5771 humansubjects@kumc.edu

Apppendix P: Phase Two Analysis Qualitative comments.

(Toolkit participants, n=11)

ID2. [22 years experience] Dietitian consult/Medical Nutrition Therapy is not covered by most insurers except for diagnosis of Diabetes or Chronic Kidney Disease. We can request consult but it is unlikely that patients will follow through after hearing the anticipated price.

ID6. [2 years as NP] very helpful and informative

ID8. [5 years as NP]It was a little hard to follow - not the best flow of the website to try to read things in the boxes. But it contained good informations

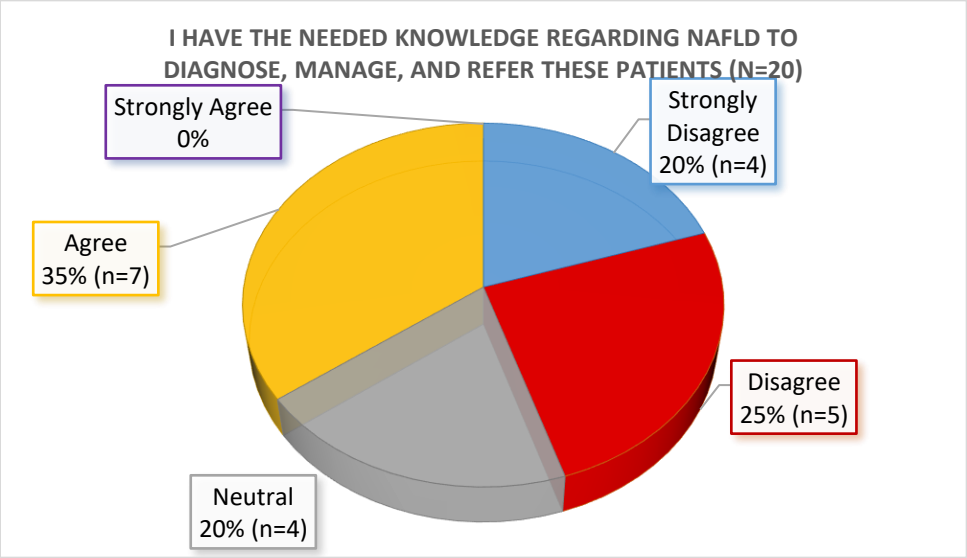
ID11. ["almost 4" years as NP] I have a large Hispanic population in my practice even as young as age 14-15 that have elevated liver enzymes and upon sonogram show fatty liver. I appreciate this activity. Thank you.

ID21. [1 year as NP] Great presentation and I hope to use this as a reminder in the future as well as for patient education.

ID24. [5 years as NP] Thank you for the useful information.

Appendix Q: Phase One analysis Question 20 analysis

(Participants only responding to pre-survey, n=20)



Appendix R: Analysis Group One - Knowledge Questions

Highlighted cells are those questions where less than 60% answered correctly

	Question	n answering correct (out of 20)	Percent answering correct
3	In the United States, the prevalence of NAFLD in the general population is:	6	0.3
4	In the United States the prevalence of NAFLD in the OBESE population (BMI>30) is:	5	0.25
5	5.The following conditions are strongly associated with NAFLD		
5a	Overweight/obesity	19	0.95
5b	T2DM	19	0.95
5c	Metabolic syndrome	18	0.9
5d	COPD	13	0.65
5e	Hypertriglyceridemia	17	0.85
5f	Alcohol consumption	11	0.55
5g	HTN	12	0.6
5h	Renal Impairment	13	0.65
6	For health men and women, the lifetime risk of harm from alcohol-related disease is reduced by drinking < 2 standard drinks per day in men, < 1 standard drink per day in women.	15	0.75
7	Isolated (simple)steatosis, or NAFL) is associated with:		
7a	liver fibrosis	4	0.2
7b	increased incidence of CVD	4	0.2
7c	cirrhosis	4	0.2
7d	future T2DM	14	0.7
7e	increased liver mortality	4	0.2
8	NASH is associated with:		
8a	liver fibrosis	17	0.85
8b	increased incidence of CVD	15	0.75
8c	cirrhosis	18	0.9
8d	future T2DM	16	0.80
8e	increased liver mortality	19	0.95
9	A diagnosis of NASH can be made using		
9a	serum liver enzymes	12	0.6

9b	liver imaging(ultrasounds, CT< or MRI)	7	0.35
9c	liver biopsy	19	0.95
9d	Fibroscan	6	0.3
10	Liver enzymes are sufficiently sensitive to detect underlying NAFLD/NASH	17	0.85
11	What tests/scores can help to identify NAFLD patients with advanced fibrosis/cirrhosis:		
11a	Liver enzymes	14	0.7
11b	platelet count	12	0.6
11c	albumin	12	0.6
11d	Prothrombin time	11	0.55
11e	NAFLDFS	13	0.65
11f	Fib-4 score	7	0.35
11g	Abdominal US	15	0.75
11h	ELF score	7	0.35
12	Current therapeutic management of NAFLD involves:		
12a	specific liver-directed pharm	6	0.30
12b	weight loss	20	1
12c	physical exercise	18	0.9
12d	pharm therapy directed at wt loss	10	0.5
12e	bariatric surgery	10	0.5
12f	treatment of concurrent metabolic disorders	19	0.95
13	What tests/scores can help to monitor patients with NAFLD for disease progression		
13a	Liver enzymes	15	0.75
13b	platelet count	9	0.45
13c	fibroscan	9	0.45
13d	NAFLDFS	14	0.7
13e	Abdominal US	16	0.8
13f	ELF score	8	0.4

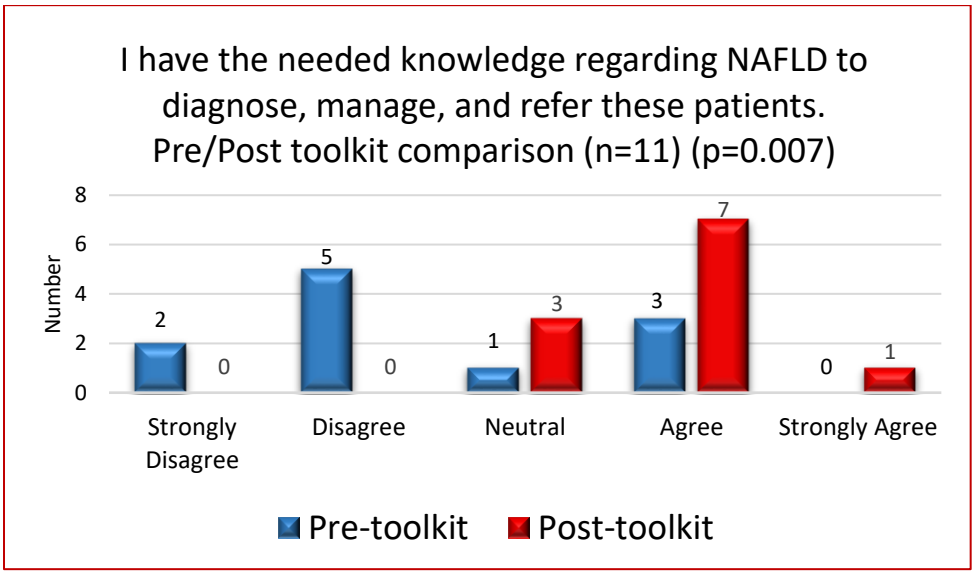
Appendix S: Analysis Group One. -Clinical behavior questions.

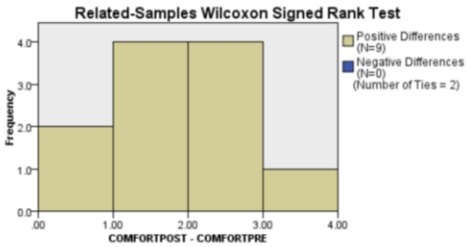
Highlighted is less than 60% selecting they used

		Question	n answering true/yes (out of 20)	percent
	16	In my clinical practice I utlize the following tools to assess/monitor my patients with NAFLD		
16a		Fibroscan	1	0.05
16b		NAFLD-FS	3	0.15
16c		Fib4	2	0.1
16d		Abd ultrasound	16	0.8
16e		liver enzymes	20	1.0
16f		APRI	3	0.15
16g		ELF test	2	0.1
	18	If I suspect one of my patients has NAFLD, I would		n/a
18a		Provide info on diet & exercise	19	0.95
18b		provide mngmt plan involving team approach	14	0.7
18c		refer to exercise/physical activity	18	0.9
18d		refer to wt loss clinic	8	0.4
18e		refer to dietician	14	0.7
18f		refer to gastroenterologist/hepatologist	15	0.75
18g		refer to endocrinologist	4	0.2
	19	I am unlikely to refer a patient to hepatology unless liver function tests are abnormal (correct answer is false)	7	0.35

Appendix T: Phase Two Analysis

Change in response on question 20 from pre-survey to post-survey





Total N	11
Test Statistic	45.000
Standard Error	8.292
Standardized Test Statistic	2.714
Asymptotic Sig. (2-sided test)	.007

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The median of differences between COMFORTPRE and COMFORTPOST equals 0.	Related-Samples Wilcoxon Signed Rank Test	.007	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

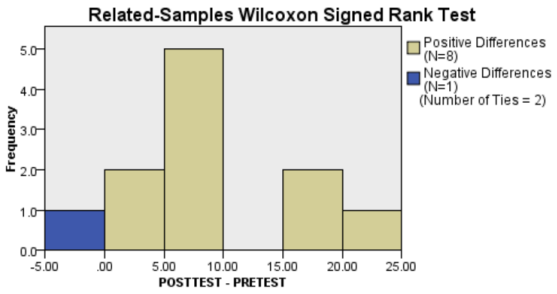
Appendix U: General Knowledge Scores – Pre-Post comparisons

	Pre-survey score	Post-survey score	Difference pre-post
	32	40	8
	16	39	23
	18	36	18
	24	32	8
	26	34	8
	34	34	0
	38	38	0
	32	38	6
	28	37	9
	15	33	18
	39	36	-3
Mean	27.45455	36.09091	8.636364
Median	28	36	8

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The median of differences between PRETEST and POSTTEST equals 0.	Related-Samples Wilcoxon Signed Rank Test	.011	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.



Total N	11
Test Statistic	44.000
Standard Error	8.404
Standardized Test Statistic	2.558
Asymptotic Sig. (2-sided test)	.011

Appendix V: Question 16b

In my clinical practice I utlize the following tools to assess/monitor my patients with NAFLD: NAFLD-FS

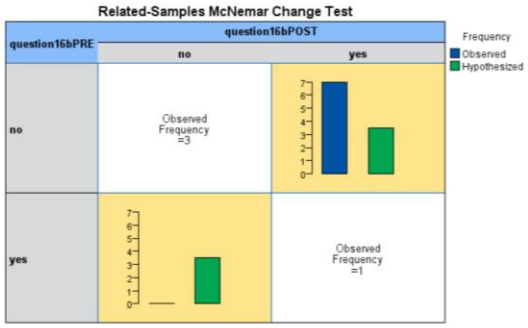
Nonparametric Tests

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distributions of different values across question16bPRE and question16bPOST are equally likely.	Related-Samples McNemar Test	.016[1]	Reject the null hypothesis.
2	The median of differences between question16bPRE and question16bPOST equals 0.	Related-Samples Wilcoxon Signed Rank Test	.008	Reject the null hypothesis.

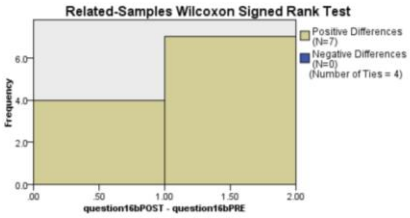
Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.



Total N	11
Test Statistic	5.143
Degrees of Freedom	1
Asymptotic Sig. (2-sided test)	.023
Exact Sig. (2-sided test)	.016

1. The exact p-value is computed based on the binomial distribution because there are 25 or fewer records.



Total N	11
Test Statistic	28.000
Standard Error	5.292
Standardized Test Statistic	2.646
Asymptotic Sig. (2-sided test)	.008

Appendix W: Question 18d

In my clinical practice I utlize the following tools to assess/monitor my patients with NAFLD: NAFLD-FS

Nonparametric Tests

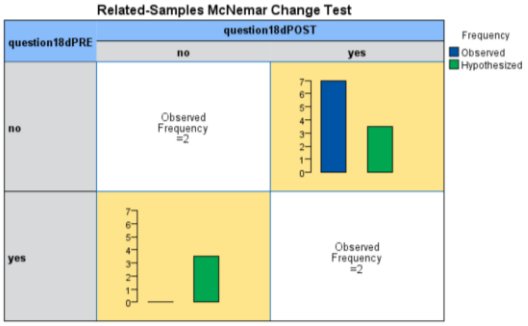
Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distributions of different values across question18dPRE and question18dPOST are equally likely.	Related-Samples McNemar Test	.016[1]	Reject the null hypothesis.
2	The median of differences between question18dPRE and question18dPOST equals 0.	Related-Samples Wilcoxon Signed Rank Test	.008	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

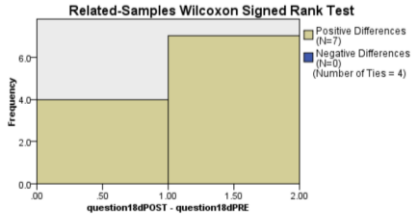
Related-Samples McNemar Change Test



Total N	11
Test Statistic	5.143
Degrees of Freedom	1
Asymptotic Sig. (2-sided test)	.023
Exact Sig. (2-sided test)	.016

1. The exact p-value is computed based on the binomial distribution because there are 25 or fewer records.

Related-Samples Wilcoxon Signed Rank Test



Total N	11
Test Statistic	28.000
Standard Error	5.292
Standardized Test Statistic	2.646
Asymptotic Sig. (2-sided test)	.008

Appendix X: Overall summary

Knowledge Questions	Pre-survey n=11	post-survey n=11	Z*	P-value
Total score				
Median score	28.0	36.0	2.558	0.011*
Mean score	27.45	36.09		
*wilcoxon matched pairs signed-rank				

Actions/Behavior questions		Pre-survey n=11	Post-survey n=11	Z*	P-value
Number reporting use/will use NAFLD-FS to assess/monitor		1	8	2.646	0.008*
Number reporting use/will use wt loss clinic referral for mngmt		2	9	2.646	0.008*
*wilcoxon matched pairs signed-rank					