Title: Comparison of diagnostic ability of focused cardiac ultrasound using an FDA approved hand-held ultrasound device with standard transthoracic echocardiogram in outpatient setting in our institution.

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1. **Protocol Title**
   Comparison of diagnostic ability of focused cardiac ultrasound using an FDA approved hand-held ultrasound device with standard transthoracic echocardiogram in outpatient setting in our institution.

2. **Objectives***
   a) To compare the diagnostic ability of focused cardiac ultrasound using an FDA approved hand-held ultrasound device in assessing cardiac anatomy, function and pericardial effusion with standard transthoracic echocardiogram in outpatient setting in our institution.
   b) To propose possible strategies for using focused cardiac ultrasound in various appropriate clinical settings in our institution.

3. **Background***
   Cardiac ultrasound is sensitive and specific for diagnosing a wide array of clinical disorders. In the field of cardiology, ultrasound is used across the entire spectrum of patient care, from fetus to elderly. Advanced imaging capabilities, such as three-dimensional (3D) and strain imaging, are incorporated in cardiac ultrasound in an effort to increase the diagnostic value. In recent years, with the development of miniaturized ultrasound systems, there is potential to change the practice of cardiac ultrasound. These devices have the advantage of smaller size, lower cost and simplified operation in comparison with the standard transthoracic echocardiographic (TTE) devices. Given the widespread availability of miniaturized ultrasound systems, several studies have demonstrated that these newer devices when used in appropriate conditions may provide diagnostic yield comparable to that of standard TTE, with regards to basic echocardiographic parameters. This study is designed to prospectively evaluate the feasibility and diagnostic accuracy of focused cardiac ultrasound (FCU) using the hand-held ultrasound device in comparison with full functionality TTE in our institution in outpatient setting. The result of this study will make an important contribution to widen the spectrum of potential usage of FCU.

Thereby, strategies for using FCU in various appropriate clinical settings could be implemented.

4. **Inclusion and Exclusion Criteria***

Inclusion criteria:

- Patients presenting to pediatric cardiology clinic at Holtz Children's hospital requiring comprehensive or limited transthoracic echocardiogram (TTE).
- Willing and able to provide informed consent or assent.
- In clinically stable condition as assessed by the principal investigator.
- With adequate echocardiographic windows.

Exclusion criteria:

- Patients with poor echocardiographic windows.
- Patients who refuse informed consent.
- Pregnant women.
- Prisoners.
- Patients deemed unfit to participate in the clinical trial as assessed by the principal investigator.

5. **Procedures Involved***

The study will take place in Jackson Memorial Hospital/University of Miami, Miami. The study will be conducted in outpatient pediatric cardiology clinic. Patients presenting for cardiac evaluation requiring a standard comprehensive or limited TTE with adequate echocardiographic views, will be included in the study. An informed consent will be obtained prior to participation from all subjects or their parents if the subject is a minor. The medical record number (MRN) and reason for referral for cardiac evaluation will be collected from medical records.

The subjects included in the study will first undergo cardiac evaluation with a standard TTE using Philips EPIQ 7 ultrasound machine. TTE will be comprehensive or limited based on the clinical indications. Immediately after the standard TTE, the same subject will then undergo FCU using an FDA approved hand-held ultrasound device (Philips Lumify broadband sector array transducer). The Philips Lumify broadband sector array transducer has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) which was announced at the American College of Emergency Physicians' (ACEP) annual meeting in October 2016. The Philips lumify portable ultrasound probe will be plugged in to a Samsung Galaxy Tablet S3. Lumify app will be installed in the Samsung Galaxy Tablet S3 which will be password protected. The echocardiographic images will be viewed and stored in Lumify app. The images will subsequently be transferred to University of Miami Philips Xcelera system, where it will be stored for 6 years. Approval for the usage of Samsung Galaxy Tablet S3 is obtained from department of biomedical engineering at Jackson Memorial Hospital. Approval for storing images in University of Miami Philips Xcelera system is obtained from the department of information technology (IT). For FCU, the images will be obtained in subcostal, apical, parasternal long, and parasternal short axis views to assess cardiac anatomy, left ventricular systolic function and pericardial effusion. All TTE images will be performed by a pediatric

cardiology fellow or a registered diagnostic cardiac sonographer (RDCS). All FCU images will be obtained by a pediatric cardiology fellow who will be blinded for findings in TTE. TTE will be interpreted and reported by an expert pediatric cardiology attending physician. FCU using hand-held ultrasound will be interpreted and reported by another expert pediatric cardiology attending physician who will be blinded for findings in TTE. The summary report will include the cardiac anatomy, left ventricular systolic function, and pericardial effusion. For each patient included in the study, the findings of TTE will be compared with that of FCU. The data obtained will be statistically analyzed as below.

6. **Data Storage***
   Relevant coded data would be stored in form of Microsoft Excel Spreadsheet in a storage drive accessible to the PI and the secondary investigators exclusively. The drive would be password protected limiting the access to primary and secondary investigators only. The data would be stored for six years following study closure.

7. **Data Management***
   Data will be analyzed using SPSS software creating frequency tables, tests of significance and univariate and multivariate analysis.
   Data collected will be coded, de-identified and stored physically in a password protective drive with limited access. All the coded data transmitted electronically would be through secured mail system of Jackson Health system.

8. **Risks to Subjects***
   Ultrasound is generally considered safe with very low risks. FCU involves standard risks associated with ultrasound.
   Patient information will be collected. Although every measure will be taken in order to prevent any possible compromise of patient data (safe storage, password encryption, limited access, etc), the risks associated with possible disclosure of patient data are present. The risks include attainment of patient information by some third party – how they could use this information even if it were compromised, is not easily foreseen. Identifying variables (name, MRN, etc) will not be stored to minimize the risks, simply the variables that we are interested in. Although disclosure of patient information is conceptually possible, it is highly unlikely seeing as how we will take every possible precaution and not store any identifying information

9. **Potential Benefits to Subjects***
   There is no direct benefit but by studying the diagnostic accuracy of FCU using hand-held ultrasound device in assessing cardiac anatomy, function and pericardial effusion in comparison with comprehensive TTE. However, based on the findings from the study, we can propose possible strategies for using FCU in various appropriate clinical settings in our institution.

10. **Vulnerable Populations***
    The study involves subjects who have not attained the legal age of consent to treatments or procedures, and a written consent will be obtained from subject's parents.

11. **Setting**
    The study will take place in Jackson Memorial Hospital/University of Miami, Miami. The study will be conducted in outpatient pediatric cardiology clinic. Patients presenting for cardiac evaluation requiring a standard comprehensive or limited transthoracic echocardiogram (TTE) with adequate echocardiographic views, will be included in the study. An informed consent will be obtained prior to participation from all subjects or their parents if the subject is a minor.

12. **Resources Available**
    a. The FCU will be performed by a pediatric cardiology fellow (secondary investigator) who is trained in performing and interpreting the cardiac ultrasound.
    b. The study will be interpreted and the findings will be compared to the findings from standard TTE by a pediatric cardiology attending (principal investigator).
    c. Data collection and analysis will be done by the secondary investigator.

13. **Prior Approvals**
    None

14. **Recruitment Methods**
    The study will take place in Jackson Memorial Hospital/University of Miami, Miami. The study will be conducted in outpatient pediatric cardiology clinic. The medical record number and the indication for cardiac evaluation will be obtained by reviewing the patient's electronic medical record. Patients presenting for cardiac evaluation to outpatient cardiology clinic requiring a standard comprehensive or limited TTE with adequate echocardiographic views, will be included in the study. On individuals meeting the inclusion criteria as above, upon completion of the standard TTE, a written consent will be obtained by the study coordinator to be included in the study. Individuals refusing consent will be excluded from the study.

15. **Local Number of Subjects**
    We expect about 40 people here will be in this research study.

16. **Provisions to Protect the Privacy Interests of Subjects**
    Data will be collected and stored using a number to identify each patient in place of their name. The final data sheet and the results of the study would be devoid of

identifiers. The identifications would be used strictly for preliminary data gathering only and would not be used for any other purpose than this study alone.

17. **Consent Process**

A written consent form will be obtained from the patient in pediatric cardiology clinic during the clinic visit.
For subjects below 18 years of age, written consent form will be obtained from the parent.
For subjects who speak Spanish, oral and written information provided to those subjects will be in Spanish.