**S3. Online Supplement 3: Echo Z-Score Lessons Learned Questionnaire**

1. Screening of participants
2. Which of the following describes how your Center screened for potential eligible participants (please mark all that apply)?

☐ Echo database

☐ Asking echo readers to note/keep track of normal echos

☐ Clinic lists/paper chart review

☐ Other (if other, please explain) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Did your Center keep a screening log?

☐ Yes

☐ No

If no, please go to question 2

If yes, did your Center keep track of the reasons for not sending and echo to the Core lab?

☐ Yes

☐ No

If yes, did you track if an echo was excluded based on:

1. Inclusion/exclusion criteria?

☐ Yes

☐ No

1. Echo quality?

☐ Yes

☐ No

1. If your Center kept a screening log, please complete the table below; if your Center did not track reasons for not sending echos to the Core lab, please put N/A in columns requesting that information):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number of echocardiograms screened, reasons for not sending to Core lab, # sent to the Core Lab | | | | |
|  | # echos screened | # echos excluded based on inclusion/exclusion criteria | # echos excluded based on echo quality | # echos sent to Core Lab |
| Start of study – 11/1/2013 (early period) |  |  |  |  |
| 11/2/2013 - 8/1/2014  (mid period) |  |  |  |  |
| 8/2/2014 – end of study (late period) |  |  |  |  |

1. When screening for echo quality, were echos screened by (please check all that apply):

☐ Sonographer alone

☐ Sonographer initially, then site PI(s)

☐ Site PI(s) alone

☐ Other (if other, please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Did your Center track specific reasons why an echo was deemed inadequate locally?

☐ Yes

☐ No

1. If your Center tracked reasons why echos were not sent to the Core lab based on echo quality, please mark the top 3 reasons/areas where measurements could not be obtained:

☐ Parasternal or subxiphoid short-axis clip at the level of the MV papillary muscles for LV wall thickness, cavity diameter (dia), and area measurements

☐ Parasternal long-axis clips of the LVOT to assess aortic annular, root, and ascending aorta dias

☐ Parasternal long-axis clip of the mitral inflow for mitral anteroposterior annular dia

☐ Parasternal long-axis clip of the tricuspid inflow for tricuspid anteroposterior annular dia

☐ Parasternal short-axis or long-axis clip of the RV outflow tract for pulmonary annular dia

☐ Apical 4-chamber clip at the cardiac crux for LV endocardial and epicardial long-axis dimensions and for mitral and tricuspid lateral annular dias

☐ Imaging to measure dias of: the main and branch pulmonary arteries OR aortic arch and isthmus OR proximal right, left main, and left anterior descending coronary arteries

☐ Other (if other, please explain)

1. Did your Center prospectively consent and enroll participants? This question is based on a Memo dated 9/3/2015, allowing “for a small number of study subjects at a limited number of participating Centers to be prospectively enrolled to this study” due to difficulty enrolling infants retrospectively. Of note, this does not refer to the prospective consent and acquisition of race/ethnicity data performed in Toronto.

☐Yes

☐ No

If your Center prospectively consented and enrolled participants, please answer the following:

1. Was an IRB amendment submitted for prospective enrollment?

☐Yes

☐No

B. If an IRB amendment was submitted for prospective enrollment, what were the dates the amendments were submitted and approved?

IRB amendment submitted: \_\_\_\_/\_\_\_\_/\_\_\_\_

IRB amendment approved: \_\_\_\_/\_\_\_\_/\_\_\_\_

C. What date did prospective enrollment start?

Prospective enrollment start date: \_\_\_\_/\_\_\_\_/\_\_\_\_

1. How many participants were prospectively enrolled? \_\_\_\_\_\_\_\_\_\_\_
2. Please complete the following tables describing participants enrolled prospectively:

Male

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Race | < 1 month | 1 month-3 yrs | 3-6 yrs | 6-12 yrs | 12-16 yrs | 16-18 yrs | Total |
| White |  |  |  |  |  |  |  |
| African-American |  |  |  |  |  |  |  |
| Other or mixed |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |

Female

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Race | < 1 month | 1 month-3 yrs | 3-6 yrs | 6-12 yrs | 12-16 yrs | 16-18 yrs | Total |
| White |  |  |  |  |  |  |  |
| African-American |  |  |  |  |  |  |  |
| Other or mixed |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |

1. How was retrospective enrollment carried out at your Center (please choose the best answer)?

☐ Clinically indicated echo studies that were performed after the launch date were eligible for enrollment and considered retrospective if enrollment took place after the study was already performed.

☐ No echo studies performed after the launch date were considered eligible for retrospective enrollment until after an IRB amendment was submitted and approved, after which studies performed prior to IRB amendment approval became eligible for retrospective enrollment.

☐ No echo studies performed after the launch date were eligible for retrospective enrollment even if an IRB amendment was submitted

1. If your Center required IRB amendments for ongoing retrospective collection, when were

amendments submitted and approved?

IRB amendment submitted: \_\_\_\_/\_\_\_\_/\_\_\_\_

IRB amendment approved: \_\_\_\_/\_\_\_\_/\_\_\_\_

4. Which of the following best describes how your Center considered Hispanic designation?

☐ As a race category alone (Your center considered Hispanic to be a race category in itself, and therefore not one of the 3 designated race categories specified by the Echo Z-score protocol (White, African-American, or Other/Mixed which included Asian, American-Indian or Alaska Native, and Native Hawaiian or other Pacific Islander), and therefore excluded subjects (Question 4A).

☐ As an ethnicity category alone [Your  center considered Hispanic as an ethnicity category, but did not have it associated with race (i.e., White Hispanic, black Hispanic, etc.), and so excluded these subjects]

☐ As an ethnicity category with a different specified race designation (i.e. White Hispanic, black

Hispanic) (Your Center considered Hispanic as an ethnicity category and it was combined with race, so no patients would have been excluded because of this).

☐ Other (if other, please explain) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Did your Center have to exclude Hispanic patients, or “throw out” data on Hispanic patients because that information was not combined with a race designation (such as White Hispanic) before the memo on 3/20/2015, stating that the “other or unknown category” would be available for patients with Hispanic ethnicity?

☐ Yes

☐ No

1. If your Center had to exclude, or “throw out” data on, Hispanic patients, are the data available regarding how many patients were excluded?

☐ Yes

☐ No

If the data are available, what is the number of patients excluded/data “thrown out”?