SYSTEMS AND METHODS FOR IMPROVING DETECTION OF FETAL CONGENITAL HEART DEFECTS

Abstract

Systems and methods are provided for aiding the detection and diagnosis of critical heart defects during fetal ultrasound examinations, in which image data (e.g., motion video clips and/or image frames) is analyzed with machine learning algorithms to detect and identify morphological and/or flow abnormalities indicative of critical CHDs. The results of the analyses are presented for review to the clinician, optionally with an overlay, for the selected image frames that identifies the abnormalities with graphical or textual indicia. The overlay further may be annotated by the clinician and stored to create documentary record of the fetal ultrasound examination.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a divisional of U.S. patent application Ser. No. 18/828,923, filed Sep. 9, 2024, which is a continuation-in-part of U.S. patent application Ser. No. 18/406,446, filed Jan. 8, 2024, now U.S. Pat. No. 12,082,969, which is a continuation-in-part of U.S. patent application Ser. No. 18/183,937, filed Mar. 14, 2023, now U.S. Pat. No. 11,869,188, which claims priority to EP patent application Ser. No. 23/305,235.6, filed Feb. 22, 2023, the entire contents of each of which are incorporated herein by reference. U.S. patent application Ser. No. 18/406,446, filed Jan. 8, 2024, now U.S. Pat. No. 12,082,969, also claims priority to U.S. Provisional Application No. 63/584,117, filed Sep. 20, 2023, the entire contents of which are incorporated herein by reference.

FIELD OF USE

[0002] The present invention is directed to systems and methods for improving detection of fetal congenital heart defects during and after ultrasound examination by using machine learning algorithms to ensure creation of a complete dataset, conduct preliminary review of the completed dataset, and determine datasets to be designated for expert review.

BACKGROUND

[0003] Congenital heart disease (CHD) is the most common birth defect with a prevalence of about 0.8-1% among all births. As of 2014, in the United States, CHD accounts for 4% of neonatal deaths, and for 30% to 50% of deaths related to congenital anomalies. A study by Nayak, et al. entitled "Evaluation of fetal echocardiography as a routine antenatal screening tool for detection of congenital heart disease," Cardiovasc. Diagn. Ther. 6, 44-49 (2016) demonstrated that 92% of CHD occurred in pregnancy defined as "low risk." Stumpflen, et al., in a study entitled "Effect of detailed fetal echocardiography as part of routine prenatal ultrasonographic screening on detection of congenital heart disease," The Lancet 348, 854-857 (1996) observed that most CHD are identified during the second trimester of pregnancy screening exam, supporting the need for a universal fetal heart screening exam during the second trimester of the pregnancy.

[0004] CHD is often asymptomatic in fetal life but causes substantial morbidity and mortality after birth. In addition to adverse cardiac outcomes, CHD is associated with an increased risk for adverse neurodevelopmental outcomes, associated with factors such as associated chromosomal

abnormalities, syndromes, postnatal cardiac dysfunction, and in utero hemodynamic abnormalities. Critical CHD (see Table 1), defined as requiring surgery or catheter-based intervention in the first year of life, accounts for approximately 25 percent of all CHD. See, Oster, M. E. et al., "Temporal trends in survival among infants with critical congenital heart defects," Pediatrics 131, e1502-1508 (2013). In infants with critical cardiac lesions, the risk of morbidity and mortality increases when there is a delay in diagnosis and timely referral to a tertiary center with expertise in treating these patients. See Kuehl, K. S., et al. "Failure to Diagnose Congenital Heart Disease in Infancy," Pediatrics, 103:743-7 (1999): Eckersley, L., et al., "Timing of diagnosis affects mortality in critical congenital heart disease," Arch. Dis. Child. 101, 516-520 (2016).

TABLE-US-00001

TABLE 1

Critical Congenital Heart Defects	Prevalence	Prenatal diagnosis (%) (based on ultrasound)
Coarctation of the aorta (COA)	4 per 10 000 birth	11% to 22%
Atrioventricular septal defect	3.8 per 10 000 live birth	40.8% to 66%
Conotruncal lesions	up to 20% of CHD	24% to 26% detected prenatally
Transposition of the great arteries (TGA)	3.7 per 10 000 live birth	14% to 19%
Total anomalous pulmonary venous connection (TAPVC)	1.3 per 10 000 live birth	0% to 9.1%
Univentricular heart	1.1 per 10 000	56% to 85%
Hypoplastic left heart syndrome (HLHS)	2.7 per 10 000	56% to 83%
Valvular stenosis Aortic valve stenosis: Aortic stenosis:	1.1 per 10 000	8.5% to 25.5%
Pulmonary valve stenosis: Pulmonary stenosis:	1.5 per 10 000	37% to 44%

[0005] Compared to postnatal diagnosis, fetal diagnosis can dramatically improve neonatal outcomes by anticipating delivery care, surgical and/or early interventional planning and in some cases, considering in utero therapies. Further, accurate antenatal diagnosis allows the parents to make an informed decision regarding the continuation of pregnancy.

[0006] Distinguishing normal fetal hearts from those exhibiting complex forms of CHD typically involves an initial screening exam performed by physicians, nurse practitioners, physician assistants, ultrasound technicians, and other providers trained in diagnostic obstetric ultrasonography. Licensed medical providers who meet the training specialty guidelines are responsible for the interpretation of the ultrasound examination. Further examination via fetal echocardiography is warranted if the ultrasound is abnormal for confirmation and diagnosis refinement. Further examination may also be warranted under circumstances such as a family history of congenital heart defect, presence of maternal diabetes, or use of in vitro fertilization. Only well-trained and/or experienced pediatric cardiologists, maternal-fetal medicine specialists, obstetricians, or radiologists who have acquired the appropriate knowledge base and skills supervise and perform such fetal echocardiograms. Low sensitivity in this task can limit palliation options, worsen postnatal outcomes and hamper research on in utero therapies, while low specificity can cause unnecessary additional testing and referrals.

[0007] The World Health Organization (WHO) recommends that all pregnant women have one ultrasound scan before 24 weeks of pregnancy to estimate gestational age (GA), assess placental placement, determine single or multiple pregnancies, increase fetal abnormality detection, and improve pregnancy outcomes. WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience (World Health Organization, 2016).

[0008] In 2013 and 2018, both the American Institute of Ultrasound in Medicine (AIUM) and the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) changed their practice guidelines for fetal heart screening of mid-gestation fetuses. See, Carvalho et al., "ISUOG Practice Guidelines (updated): sonographic screening examination of the fetal heart: ISUOG Guidelines," Ultrasound Obstet. Gynecol. 41, 348-359 (2013); "AIUM-ACR-ACOG-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetric Ultrasound Examinations," J. Ultrasound Med. 37, E13-E24 (2018). These updated guidelines specified a minimum of three views: the four-chamber view (4C) and views of the left (LVOT) and right (RVOT) ventricular outflow tracts (2, 3). Unfortunately, several heart malformations are not well detected prenatally with this approach. While the three-vessel (3V) and three-vessels-and-trachea (3VT) views are not

mandatory in the AIUM and ISUOG practice guidelines, both guidelines state that these views are desirable and should be attempted as part of routine screening. See Table 2. Many groups already perform additional views during routine screening and report higher fetal heart malformation detection rates, of 62-87.5%, compared with 40-74% using the recommended three views, as described in "Committee on Practice Bulletins—Obstetrics and the American Institute of Ultrasound in Medicine, Practice Bulletin No. 175: Ultrasound in Pregnancy," Obstet. Gynecol. 128, e241-e256 (2016).

TABLE-US-00002 TABLE 2 Transverse abdominal view Transverse abdominal view showing the fetal stomach (St), cross-section of the descending aorta (dAo), spine (Sp) and liver (Li). Four-chamber view (4C) 4C view showing the right and left ventricles (RV, LV) and atria (RA, LA), foramen ovale (FO) and pulmonary veins (PV) to the right and the left of the descending aorta (dAo). Left ventricular outflow LVOT view showing the tract view (LVOT) aortic root (Ao), LV, RV, LA and RA and a cross-section of the dAo. Right ventricular outflow RVOT view showing the tract view (RVOT) main pulmonary artery (MPA) and the bifurcation into the right (RPA) and left (LPA) pulmonary arteries and cross-sections of the ascending aorta (Ao) and descending aorta (dAo).

[0009] Some critical CHD are more amenable to visualization through ultrasound screening during the pregnancy than others. Using 1997-2007 data from the Utah Birth Defect Network, Pinto et al., in "Barriers to prenatal detection of congenital heart disease: a population-based study," Ultrasound Obstet. Gynecol. Off. J. Int. Soc. Ultrasound Obstet. Gynecol. 40, 418-425 (2012), observed that the defects most likely to be detected prenatally included those with abnormal four-chamber views, while defects exhibiting abnormal outflow tracts were much less likely to be detected prenatally. In a study of members of a large health maintenance organization (HMO) in California from 2005 to 2010, Levy et al., in "Improved prenatal detection of congenital heart disease in an integrated health care system," Pediatr. Cardiol. 34, 670-679 (2013), showed that women who received care from HMO clinics that had instituted a policy to examine outflow tracts during prenatal ultrasound had much higher prenatal diagnosis rates (59%) compared to HMO clinics that had not instituted such a policy (28%).

[0010] In current triaging workflows, a patient typically presents at a first point of care (OB-Gyn, Midwife or radiologist), where an assessment of the fetus is performed, e.g., via a fetal ultrasound screening performed by the healthcare professional or by a sonographer. The image data is interpreted in real time by a first line practitioner during the ultrasound exam or off line, after the exam has been performed. The report is generated by the first line practitioner and might be pre-filled in by the sonographer. If a congenital heart defect is suspected, the patient is referred to a specialist who will review the report, and perform a specific exam (echocardiography, genetic test) intended to confirm the presence or absence of the potential congenital defect. Depending upon the outcome of that further exam or test, a decision is made regarding treatment and/or transfer of the patient to a follow-up point of care.

[0011] Drawbacks to previously-known CHD screening workflow are numerous, and generally include: inaccuracy and low specificity caused by improper examination technique, time pressure, obesity of the mother, and simple misdiagnosis. In particular, CHD detection during a second trimester ultrasound exam is often as low as 30%. Specificity also is suboptimal, as low as 40-50% due to a lack of skill in adapting ultrasound images (i.e., ultrasound operator lacks the skill needed to obtain data from which a correct diagnosis can be made, resulting in about 49% of the misdiagnoses; lack of experience in formulating an accurate diagnosis (i.e., the images obtained are sufficient and the prenatal pathology is visible, but not recognized by the operator, resulting in about 31% of the misdiagnoses; the pathologies cannot be detected because they are not visible on the ultrasound images, accounting for about 20% of missed diagnoses. Time pressures associated with achieving adequate patient throughput in the clinical setting can exacerbate the foregoing issues, especially when transfer of a patient to a specialist is required.

[0012] While some efforts have been made to improve CHD detection during routine prenatal ultrasound examination, much is left to be done. For example, there is considerable guidance available to ultrasound technicians describing how to obtain a complete, high diagnostic quality dataset of images during an examination, and how to confirm the presence of cardiac structure in real time during an examination. For example, U.S. Pat. No. 7,672,491 to Krishnan et al. describes a system for evaluating the diagnostic quality of images acquired during an ultrasound examination that uses machine learning to compare the acquired images to expected images.

[0013] As discussed above, the ISUOG Practice Guidelines, published in Ultrasound Obstet. Gynecol. 2013; 41:348-359 suggests five axial locations that should be imaged during a routine fetal heart ultrasound examination, as well as the principal organs and vessels and orientations of each that should be confirmed at each location. European Patent Application Publication EP 3964136 to Voznyuk et al. describes a machine learning system that analyzes ultrasound images generated during an examination, uses a first convolutional neural network (CNN) to compare acquired images to views required by those guidelines, and a second CNN to analyze the images to identify potential abnormalities.

[0014] U.S. Patent Application Publication No. US 2021/0345987 to Ciofolo-Veit et al. describes an ultrasound imaging system that uses machine learning algorithms to analyze acquired images to detect anomalous features, and if an anomalous feature is detected, uses machine learning algorithms to determine and display other previously-acquired ultrasound images that provide complementary views of the potential anomalous feature to permit improved diagnosis.

[0015] In addition, a fetal ultrasound screening examination typically generates thousands of image frames spanning multiple structures per single video "sweep," so the diagnostic frames of interest for CHD may be only a handful and thus are easily missed. Moreover, the prevalence of CHD in the population (~0.8-1%) is low enough that non-experts see it only rarely and may discount or overlook abnormal images. Together, these factors make CHD detection one of the most difficult diagnostic challenges in ultrasound, with a dramatic impact on post-natal outcomes and quality of life.

[0016] In view of the foregoing, it would be desirable to provide methods and apparatus for triaging prenatal ultrasound scanning to improve accuracy of congenital defect detection, and subsequent management.

[0017] It further would be desirable to provide a machine-learning enabled system for pre-natal fetal ultrasound configured to review recorded ultrasound video and to identify images from the video that correspond to the views recommended by the guidelines.

[0018] It still further would be desirable to provide methods and systems for conducting prenatal ultrasound examinations that assist the sonographer in collecting a high-quality dataset in accordance with applicable guidelines, assist the interpreting physician and/or technician in identifying potential abnormalities in the acquired data, and moreover, in real time guides the sonographer to acquire additional views to augment the image dataset, e.g., to facilitate specialist review.

[0019] It still further would be desirable to provide methods and systems for objectively evaluating the performance of the sonographer over multiple exams.

SUMMARY

[0020] The present invention is directed to systems and methods for conducting fetal ultrasound examinations that aids in the detection of critical heart defects during a second semester ultrasound exam. The inventive systems and methods help trained and qualified physicians to interpret ultrasound recording motion video clips by analyzing video clips and identifying a risk of one or more abnormalities of the fetal anatomy. For example, the systems and methods of the present invention may assist in detecting and identifying morphological abnormalities that might be indicative of critical CHDs.

[0021] In one embodiment, the systems and methods are embodied in a computer assisted

diagnostic aid for use in two-dimensional prenatal ultrasound exams of fetuses, such as usually performed during the second trimester of pregnancy. Machine learning algorithms are employed to assist users with the identification and interpretation of standard views in fetal cardiac ultrasound motion video clips. In particular, the inventive systems and methods are embodied in software that may be executed to support identification of critical CHDs. In addition, information generated during the machine learning augmented analyses may be stored for later referral to an expert (e.g., specialist) to assist further diagnosis and treatment planning.

[0022] In a preferred embodiment, the inventive system employs two components: a user interface component that provides a clinician tools to analyze and review fetal ultrasound images and ultrasound motion video clips, and a machine learning interpretative component that receives ultrasound motion video clips and images from a conventional fetal ultrasound screening system, identifies images within the motion video clips that correspond to fetal ultrasound screening guidelines. The interpretative component also analyzes the identified images to detect and identify the presence of morphological abnormalities, and provides that information to the user interface component to highlight such abnormalities for the clinician's review. The interpretative component may be executed partially or fully on a local computer workstation in real-time. Alternatively, the interpretative component may reside on a cloud-based server and interact with the user interface component via a secure connection on a local or wide area network, such as the Internet.

[0023] In accordance with another aspect of the invention, the methods and systems provide a consistent process to ensure that all views suggested by the practice guidelines for fetal exams are acquired. In particular, if the machine-learning based review of the motion video clips from the fetal ultrasound scan does not identify an image frame determined as appropriate for review, the system will flag that view as being unavailable or of inadequate quality to permit analysis for abnormality detection, the user interface will direct the clinician to re-perform the ultrasound scan to acquire the missing data. The new motion video clip then is transmitted to the interpretive component for analysis and a supplemental analysis will be returned to the user interface for presentation to the clinician.

[0024] In accordance with another aspect of the invention, the analysis results returned to the user interface component may be displayed and further annotated by the clinician to include additional graphical indicia or textual remarks. The resulting analysis results and annotations may be stored for later referral to an expert to develop a plan for further diagnosis or treatment.

[0025] In accordance with another aspect of the invention, analysis and/or results, including detected morphological abnormalities, may be used to generate a report. The report may be automatically populated with entries for each standard view using frames of video clips, which may include bounding box overlays. Information about the view may be included in the report to add context to the images.

[0026] In accordance with another aspect of the invention, the system may recommend a referral to a clinician and/or expert. In accordance with another aspect of the invention, the system may perform an objective evaluation of the technician that performed the imaging (e.g., the sonographer). In accordance with another aspect of the invention, the system may automatically organize the results with the most relevant information appearing first or otherwise most prominently. Additionally, or alternatively, the results may be organized by patient in order of severity.

[0027] In another embodiment, systems and computer implemented methods for analysis of fetal ultrasound images are provided. The systems and methods may include receiving a plurality of sets of image data generated by an ultrasound system during a fetal ultrasound examination, each set of image data of the plurality of sets of image data including a plurality of frames; analyzing a set of image data of the plurality of sets of image data to automatically determine that one or more frames of the set of image data corresponds to a standard view of a plurality of standard views; analyzing the set of image data to automatically determine that the one or more frames is indicative of a first

morphological abnormality of a plurality of morphological abnormalities; generating a user interface for display, wherein the user interface includes: an image data viewer adapted to visually present the set of image data; a standard view indicator corresponding to the set of image data presented on the image data viewer and visually indicating whether each standard view of the plurality of standard views is present in the set of image data; and a morphological anomaly indicator corresponding to the set of image data presented on the image data viewer and visually indicating whether each morphological abnormality of the plurality of morphological abnormalities is present in the set of image data, wherein the standard view indicator indicates that a first standard view is present in the set of image data and the morphological anomaly view indicator indicates a first morphological abnormality is present when the image data viewer visually presents the set of image data.

[0028] The user interface may be generated on a display of the ultrasound system and/or generated on a display of a health care provider device. The standard view indicator may include a plurality of color indicators each corresponding to one of the plurality of standard views, each color indicator of the plurality of color indicators adapted to present a first color when a respective standard view of the plurality of standard views is present in the set of image data and a second color when the respective standard view of the plurality standard views is not present in the set of image data. The morphological anomaly indicator may include a plurality of color indicators each corresponding to one of the plurality of morphological anomalies, each color indicator of the plurality of color indicators adapted to present a first color when a respective morphological abnormality of the plurality of morphological abnormalities is present in the set of image data and a second color when the respective morphological abnormality of the plurality of morphological abnormalities is not present in the set of image data. Each color indicator of the plurality of color indicators may be further adapted to present a third color indicative that a presence of the respective morphological abnormality of the plurality of morphological abnormalities in the set of image data is inconclusive

[0029] In another embodiment, a system for analysis of fetal ultrasound images is included. The system may include memory configured to store computer-executable instructions, and at least one computer processor configured to access memory and execute the computer-executable instructions to receive image data corresponding to data generated by an ultrasound system, the image data including a plurality of frames forming one or more video clip and showing a portion of fetal anatomy, determine a machine learning model including one or more neural networks trained to analyze the one or more video clip and generate outputs indicative of one or more of contours or coordinates corresponding to anatomy, analyze the image data using the machine learning model to generate at least one output, the at least one output indicative of at least one of first contours or first coordinates corresponding to the portion of fetal anatomy, determine a first value corresponding to the fetal anatomy and based on the at least one output, determine, based on the first value, an increased likelihood of a presence of a morphological abnormality in the fetal anatomy as compared to a default likelihood corresponding to the morphological abnormality, the morphological abnormality associated with a threshold value, generate an adjusted threshold value for the morphological abnormality based on the first value corresponding to the increased likelihood of the presence of a morphological abnormality, and replace a default threshold value associated with the morphological abnormality with the adjusted threshold value.

[0030] The at least one computer processor is further configured to access memory and execute the computer-executable instructions to: compare the first value to a first threshold value, and determine the first value does not satisfy a first threshold value. The at least one computer processor may be further configured to access memory and execute the computer-executable instructions to determine an increased likelihood of the presence of the morphological abnormality is based on the first value not satisfying the first threshold value. The at least one computer processor may be further configured to access memory and execute the computer-executable

instructions to determine a score indicative of a difference between the first value and a default value corresponding to one or more patients different than the patient, compare the score to a first threshold value, and determine the score does not satisfy a first threshold value.

[0031] Determining the increased likelihood of the presence of the morphological abnormality may be based on the score not satisfying the first threshold value. The first value corresponds to a length, volume, or area of a feature of the fetal anatomy. The portion of anatomy may be a portion of cardiovascular anatomy. The at least one output may be indicative of a second value different than a first value, the second value corresponding to a second length, volume or area of a feature of the fetal anatomy. The at least one computer processor may be further configured to access memory and execute the computer-executable instructions to: determine that the second value does not satisfy the adjusted threshold value, and determine that the morphological abnormality corresponding to the adjusted threshold value is present based on the second value not satisfying the adjusted threshold value. The morphological abnormality may be one of enlarged cardiothoracic ratio, right ventricular to left ventricular size discrepancy, tricuspid valve to mitral valve annular size discrepancy, cardiac axis deviation, pulmonary valve to aortic valve annular size discrepancy, overriding artery, septal defect at a cardiac crux, or abnormal relationship of outflow tracts.

[0032] In another embodiment, a computer implemented method for analysis of fetal ultrasound images corresponding to a patient is provided. The computer implemented method may include receiving image data corresponding to data generated by an ultrasound system, the image data including a plurality of frames forming one or more video clip and showing a portion of fetal anatomy, determining a machine learning model including one or more neural networks trained to analyze the one or more video clip and generate outputs indicative one or more of contours or coordinates corresponding to anatomy, analyzing the image data using the machine learning model to generate at least one output, the at least one output indicative of one or more of first contours or first coordinates corresponding to the portion of fetal anatomy, determining a first value of the fetal anatomy based on the at least one output, determining, based on the first value, an increased likelihood of a presence of a morphological abnormality in the fetal anatomy as compared to a default likelihood corresponding to the morphological abnormality, the morphological abnormality associated with a threshold value, generating an adjusted threshold value for the morphological abnormality based on the first value corresponding to the increased likelihood of the presence of a morphological abnormality, and replacing a default threshold value associated with the morphological abnormality with the adjusted threshold value.

[0033] The computer implemented may further include comparing the first value to a first threshold value, and determining the first value does not satisfy a first threshold value.

[0034] Determining an increased likelihood of the presence of the morphological abnormality may be based on the first value not satisfying the first threshold value. The computer implemented method may further include determining a score indicative of a difference between the first value and a default value corresponding to one or more patients different than the patient, comparing the score to a first threshold value, and determining the score does not satisfy a first threshold value. Determining the increased likelihood of the presence of the morphological abnormality may be based on the score not satisfying the first threshold value. The first value may correspond to a length, volume, or area of a feature of the fetal anatomy. The portion of anatomy may be a portion of cardiovascular anatomy. The at least one output is indicative of a second value different than a first value, the second value corresponding to a second length, volume or area of a feature of the fetal anatomy.

[0035] The computer implemented method may further include determining that the second value does not satisfy the adjusted threshold value and determining that the morphological abnormality corresponding to the adjusted threshold value is present based on the second value not satisfying the adjusted threshold value. The morphological abnormality may be one of enlarged

cardiothoracic ratio, right ventricular to left ventricular size discrepancy, tricuspid valve to mitral valve annular size discrepancy, cardiac axis deviation, and pulmonary valve to aortic valve annular size discrepancy, overriding artery, septal defect at a cardiac crux, or abnormal relationship of outflow tracts.

[0036] In another embodiment, a computer implemented method for analysis of fetal ultrasound images corresponding to a patient is a provided. The computer implemented method may include: receiving image data corresponding to data generated by an ultrasound system, the image data including a plurality of frames forming one or more video clip and showing a portion of fetal anatomy, analyzing the image data using a classification model including a first neural network to generate a first output, the classification neural network adapted to extract features from the plurality of frames and generate the first output indicative of a likelihood of a presence of a first morphological abnormality, analyzing the image data using a keypoint detection model including a second neural network to generate a second output, the keypoint detection neural network adapted to extract features from the plurality of frames, extract feature maps from the plurality of frames, and generate the second output indicative of coordinates of a plurality of anatomical features corresponding to the portion of the fetal anatomy, analyzing the image data using a segmentation model including a third neural network to generate a third output, the segmentation neural network adapted to extract features from the plurality of frames, extract feature maps from the plurality of frames, and generate the third output indicative of contours of a plurality of anatomical features corresponding to the portion of the fetal anatomy, and determining a presence of at least one abnormality corresponding to the portion of fetal anatomy based on one or more of the first output, the second output, or the third output.

[0037] The first morphological abnormality may be one of overriding artery, septal defect at the cardiac crux, or abnormal relationship of the outflow tracts. The computer implemented method may further include determining one of the following based on the second output: a location of one or more of a tricuspid valve, a mitral valve, a pulmonary valve, an aortic valve, an apex of a heart, a long axis of a heart, or an anteroposterior axis of a chest. The computer implemented method may further include calculating one or more of the following based the location of one or more of the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve: tricuspid valve to mitral valve annular size discrepancy, pulmonary valve to aortic valve annular size discrepancy, and cardiac axis deviation. The computer implemented method may further include calculating one or more of the following based the location of one or more of the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve: an enlarged cardiothoracic ratio or a right ventricular to left ventricular size discrepancy. The computer implemented method may further include determining, based on the third output, a contour of one or more of a left ventricle, a right ventricle, a heart, or a thorax.

[0038] The foregoing summary is illustrative only and is not intended to be in any way limiting. In addition to the illustrative aspects, embodiments, and features described above, further aspects, embodiments, and features will become apparent by reference to the following drawings and the detailed description.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] FIGS. **1**A-**1**C are schematic views of an exemplary server-based and/or local models for implementing the methods and systems of the present invention.

[0040] FIG. **2** is an exemplary screen display presented to the clinician showing the results returned to the user interface by the interpretive component.

[0041] FIGS. **3**A-**3**B are an exemplary flowchart and data flow showing the analysis process

undertaken by the interpretive component to analyze motion video clips generated during a fetal ultrasound examination.

[0042] FIGS. **4**A and **4**B are exemplary images presented to a clinician via the user interface module after analysis results are returned from the interpretive module, in which FIG. **4**A shows an image selected as corresponding to the four chambers view and FIG. **4**B is a similar view for a different fetus including a bounding box identifying a large atrioventricular defect.

[0043] FIG. **5** is an exemplary graphic user interface including a representation of the image of the patient and a list of standard views and abnormalities.

[0044] FIG. **6** is an exemplary data flow for obtaining medical images, identifying red flags, annotating the images, and providing the flagged and annotated images in a graphic representation.

[0045] FIG. **7** is an exemplary graphic user interface including a representation of the images of the patient, patient information, and a list of abnormalities.

[0046] FIGS. **8**A-**8**C are exemplary user interfaces for displaying image data generated by an ultrasound system as well as standard view and abnormality indicators

[0047] FIG. **9** is an exemplary flowchart for dynamically requesting additional image views and logging the presence and absence of standard views and morphological abnormalities.

DETAILED DESCRIPTION OF THE INVENTION

[0048] Systems and methods are disclosed for conducting fetal ultrasound examinations that aid in the detection of critical heart defects during a fetal ultrasound exam, typically conducted during the second trimester. In particular, the inventive systems and methods assist trained and qualified physicians to interpret ultrasound recording motion video clips to assist in detecting and identifying morphological and flow abnormalities that may be indicative of critical CHDs. Table 3 provides an exemplary correspondence between representative CHDs, the views in which those CHDs usually appear, and the morphological abnormalities that typically can be identified in those views.

[0049] In an exemplary system depicted in FIG. **1**A, the system may include a conventional ultrasound system **10**, display computer **20**, and server system **30** that communicate with each other via wide area network **40**, illustratively, the Internet or any other suitable network (e.g., local area network). In an embodiment, the systems and methods are embodied in a computer assisted diagnostic aid for use in two-dimensional fetal ultrasound exams, such as usually performed during the second trimester of pregnancy. Machine learning algorithms are employed to assist users with the identification and interpretation of standard views in fetal cardiac ultrasound motion video clips. While ultrasound systems are described throughout, it is understood that the same or a similar approach may be used with any other suitable medical imaging system (e.g., CT (computed tomography) scan, Magnetic resonance imaging (MRI), etc.).

[0050] In one embodiment, the inventive methods and systems employ two software components: a user interface component and an interpretative component. The user interface computer may be resident on display computer **20** and provide a clinician tools to analyze and review fetal ultrasound images and ultrasound motion video clips. The interpretative component may reside on server computer **30**, receives ultrasound motion video clips and images from ultrasound system **10** or display computer **20**, and uses machine learning algorithms to identify images within the motion video clips that correspond to fetal ultrasound screening guidelines. The interpretative component also analyses the identified images as well as any non-identified images (e.g., corresponding to non-standard or non-recommended views) to detect and identify the presence of morphological abnormalities, and provides that information to the user interface component to highlight such abnormalities for the clinician's review. In an alternative embodiment, the interpretive component may be executed partially or fully on a local computer workstation in real-time.

[0051] As is typical, ultrasound system **10** includes a handheld probe that a clinician moves across a patient's abdomen to generate motion video clips of the fetus during a pre-natal fetal examination, which clips may be transmitted to display computer **20** during the scanning process for storage and display on a display screen associated with display computer **20**. The motion video clips generated

during the examination may be any suitable period of time (e.g., series of still images, one second video clip, multi-second video clip, multiple minute video clip, etc.), and may be directly uploaded from ultrasound system **10** to server system **30** via wide area network **40** or any other suitable wireless technology, and/or may be transmitted by a user interface module executing on display computer **20**.

[0052] Display computer **20** may be configured to display real-time video generated by ultrasound system **10**, and in addition, is configured to display to the clinician analysis results generated by the interpretive component executing on server system **30**. Display computer may include a display screen, storage, CPU, input devices (e.g., keyboard, mouse) and network interface circuitry for bi-directionally communicating with server system **30** via wide area network **40**. In an embodiment, display computer **20** executes the user interface component of the invention, which accepts and stores physiologic information about the patient. Display computer **20** also receives and stores real-time ultrasound video from ultrasound system **10** and relays that image data, together with the patient's physiologic information, to the interpretative component that executes on server system **30**.

[0053] Server system **30** includes the interpretive component of the inventive system, including machine learning algorithms for analyzing the motion video clips received from display computer **20** to compare the ultrasound video clips to a set of the preferred image templates that correspond to the fetal ultrasound examination guidelines. In an embodiment, the interpretive component may include image templates that correspond to each of the views recommended in the fetal heat ultrasound screening guidelines set forth in Table 2, including: (1) the transverse abdominal view; (2) the four chamber view (4C); (3) left ventricular outflow tract view (LVOT); (4) right ventricular outflow tract view (RVOT); (5) the three vessel view (3V) and (6) the three vessel and trachea view (3VT). The forgoing list is exemplary and non-limiting. Other standard views may include ductal arch view, bicaval view, abdominal situs view, and aortic arch view, for example. As described in further detail below, the interpretative component may employ machine learning to compare each frame of the input motion video clips to the foregoing view templates, and select one or more high quality image frames as corresponding to the selected template. If an abnormality is detected, an image frame showing the abnormality may be selected. The interpretative component may employ a machine learning model to analyze each of the image frames, selected as representative of the guideline views, and optionally other non-selected image frames, for the presence of the abnormalities known to be present in those image templates as set forth in Table 3.

[0054] For example, one the interpretive component has identified and selected an image frame from an uploaded motion video clip as representative of the 3VT view, the machine learning feature will analyze the selected image frame for features identified in Table 3 as being visible in the 3VT view: aorta greater than pulmonary artery, associated with coarctation of the aorta and conotruncal lesions; right aortic arch, associated with conotruncal lesions; abnormal vessel alignment, associated with transposition of the great arteries; and additional visible vessel, associated with anomalous pulmonary venous connection.

[0055] If the interpretative component of the system identifies one or more of the features described in Table 3 as being present in the selected image frame, the system further may create an overlap on the selected image that includes a bounding box that surrounds the detected abnormality and optionally, a textual label associated with the suspected defect. The selected image frames and analytical results then are transmitted back to display computer **20** for presentation to, and consideration by, the clinician. As clinicians often have multiple patients, the clinician may be sent or may otherwise be tasked with reviewing results from several patients. To facilitate efficient review by the clinician and/or expert, the system may automatically organize the results with the most relevant information, such as detected morphological abnormalities, appearing first or otherwise most prominently. Additionally, or alternatively, the results may be organized by patient in order of severity.

[0056] Display computer **20** may provide the ability to annotate the selected image frames with additional graphical or textual notes, which are then saved with the results for later recall during preparation of a documentary report concerning the fetal ultrasound examination.

[0057] If during analysis by the interpretative component no motion video clip image frame is identified as corresponding to a standard view template, or the identified image frame is adjudged to be of too poor quality to permit analysis for potential defects, that image template is identified as missing when the analysis results are transmitted back to display computer **20**. In this case, the clinician may be prompted by display computer **20** to rescan the fetus to acquire the missing view, and that motion video clip may be resubmitted to the interpretative component for supplemental analysis. The results of the supplemental analysis may then be sent back to display computer **20** for presentation to, and consideration by, the clinician.

[0058] Referring now to FIG. **1**B, the exemplary system of FIG. **1**A is illustrated. System **15** may be the same as the system illustrated in FIG. **1**A and may include ultrasound system **10**, display computer **20**, and server **30**. As shown in FIG. **1**B, ultrasound scan system **10** may be any suitable ultrasound scan system for performing fetal anatomic ultrasound examinations (e.g., second-trimester fetal anatomic ultrasound examinations between 18 and 24 weeks of gestation, first-trimester examinations, third-trimester fetal examinations, or otherwise), however, the inventive software/programming described herein is stored and executed on the controller of ultrasound scan system **10**. In one example, ultrasound scan system **10** may be Samsung's WS80A ultrasound system, or any other suitable ultrasound scan system. Ultrasound scan system **10** may include ultrasound probes (e.g., probe **13**), a display, one or more computers, inputs (e.g., keyboard, mouse, knobs, dials, switches, toggles, and the like), speakers, a microphone, and the like. System **15** may optionally also include healthcare provider device **25** which may include display **22**.

[0059] Healthcare provider device **25** may be a standalone computer device which may display to healthcare provider (e.g., doctor, technician, specialist, etc.) analysis results generated by the interpretive component executing on server system **30**. Display computer may include a display screen, storage, CPU, input devices (e.g., keyboard, mouse) and network interface circuitry for bi-directionally communicating with server system **30** and/or computer device **20** via any suitable wired or wireless connection. Display computer **20** and optionally healthcare provider device **25** may execute the user interface component of the invention. For example, display computer **20** and/or healthcare provider device **25** may display graphic user interface **17** which may be any graphic user interface described herein (e.g., graphic user interface **200** of FIGS. **8**A-**8**C). Healthcare provider device **25** may communicate with server **30** and/or computer device **20** to provide input, comments, edits, and otherwise adjust or modify the graphic user interface.

[0060] Referring now to FIG. **1**C, a clinical workflow of the systems illustrated in FIGS. **1**A-**1**B is illustrated. As shown in FIG. **1**C, clinical center **12** may communicate with back end **14**, which may be running on a server (e.g., server **30** of FIG. **1**A). Clinical center **12** may include ultrasound module **16** which may run on the ultrasound scan device (e.g., ultrasound scan device **10** and/or display computer **20** of FIG. **1**A), Picture Archiving and Communication (PACS) system **18**, which may run on the ultrasound scan device or device located in the same building or campus as the ultrasound scan device and/or on a remote server, Digital Imaging and Communications in Medicine (DICOM) viewer **22**, and DICOM router **24**.

[0061] Ultrasound module **16** may generate, receive, obtain, and/or store ultrasound images (e.g., image data such as motion video clips and image frames). The image data may be communicated from ultrasound module **16** to PACS system **18**. PACS system **18** may securely store image data received from ultrasound module **16**. The image data saved in PACS system **18** may electronically label the record based on user selection input. Once the image data is saved and/or labeled in PACS system **18**, DICOM router **24** may connect to PACS system **18** to retrieve the image data and may also connect to back-end **14**, which may run on a server (e.g., server **30** of FIG. **1**A). For example, DICOM router **24** may be connected to implementation module **26** and may send the image data to

implementation module **26**. In one example, DICOM router **24** may pseudonymize files so that only pseudonymized files are sent to the back end **14**. For example, all patient information may be removed except for certain necessary variables (e.g. fetal age), and pseudonym identifiers may be added to the file for the exam and/or for each recording. Once DICOM router **24** receives outputs from back end **14**, it may then perform re-identification, by replacing the pseudonym identifiers with the patient information. Implementation module **26** may upload the image data to storage **28**. For example, storage **28** may store encrypted and otherwise secured image data.

[0062] Implementation module **26** may retrieve certain image data from storage **28** and may communicate such image data to analysis module **29**. Analysis module **29** may process the image data (e.g., video clip) using machine learning algorithms to identify the presence of morphological abnormalities in the image data, as described in more detail herein with respect to FIGS. **3**A and **3**B. In one example, the outcomes and/or outputs of analysis module **29** may be stored in storage **28** as annotated DICOM files. The annotated DICOM files (e.g., indicating morphological anomalies) may be communicated back to DICOM router **24** and stored in PACS **18**. Once stored in PACS **18**, a healthcare provider (e.g., physician) using DICOM viewer **22** to access the annotated DICOM files from PACS **18** and view the annotated DICOM files (e.g., using a healthcare provider device).

[0063] Referring now to FIG. **2**, an exemplary display suitable for summarizing the results returned to display computer **20** by the interpretative component residing on server system **30** is described. Display **50** includes three columns **51-53**, which may include links that can be activated using the input device, e.g., a mouse, associated with display computer **20**. Column **51**, labeled "View," describes the standard guidelines views (e.g., 4C, LVOT, etc.). Column **52**, labeled "Image," includes checkboxes indicating whether the interpretative component of the system has identified and selected an image frame as corresponding to the standard guidelines view. Column **53**, labeled "Obser," denotes whether any observations, such as potential abnormalities, have been detected in a selected image frame.

[0064] Activating a link in the View column, column **51**, such as by clicking on the view title with a mouse, will display an idealized generic image of the standard guideline view, such as those shown in Table 2. In column **52**, the presence of a checkbox indicates that an image frame was selected by the interpretative component on server computer **30**. Clicking on that checkbox will cause the display computer to display the raw image selected by the interpretative component. The absence of a checkbox in column **52** indicates that the interpretative component was unable to locate an image in the motion video clips suitable for analysis by the machine learning feature. Clicking on the empty checkbox, for example, for RVOT in FIG. **2**, may be configured to display a prompt to the clinician to rescan a portion of the patient's abdomen to acquire a new motion video clip containing the desired view, which then may be sent to server computer **30** for supplemental analysis.

[0065] Column **53** may include textual descriptions for any observations noted by the interpretative component in the selected image frames. For example, in FIG. **2**, column **53** presents the labels "None" for all views except the RVOT view. Because display **50** may be visible to the patient, column **53** may use neutral labeling, "Review," to indicate to the clinician that a potential abnormality was detected in that view, rather than a more descriptive label that could cause undue concern to the patient. In one embodiment, the textual indicators for each standard view may be clickable links. For example, clicking on a label that states "None" for the 4C, LVOT, 3V and 3VT views in FIG. **2** may display the image frame selected by the interpretative component along with labels that indicate where the interpretative component adjudged the anatomical landmarks to be located. On the other hand, clicking on the label "Review" for the RVOT view in FIG. **2** may display the selected image frame, labeled anatomical landmarks, and a bounding box surrounding the suspected abnormality, along with a textual description of the potential defect.

[0066] In a fetal ultrasound examination conducted in accordance with the principles of the present

invention, following review of the real-time ultrasound motion video clips generated by the ultrasound scanner **10** as displayed on display computer **20**, the clinician then may review the analysis results generated and returned by the interpretative component residing on server computer **30**. In this manner, the clinician may review the contents of display **50** of FIG. **2**, review the selected raw image data corresponding to each standard guideline view (by clicking on the checkboxes in column **52**), and review the detailed machine learning analysis of that selected image frame by clicking on the labels in column **53**. The clinician therefore may be able to corroborate his or her own observations during review of the real-time video clips or adjust his or her findings based on the machine learning analysis results. As noted above, display computer **20** may include the ability to open additional boxes associated with any of the image frames presented in column **53** to record and store additional findings for later recall in preparing a written or electronic report documenting the fetal ultrasound examination.

[0067] Turning now to FIG. **3**A, exemplary flowchart **60** for the interpretative component of the analysis software is described. It is understood that the tasks and/or operations performed in flowchart **60** may be performed on a server (e.g., server **30** of FIG. **1**), ultrasound scan system (e.g., ultrasound scan system **10** of FIG. **1**), and/or display (e.g., display **20** of FIG. **1**). At step **61**, image data (e.g., motion video clips having a duration less than 1 second, between 1 second and one minute, or between 1 minute and one or more hours, image frames, and the like) are received from and/or determined by ultrasound system **10** or display computer **20**. The image data may be any type of medical image such as, for example, greyscale ultrasound images, ultrasound images representing the intensity and/or direction of the flow (e.g., using Color Doppler, Power Doppler, etc.). At step **62**, standard guideline view and/or a template corresponding to a standard guideline view is selected, e.g., 4C, LVOT, RVOT, 3V or 3VT. The template may consist of an idealized version of the images shown in Table 2 or other standard views or desirable views. At step **63**, the received image data, which may be video image clips, is analyzed using a machine learning algorithm, e.g., convolutional neural network and/or deep neural network, to compare each frame (e.g., image frame) of the received motion video clip and/or pixels of the motion video clip to the standard template to determine which frame or frames best match the standard view guideline template. It is understood that a video clip, formed from a set of image frames and/or pixels, or individual image frames may be analyzed at step **63**. The interpretative component also may analyze the selected image frame or frames to confirm that the image meets specified quality requirements for clarity. If no frame in the image data is determined to correspond to the standard view, at decision box **64**, the process moves to step **65**, where a flag is set indicating that no suitable image frame is available, and the process continues with selection of the next standard view template at step **62**.

[0068] If the interpretative component adjudges that a corresponding frame is available in the received image data, the process moves to step **66**, where the image data (e.g., selected image frames), and optionally non-selected image frames, are analyzed by another machine learning algorithm to detect the presence or absence of an abnormality associated with that image data (e.g., the image data in the standard view). For example, if the selected image frame corresponds to the 4C standard view template, the algorithm will analyze the selected frame for the presence of any of the defects and/or abnormalities listed in Table 3 for that standard view. If a defect is detected in the image data (e.g., the selected image frame), the algorithm may look at adjacent frames of the video clip to confirm the presence of the same defect.

[0069] Morphological abnormalities may include, in one example, overriding artery (e.g., artery going out of the left ventricle is positioned over a ventricular septal defect), septal defect at the cardiac crux (e.g., the septal defect located at the crux of the heart, either of the primum atrial septum or of the inlet ventricular septum), parallel great arteries, enlarged cardiothoracic ratio (e.g., ratio of the area of the heart to the thorax measured at the end of diastole above 0.33), right ventricular to left ventricular size discrepancy (e.g., ratio of the areas of the right and left ventricles

at the end of diastole above 1.4 or below 0.5), tricuspid valve to mitral valve annular size discrepancy (e.g., ratio between the tricuspid and mitral valves at the end of diastole above 1.5 or below 0.65), pulmonary valve to aortic valve annular size discrepancy (e.g., ratio between the pulmonary and aortic valves at the end of systole above 1.6 or below 0.85), abnormal outflow tracts relationship (e.g., absence of the typical anterior-posterior cross-over pattern of the aorta and pulmonary artery), cardiac axis deviation (e.g., cardiac axis (angle between the line bisecting the thorax and the interventricular septum) below 25° or above) 65°, abnormal pulmonary venous return, coarctation of the aorta, and mitral regurgitation, tricuspid regurgitation, pulmonary regurgitation, or aortic valve regurgitation. Alternatively, or additionally, any other morphological abnormalities may be detected step **66**.

[0070] Additionally, or alternatively, image data (e.g., Doppler ultrasound image data such as color Doppler ultrasound image data and/or Power Doppler ultrasound image data) may be analyzed by a machine learning algorithm to detect the presence or absence of a blood flow abnormality. For example, video clips generated by Doppler ultrasound may show color patterns and/or changes indicative of abnormal blood flow. One or more frame from such color video clips may be analyzed by a machine learning algorithm trained to detect abnormal blood flow (e.g., abnormal blood flow at certain standard views (e.g., LVOT)) and may process color images from color video clips and generate an output indicative of normal or abnormal blood flow, or optionally an inconclusive finding. It may be desirable to train machine learning models to detect changes in patterns and other features indicative of blood flow to determine whether the flow is abnormal. Analysis of multiple sequential image frames may be necessary to determine whether the blood flow is abnormal. Analyzing blood flow may be helpful in determining if certain anatomy is functioning properly and/or determine if certain anatomy is properly connected (e.g., such anatomy may be too small to tell from greyscale ultrasound images alone). It will be understood by one of ordinary skill in the art that color video clips and images may be used to identify morphological abnormalities as well as blood flow abnormalities. For example, the color video clip may be analyzed by a machine learning algorithm and may generate an output indicative of a morphological abnormality due to blood flow found in regions of the heart not found in a properly functioning heart. In one example, using color Doppler ultrasound image data, the direction of blood flow may be determined. Using the direction of the blood flow as an input, a machine learning algorithm may detect a presence, absence, and/or inconclusiveness of a finding, such as one or more morphological defects (e.g., ventricular septal defect, atrial septal defect, abnormal pulmonary venous return, coarctation of the aorta, pulmonary valve atresia, or overriding artery).

[0071] In another example, blocks **62**, **63** and **65** and decision **64** may be optional and block **66** may be initiated directly after block **61**. In this example, all of the image data may be analyzed at block **66** to determine the presence or absence of morphological or flow abnormalities. For example, image data may include a one second video clip made up of multiple image frames and each image frame may be analyzed at block **66** to determine a presence or absence of morphological or flow abnormalities, or otherwise that such analysis is inconclusive.

[0072] At optional step **67**, an overlay may be created for the selected image frame that includes graphical pointers to the detected anatomical landmarks, as well as a bounding box that surrounds the abnormality detected in the image frame. The overlay also may additionally or alternatively include textual information that describes the specific abnormality and/or the associated class of CHD, as set forth in Table 3. At step **68**, the information generated by the interpretative component, i.e., the overlay and graphical/descriptive information is associated with the image data (e.g., selected image frame) and stored in server computer **30** for later transmission to display computer **20**. At optional decision box **69**, a determination is made whether all image data received at step **61** has been analyzed and/or if all standard views have been determined to be present. If not all standard views have been determined to be present and/or all image data received at step **61** has not been analyzed, the process may return to step **62**, where the next standard view template is selected

for analysis. Alternatively, if at decision box **69** is it determined that all standard views have been determined to be present and/or all image data has been analyzed, the process may move to step **71**, where the results are returned to display computer **20** for presentation and review by the clinician. Alternatively, decision **69** may be optional and may be bypassed to initiate blocks **71** and/or **72**. For example, a user may determine to return the analysis results to the user interface for display and/or generate a report even if all the standard views have not been determined to be present and/or all the image data has not been analyzed.

[0073] At optional step **72**, the analysis and/or results may be used to generate a report. For example, the report may identify detected morphological and/or blood flow abnormalities and/or may include an entry for each standard view. Alternatively, only an entry for standard views that are determined to be present may be included in the report. For example, detected anomalies may include one or more of abnormal ventricular asymmetry, coarctation of the aorta, pulmonary or aortic valve stenosis, ventricular hypoplasia or univentricular heart and/or any other cardiovascular abnormality. The report may be prepopulated such that, for each standard view entry, a representation image may be selected. If a morphological and/or flow abnormality is detected, an image representative of the morphological and/or flow abnormality for a given standard view may be included in the report at the entry for the corresponding view. If a bounding box is generated for a given frame, such image with the bounding box overlay may be used in the report. Information about the view, the anatomy, any textual description of the detected morphological defect and/or abnormality and/or flow abnormality, and/or any other relevant information may additionally be included in the report to add context to the images and otherwise generate a more informative report. The resulting analysis, results, annotations, and/or report may be stored for later reference.

[0074] The images, image frames, video clips, analysis, results, annotations, and/or report may be shared with or otherwise made available to an expert or clinician (e.g., upon referral to an expert or clinician). Each type of morphological and/or flow abnormality may be associated with an expert or clinician and their contact information. If a morphological abnormality is detected at step **66**, an expert or clinician corresponding to the morphological abnormality may optionally be recommended.

[0075] In addition to performing the steps **61**-**72** illustrated in FIG. **3**A, the system may perform an objective evaluation of the exam, the images generated, and/or the technician that performed the imaging (e.g., the sonographer). The system may consider data such as the mean duration of the exam and/or image collection, the quality of the images acquired, the percentage of standard views for which a suitable image is acquired, and/or any other information indicative of the quality of the exam, the images and/or the sonographer. For example, a model trained to generate one or more quality values indicative of the quality of the exam and/or images may be used to process such data. The data may be determined over the course of several exams. For example, the percentage of standard views for which a suitable image is acquired for multiple exams by the same technician may be used to determine a quality value indicative of the rate at which a technician performs a complete exam.

[0076] Turning now to FIG. **3**B, neural network outputs and post processing steps of the analysis software is described. As shown in FIG. **3**B, input **32** may be input into model **33** of analysis system **31**. Model **33** may be one or more neural networks. Input **32** may be image data such as a motion video clip (e.g., one second video clip), image frame, and the like. In one example, input **32** may be raw digital data representing or forming the image data. Model **33** may include convolutional base **34**, classification head **35**, segmentation head **36**, and key-point detection head **37**. Convolutional base **34** may be a convolutional neural network (CNN) which may process input **32**. Convolutional base **34** may include classification head **35**, segmentation head **36**, and key-point detection head **37**.

[0077] Classification head **35** may be or may include a machine learning model which may include a classification neural network that may be trained to process input **32** to determine a probability of

a presence or absence of one or more morphological and/or flow abnormalities and/or a likelihood that one or more of the morphological and/or flow abnormalities is inconclusive. The neural network may extract features of frames of the image data and may generate an output indicative of a likelihood of a presence of a morphological abnormality. For example, classification head **35** may generate outputs indicative of overriding artery, septal defect at the cardiac crux, and/or abnormal relationship of the outflow tracts. In one example, the neural network of classification head **35** may be a vision transformer neural network. Vision transformers are a family of deep learning models which create linear embeddings from an input image. These embeddings may then be passed to a transformer encoder network which may create an embedding for the entire image. A classification head can then be used to convert this embedding into class predictions.

[0078] The vision transformer neural network may have three blocks: (i) a downsizing block used to resize the input image, (ii) a vision transformer neural network backbone or similar system that extracts features from each image, a (iii) a classification head that converts outputs into a probability of presence, absence or inconclusiveness for each classification radiographic finding. The downsizing block may take as input a preprocessed image and may resize it to a dimension using bilinear interpolation. The vision transformer neural network backbone may extract features for each frame of the video clip. The output of this block is an array with the number of input frames x the number of features. The classification head of the neural network may be a linear layer network followed by three independent softmax functions (e.g, 1 per radiographic finding). The linear network may take as input the features computed by the vision transformer neural network backbone, and output an array of the shape: number of input frames×3×3 (3 classes for each of the 3 classification findings, representing presence, absence and inconclusiveness for the finding). This array is then normalized into a probability array for each radiographic finding (representing the probability for presence, absence or inconclusiveness of a finding) using the 3 independent softmax functions.

[0079] Segmentation head **36** may be or may include a machine learning model which may include a segmentation neural network that may be trained to determine a counter, periphery and/or area interpretable or otherwise corresponding to certain anatomy in image data represented by input **32**. The neural network may extract features from frames of the image data, may extract feature maps from the frames, and may generate an output indicative of contours of a plurality of anatomical features corresponding to the portion of the fetal anatomy. The segmentation neural network may be involved in the computation of enlarged cardiothoracic ratio and right ventricular to left ventricular size discrepancy, for example, and/or may detect the counter of certain anatomical features such as the counter of the left and right ventricles, the contour of the heart and the thorax. If there is no detection of an element by the algorithm or if a part of a detected element goes out of the image (e.g., if the image of the heart is cropped), this element may be marked as inconclusive for the respective frame. The segmentation neural network may independently perform predictions (e.g., absence, presence, or inconclusiveness) for each of the anatomical features. The detection head may be used for segmentation and may identify which of the anatomical features are detected with a confidence score. A threshold may be applied per anatomical feature to select only the most relevant predictions. Then, the segmentation head may generate binary masks for each detected object to accurately outline the shape of the anatomical structure. A contour may then be extracted from this binary mask. As a final process, each prediction having the highest confidence score for each anatomical feature may be selected. Anatomical features that are missing may be marked as inconclusive for that frame.

[0080] Key-point detection head **37** may be or may include a machine learning model which may include a neural network that may be trained to determine the positions of certain anatomy and/or points in the image data represented by input **32**. The neural network may extract features from frames of the image data, may extract feature maps from the frames, and may generate an output indicative of coordinates of a plurality of anatomical features corresponding to the portion of the

fetal anatomy. For example, a neural network may be trained to determine whether anatomy is present and/or is in the correct position (e.g., whether the heart and lungs are in the correct position). Additionally, or alternatively, locations of features of the patient's anatomy (e.g., heart and lungs) may be identified and distances between anatomy may be measured and compared to thresholds to determine whether the positions of certain anatomy is normal or abnormal. In one example, output of the trained neural network may be indicative of Heterotaxy syndrome.

[0081] The key-point detection neural network may generate outputs indicative of the presence of tricuspid valve to mitral valve annular size discrepancy, pulmonary valve to aortic valve annular size discrepancy, and/or cardiac axis deviation and/or may be indicative of the location the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve as well as the long axis of the heart and/or the anteroposterior axis of the chest. If there is no detection of an element by key-point detection neural network or if a part of a detected element goes out of the image (e.g., if the image of the heart is cropped), this element is marked inconclusive for the respective image frame. The keypoint detection neural network may independently perform the predictions for each of the anatomical features.

[0082] The neural network utilized for key-point detection may be a Mask R-CNN model or similar model and/or may include a resizing block that resizes the input image. The resizing block may resize the image to have a minimum scale while preserving the aspect ratio (e.g., using bilinear interpolation). A ResNet-50-FPN backbone or similar system may then extract features from each image at various scales. A region proposal network and MultiScaleRoiAlign or similar system may then extract a set of fixed-size feature maps from these multi-scale feature maps of the backbone by detecting regions of interest that might contain anatomical features. The key-point detection head may then output the coordinates (e.g., cartesian coordinates) of the extremities for the anatomical features on the image.

[0083] As shown in FIG. **3**B, model **33** may output neural network outputs **39** which may include output **38**, output **40**, and output **41**. Output **38** may be output from classification head **35** and may be a probability of a presence or absence of a morphological and/or flow abnormality (e.g., overriding artery, septal defect at the cardiac crux, parallel great arteries, etc.). Output **40** may be output from segmentation head **36** and may identify data points corresponding to the image data forming contours of anatomy shown in the image data (e.g., contours of the left ventricle, right ventricle, heart, thorax, etc.). Output **41** may be output from key-point detection head **37** and may identify data points corresponding to the position in the image data of features of the anatomy represented in the image data (e.g., extremities of the tricuspid valve, extremities of the mitral valve, extremities of the pulmonary valve, extremities of the aortic valve, long axis of the heart, and/or anteroposterior axis of the chest).

[0084] Neural network outputs **39** may then be processed by post processing module **42**. For example, output **38** may be processed by module **43** to determine whether morphological and/or flow abnormalities are absent or present or whether the absence or presence is inconclusive. For example, output **38** may be one or more vectors and may include a value indicative a probability of the presence, absence, and/or inconclusiveness of the presence or absence for each morphological and/or flow abnormality. Module **43** may process the vectors by comparing each to certain threshold values to determine whether each morphological and/or flow abnormality is absent, present or inconclusive. For example, for the morphological and/or flow abnormality "overriding artery," a vector may be output having the value 0.95 for present, 0.1 for absent, and, 0.1 for inconclusive. A threshold may be set at 0.9 for each of present, absent, and inconclusive, and the value 0.95 for present may then satisfy the threshold. As a result module **43** may determine that the abnormality "overriding artery" is present. It is understood that other thresholds and/or limits may be used to determine the presence, absence, and/or inconclusiveness of a morphological and/or flow abnormality.

[0085] Output **40** may be processed by module **44** which may determine measurements (e.g., area,

length, volume, diameter, perimeter, and the like) for contours of anatomy shown in the image data, such as, for example, area of left ventricle, area of right ventricle, perimeter of the heart, and/or perimeter of the thorax. In one example, for particularly small or large features, the measurement may be only that the value is smaller or larger than a preset valve (e.g., smaller than 4 mm). These measurements may then be provided to and processed by module **47** which may determine ratios and/or comparisons of the measurements (e.g., area of the right ventricle divided by area of the left ventricle, perimeter of the heart divided by perimeter of the thorax, etc.). The ratios and/or comparisons may then be provided to and processed by module **50** which may determine the absence, presence, or inconclusiveness of certain abnormalities based on ratios and/or comparisons determined at module **47** by comparing such ratios and comparisons to thresholds and/or limits. In one example, module **50** may determine the presence, absence, or inconclusiveness of a right ventricle/left ventricle size discrepancy or the presence, absence, or inconclusiveness of an enlarged cardiothoracic ratio. For example, the valves determined by module **46** may be compared against threshold values to determine if such values exceed the threshold values. For example, the valves determined by module **47** may be compared against threshold values to determine if such values exceed the threshold values.

[0086] Output **41** may be processed by module **45,** which may determine certain measurements (e.g., length, angle, area, etc.) based on features of the anatomy represented in the image data. For example, module **45** may determine values such as size (e.g., length, width, area) of the tricuspid valve, size of the mitral valve, size of the pulmonary valve, size of the aortic valve, and/or cardiac axis angle (e.g., angle between the long axis of the heart and the anteroposterior axis of the chest). The values determined by module **45** may be provided to module **46** which may demine ratios and/or comparisons based on the values. For example, ratios such as the size of the tricuspid valve divided by the size of the mitral valve, and/or the size of the pulmonary valve divided by the size of the aortic valve may be determined. The ratios and/or comparisons may then be provided to and processed by module **48** which may determine the absence, presence, or inconclusiveness of certain abnormalities based on ratios and/or comparisons determined at module **46** by comparing such ratios and comparisons to thresholds and/or limits. In one example, module **48** may determine the presence, absence, or inconclusiveness of a tricuspid valve versus mitral valve size discrepancy, a pulmonary valve/aortic valve size discrepancy, cardiac axis deviation. For example, the valves determined by module **46** may be compared against threshold values to determine if such values exceed the threshold values.

[0087] Representative frames of input **32** may be analyzed by analysis system **31**. Alternatively, all image frames of input **32** may be analyzed by analysis system **31**. In one example, measurements and other calculations performed by analysis system **31** may be performed on each image frame and the output may be combined to determine a single value. For example, a calculation of the area of the right and/or left ventricle may be calculated for each image frame, or each image frame clearly showing the anatomy, and the average, median, or mode of each calculation may be determined to determine a single value representative of the area of the right and/or left ventricle. The representative image frame showing the respective dimension may be selected and annotated to show the value on the image and/or arrows indicating the dimension. Alternatively, or additionally, metadata or other data may be associated with the image and include such information. Such a value may be used to determine if an abnormality is present or absent. By combining the calculations or measurements of multiple frames, a more accurate calculation or measurement may be determined than a value from single image frame and thus a more accurate determination of a presence or absence of an abnormality may be made.

[0088] In determining whether certain calculations, measurements, and/or other positional information is indicative of an abnormality, a gestational age may be determined. For example, the gestational age may be input by a user and certain thresholds and/or models (e.g., neural networks) may be adjusted and/or selected based on and corresponding to the gestational age. In one example,

the length of the femur may be measured. In another example, a neural network may be trained to estimate a gestational age based on the image data and such estimated age may then be used to adjust and/or select certain thresholds and/or models for determining whether abnormalities are present. For example, a neural network may be trained to automatically determine the length of femur, which then may be used to adjust and/or select certain thresholds and/or models for determining whether abnormalities are present.

[0089] Thresholds and limits indicative of a presence of an anomaly may be based on measurements informed by the general population and/or may be adjusted based on gestational age. Scores (e.g., z-scores) may be determined for differences between the patient's measurement and the measurement corresponding to the general population. Additionally, thresholds and other analysis may be adjusted and/or modified according to known correlations based on information from other individuals and/or the general population. For example, certain measurements or presence of a type of abnormality may increase the likelihood of a certain other abnormality. Accordingly, if a certain measurement is above or below a threshold value and/or one type of abnormality is determined to be present, a threshold and/or limit for determining the presence of another abnormality may be adjusted (e.g., the threshold for detecting the other type of anomaly may be lowered). This is referred to as adjusting the sensitivity for the abnormality. For example, a patient determined to have asymmetric ventricles may be more likely to have an overriding artery and thus a threshold value for determining that an overring artery is present may be lowered to increase sensitivity to the overriding artery being present.

[0090] In another example, if the measurement of the area of the heart (e.g., meaning its dimension or its z-score at a given gestational age and optionally normalized by the patient's thorax) is above a certain threshold valve, then threshold values for detecting a presence of septal defect at the cardiac crux, overriding artery, and abnormal relationship of the outflow tracts may be adjusted to be more sensitive (e.g., by lowering such threshold value). In yet another example, if (i) the annulus size of the pulmonary valve (e.g., meaning its dimensions or its z-score at a given gestational age and optionally normalized by the annulus size of the aortic valve) is too large or too small, (ii) the annulus size of the tricuspid valve (e.g., meaning its dimensions or its z-score at a given gestational age and optionally divided by the annulus size of the mitral valve) is too small or too large, or (iii) the area of the right ventricle (meaning its dimensions or its z-score at a given gestational age and optionally normalized by the area of the left ventricle) is too small or too large, then thresholds indicating the presence of overring artery and abnormal relationship of the outflow tracts may be made more sensitive (e.g., lowered). The foregoing examples are non-limiting and it will be understood by one of ordinary skill in the art that adjusting thresholds indicative of a presence of an abnormality may generally be used for any correlated abnormalities, conditions, measurements or the like.

[0091] The adjustments made to the thresholds and limits to increase sensitivity may be a single adjustment, tiered adjustments, or a sliding scale of adjustments. For example, a single adjustment means that if a first measurement satisfies a certain threshold a second threshold for an abnormality is made more sensitive by changing the threshold one time to a different value. Tiered adjustments means that a first measurement (e.g., of the area of the heart) satisfying a first threshold will result in adjustment of the second threshold to be more sensitive and a second measurement (e.g., of the area of the heart) will result in an adjustment of the second threshold to be even more sensitive and so on. A sliding scale adjustment means that a threshold value indicative of a certain anomaly will be continuously adjusted to different values to be more sensitive depending on the value of a measurement (e.g., the greater the area of the heart, the lower the detection threshold for determining a presence of an abnormality). In one example, a default threshold for identifying a tricuspid valve to mitral valve annular size discrepancy may be (1.6, 0.85) but if the area of the heart is determined to be too high (e.g., above a certain threshold value), then the threshold for identifying the tricuspid valve to mitral valve annular size discrepancy may be adjusted and

replaced with (1.55, 0.8).

[0092] Referring now to FIGS. **4**A and **4**B, examples of screen displays that may be presented at display computer **20** corresponding to clicking on the text labels identified in FIG. **2** are described. As noted above, if a standard view is identified by the interpretative component as being present in the motion video clips transmitted to server computer **30**, a checkmark will appear in column **52** in FIG. **2**. As previously described, clicking on the checkbox will cause the raw image selected by the interpretative component to be displayed on display computer **20**. Clicking on the "None" label in column **53** will cause the selected image frame, annotated with the overlay generated by the interpretative component, to be displayed on display computer **20**. FIG. **4**A is an example of an image frame corresponding to a 4C standard view, without abnormalities and with the foramen ovale identified. FIG. **4**B is an example of a selected image frame corresponding to a standard 4C view, in which a large atrioventricular defect is detected. In FIG. **4**B, the defect is surrounded with a white bounding box; other cardiac structures are identified by textual and graphical labels.

[0093] Referring now to FIG. **5**, an exemplary graphic user interface is depicted including at least a portion of the image and/or video captured by an imaging system (e.g., ultrasound imaging system), a list of standard views, and a list of abnormalities. Graphic user interface **80** may be a digital display and may be presented on a device (e.g., computing device, laptop, desktop, tablet, smartphone, display, etc.) of a healthcare provider. Graphic user interface **80** may present information about whether the image corresponds to a type of standard view and/or whether a certain abnormality or condition is present in the image from the imaging system.

[0094] As shown in FIG. **5**, image **81** may be an image frame from a video clip generated by an imaging system (e.g., an ultrasound video frame and/or clip). Time bar **87** may include cursor **90** that may move along the time bar to indicate a time point along the video clip corresponding to the image presented in image **81**. Time bar **87** may further include indicator **91** which may visually indicate (e.g., via color or marker) the presence and location of an abnormality in the video clip. Cursor **90** may be moved along time bar **87** to a an image frame or other time point in the time bar corresponding to an abnormality and/or standard view. Moving cursor **90** may then cause image **81** to change to the image frame at the respective time point. In one example, image **81** may be annotated with color, bounding boxes, text, or other visual indicators to identify the location of the abnormality in image **81**.

[0095] Standard view list **82** may include a list of standard imaging views (e.g., 4C, LVOT, RVOT, 3V, 3VT, etc.). Any other image view other than those listed in FIG. **5** may alternatively or additional be included. For each standard view, image **81** includes record and frame indicator **83**, which identifies whether or not a record is present for each view and whether or not a representative frame is identified for each view. Time bars **84** are also included for each view and are commensurate in length with the length of time of a given video clip. For each time bar, a visual indicator (e.g., visual indicator **85**) is included to show where in the video clip the given standard view appears. If no visual indicator is provided for a given time bar, then the respective standard view does not appear in the video clip. Cursor bar **86** is also included on time bars to indicate the location on time bars **84** that corresponds to the image frame presented at image **81**.

[0096] Abnormality list **89** may include a list of abnormalities and/or conditions corresponding to image **81**. For example, abnormality list **89** may include enlarged CTR, cardiac axis deviation, RV/LV size discrepancy, TM/MV size discrepancy, septal defect at the cardiac crux, overriding artery, parallel great arteries, PV/AV size discrepancy, abnormal outflow tracts relationship, and/or any other abnormality and/or condition. For each abnormality and/or condition, graphic user interface **80** includes record and frame indicator **88**, which identifies whether or not a record is present for each view and whether or not a representative frame is identified for each view. For purposes of identifying whether a record is present or absent, if at least one frame of the record is identified as present, any other frames identified as absent will be disregarded or relabeled as inconclusive.

[0097] Time bars **95** are also included for each view and are commensurate in length with the length of time of a given video clip. For each time bar of time bar **95**, visual indicator **96** is included to show where in the video clip the given view appears. If no visual indicator is provided for a given time bar, then the given abnormality or condition corresponding to the time bar does not appear in the respective video clip. Cursor bar **86** may also be included on time bars to indicate the location on time bars **95** that corresponds to the image frame presented at image **80**.

[0098] Time bar **94** may also be included below time bars **84** and time bars **95** and may indicate the location of cursor bar **86** along the length of the respective video clip via cursor **93**. Moving cursor **90**, cursor bar **86**, and/or cursor **93** may cause the other cursors and/or cursor bars to respectively move. Time bar **94** may include a play and/or pause button. When the play button is engaged, the video clip may play, showing the various image frames of the video clip in image **81**. As the video clip progresses in image **81**, cursor bar **86** and cursors **90** and **93** may progress along their respective time bars. When the pause button is engaged, the video clip may be paused. Graphic user interface **80** may optionally include buttons **98** to move to the next or previous video clip.

[0099] Referring now to FIG. **6**, an exemplary process flow for obtaining medical images, identifying red flags, annotating the images, and providing the flagged and annotated images in a graphic representation is depicted. As shown in FIG. **6**, fetal images (e.g., **2**T fetal ultrasound images, videos, and/or recordings) are generated and transferred to a platform, which may be a cloud-based platform on a server which may be a remote server or a local server. The platform may process the images using techniques described herein to identify red flags (e.g., the presence of anomalies, abnormalities, and/or conditions in the images). The images may be annotated to indicate the presence of the anomalies, abnormalities, and/or conditions. Alternatively, or additionally, metadata or other data may be associated with the image and include such information. The annotated images may be presented to a health care provider (e.g., clinician) on a healthcare provider device for immediate or near immediate (e.g., 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, etc.) review by the healthcare provider. The review by the healthcare provider may occur while the patient is onsite. The device that generates the images and/or the healthcare provider device may be in wireless communication (e.g., via the internet) with the platform. The healthcare provider device and the imaging device may be the same or different devices.

[0100] Referring now to FIG. **7**, an exemplary graphic user interface including a representation of images of the patient, patient information, and a list of abnormalities is depicted. Graphic user interface **100** may include patient information **101** include a patient ID, the healthcare provider center, the date, the time, and any other relevant information. Graphic user interface **100** may further include images **102** which may include a play and/or pause button for playing a video of the images (e.g., ultrasound video). A user may scroll to the next video or image by moving the graphic user interface up and down.

[0101] Graphic user interface **100** may further include abnormality analysis **103** for each image **102**, which may include a list of abnormalities and for each abnormality a time bar may be provided on which a visual indicator may indicate whether that respective abnormality is present in the video. The visual indicator may be a color bar which may extend the portion of the time bar for which the abnormality is present. The time bars may include a cursor for indicating the location along the time bar corresponding to the image frame present on image **102**. Abnormality analysis may further include a time bar with a cursor and a pause and play button. Moving the cursor, and/or engaging pause or play may cause image **102** to move to a certain time point, to pause, or to play.

[0102] Referring now to FIGS. **8**A-**8**C, exemplary user interfaces for displaying image data generated by an ultrasound system as well as standard view and abnormality indicators are illustrated. For example, user interface **200** of FIG. **8**A may be generated by an ultrasound system (e.g., ultrasound system **10** of FIG. **1**B). User interface **200** may be presented on display computer **20** of ultrasound system **10** and/or display **22** of healthcare provider device **25**.

[0103] User interface **200** may include user section **202** which may include exam title, which may

be an identifier for an ultrasound examination, user information **206**, which may include a user identifier (ID), a date, center data, age of the fetus, age of the mother, a status (e.g., processed), and the like. User section **202** may include comment portion **208** for a technician or other healthcare provider to make notes about an examination and/or about a set of image data (e.g., video clip).

[0104] User interface **200** may further include thumbnail viewer **210**, detailed viewer **230**, and exam summary **214**. Thumbnail viewer **210** may be a collection of thumbnail images, each corresponding to a video clip and/or image frame generated by ultrasound device **10**. For example, during an ultrasound examination, image data such as image clips and/or image frames may be generated. In one example, a thumbnail image for each video clip generated for a given examination may be included in thumbnail viewer **210**. Thumbnail viewer **210** may further include video indicator **222** which may visually indicate whether or not the image data includes a video clip, and/or indicator **224**, which may visually indicate whether or not the fetal heart is interpretable in at least one frame of the corresponding set of image data. For example, if the set of image data is corrupt or if the fetal heart is not present in the set of image data, indicator **224** may not be included in thumbnail viewer **210** or otherwise indicator **224** may visually indicate that the fetal heart is not interpretable.

[0105] Each set of image data (e.g., video clip and/or one or more image frame) generated during an examination may be viewed in detailed viewer **230** (e.g., by clicking on a thumbnail image (e.g., thumbnail image **220**) of thumbnail viewer **210**. For example, detailed viewer **230** may correspond to thumbnail image **220**. A user may click on a different thumbnail image in thumbnail viewer **210** to update detailed viewer **230** to present the set of image data corresponding to thumbnail image **220**.

[0106] Detailed viewer **230** may include image data viewer **232**, standard view indicator **234**, and morphological anomaly indicator **236**. Image data viewer **232** may present a video clip and/or still frame of the image data (e.g., the set of image data corresponding to thumbnail image **220**). Standard view indicator **238** may include list of standard views **242** and color indicators **238** indicating whether or not each standard view in list of standard views **242** is present in the image data or if the presence of such standard view is inconclusive. For example, a color indicator may indicate whether or not a certain standard view is present in the image data (e.g., using different colors for present and absent).

[0107] Morphological abnormality indicator **236** may include list of morphological abnormalities **244** and color indicators **240** indicating whether or not each morphological abnormality in the list of morphological abnormalities is present in the image data. For example, color indicator **240** may indicate whether or not a certain morphological abnormality is present in the image data or alternatively if the presence of the morphological abnormality is inconclusive. The color indicator for standard view indicator **234** may be different than the color indicator for morphological abnormality indicator **236** (e.g., each using different and unique colors for present and absent). Also, a different and unique color may be used for inconclusive.

[0108] Referring now to FIG. **8**B, user interface **200** may be adjusted by the user to present detailed viewer **250**, thumbnail viewer **210**, and exam summary **270**. A user may select thumbnail image **240** of thumbnail viewer **210** and/or otherwise navigate user interface **200** to view detailed viewer **250**, which may correspond to thumbnail image **240**. Detailed viewer **250** may be the same as or similar to detailed viewer **230** of FIG. **8**A. Detailed viewer **250** may include image data viewer **251** which may include a still frame or video clip of image data (e.g., the set of image data corresponding to thumbnail image **240**). Time bar **252** may be included in detailed viewer **250** and as well as cursor **254** which may indicate a time point along the time bar corresponding to the image frame presented in image data viewer **251**.

[0109] Detailed viewer **250** may further include standard view indicator **253** and morphological abnormality indicator **255**, which may be the same as or similar to standard view indicator **234** and morphological abnormality indicator **236** of FIG. **8**A. As shown in FIG. **8**B, the standard view

"4C" may be present in standard view indicator **253** and with color indicator **261** indicating "yes" for present, which is presented in blue. Several morphological abnormalities are indicated as being absent in morphological abnormality viewer **255** such as enlarged CTR, RV/LV size discrepancy, TV/MV size discrepancy, and cardiac crux septal defect. The other abnormalities in morphological abnormality viewer **255** are indicated as being inconclusive. Color indicator **263** may show green to indicate a presence of each of the abnormalities in the image data presented in image data viewer **251** and white to indicate inconclusive.

[0110] Standard view indicator may also include a time bar for each standard view in the list of standard views. For example, time bar **256** may correspond to the standard view "4C." Similarly, morphological abnormality indicator **255** may include a time bar for each abnormality in morphological abnormality viewer **255**. For example, time bar **258** may correspond to enlarged CTR. Each time bar may present a color along some or all of the time bar when the corresponding standard view or abnormality is determined to be present or absent in the image data. For example, time bar **256** may be blue to indicate the presence of standard view "4C" and time bar **258** may be green to indicate an absence of enlarged CTR.

[0111] Each time bar for standard view indicator **253** and morphological abnormality viewer **255** may include a visual indicator that moves together with cursor **254**. For example, time bar **256** may include visual indicator **262** and time bar **258** may include visual indicator **260**. Additionally, below each time bar for standard view indicator **253** and morphological abnormality viewer **255**, time bar **264** may be included which may be aligned with each time bar (e.g., time bar **256** and time bar **258**) and may include a cursor that aligns with visual indicators **262** and **260**, which may be used by user to move cursor **254** to different time points along time bar **252**.

[0112] User interface **200** may further include exam summary **270** which may include standard view summary **272** and abnormality summary **276** which may summarize standard views and morphological abnormalities determined to be present, absent, or inconclusive in the sets of image data uploaded from the ultrasound system. Standard view summary **272** may include a list of standard views as well as a color indicators to indicate whether or not each standard view is present, absent, or inconclusive. Standard view summary **272** may include advance buttons **274** for each standard view which may be used by a user to advance user interface **200** to a detailed viewer including image data with the standard view present and may automatically adjust the image data viewer such that an image frame with the standard view present is in view. For example, each time advance button **274** is engaged, the next image frame determined to correspond to the respective standard view will be displayed in the detailed viewer permitting the user to efficiently view image frames and/or sets of image data corresponding to the standard views. Exam summary **270** may permit a user to efficiently determine whether a view and/or abnormality is absent, present, or inconclusive (e.g. whether or not at an abnormality is inconclusive).

[0113] Exam summary **276** may further include abnormality summary **272**. Abnormality summary **276** may include a list of abnormalities as well as color indicators to indicate whether or not each abnormality is present. Abnormality summary **276** may include advance buttons **278** for each abnormality which may be used by a user to advance user interface **200** to a detailed viewer including image data with the abnormality present and may automatically adjust the image data viewer such that an image frame with the abnormality present is in view. For example, each time advance button **278** is engaged, the next image frame determined to correspond to the respective abnormality will be displayed in the detailed viewer permitting the user to efficiently view image frames and/or sets of image data corresponding to the abnormalities. User interface **200** may further include a save button **279** to save any image data, images, determinations, and/or data from user interface **200**, settings, notes, comments, or the like.

[0114] Referring now to FIG. **8**C, detailed viewer **250** of user interface **200** may be updated to indicate that an abnormality has been determined to be present in the image data. For example, morphological abnormality indicator **255** may be updated to change color indicator **284**,

corresponding to deviated cardiac axis, to red to indicate that the image data presented in image data viewer **251** defines a "deviated cardiac axis." Time bar **282** may be changed to the same color as color indicator **255** (e.g., red) to indicate the presence of the morphological abnormality. Time bar **282** may alternatively be changed to the same color as the "absence" indicator (e.g., green) to indicate one or more frames along the time bar corresponding to an absence of the abnormality. Alternatively, only portions of time bar **282** corresponding time points in the image data associated with image frames showing the abnormality will be colored.

[0115] Referring now to FIG. **9**, process flow **300** is illustrated for dynamically requesting additional image data based on the presence or absence of standard views and morphological abnormalities in the image data. Some or all of the blocks of the process flows in this disclosure may be performed in a distributed manner across any number of devices. Some or all of the operations of the process flow may be optional and may be performed in a different order. Image data may be any medical imaging data, such as image data from an ultrasound system, for example. The image data from an ultrasound system may be greyscale ultrasound images and/or Doppler ultrasound images (e.g., color Doppler ultrasound, Power Doppler ultrasound, etc.).

[0116] At optional block **302**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system (e.g., display computer **20** of FIG. **1**B), may be executed to present a request for image data (e.g., image frames, video clips, etc.) having a certain standard view (e.g., **4**C) from a predetermined set of standard views. For example, a list of standard views that should be collected in an ultrasound examination may be predetermined. At block **304**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to determine image data (e.g., image frames, video clips (e.g., that less than 1 second, between 1 second and one minute, or between 1 minute and one or more hours), etc.). For example, the ultrasound system may present a prompt for certain image data and a user may generate the image data using the ultrasound system, which may include an ultrasound probe.

[0117] At optional block **306**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to analyze the image data to determine a presence or absence of a certain standard view from the set of standard views. For example, the image data may be processed using the approach described above with respect to FIG. **3**A. Alternatively, the image data may be processed by one or more machine learning models trained to detect standard views from image data. For example, a machine learning model may be trained using images and/or video clips known to represent a standard view and the trained model may identify a type of standard view or otherwise generate an output indicating that a standard view is not present in the image and/or video clip. At optional decision **307**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to determine whether the image data satisfies a standard view (e.g., whether the standard view is present in the image data).

[0118] In one example, at optional decision **307**, image data may be determined to satisfy a standard view only if the view is present for a certain period of time (e.g., 0.5 seconds, 1 second, 3 seconds, 5 seconds, etc.). The period of time may be in the aggregate, meaning an aggregation of all frames and/or clips showing the view in question. Alternatively, the period of time may be continuous time, meaning the standard view must be deemed present continuously for the set period of time (e.g., 1 second).

[0119] Additionally, the image data may optionally be pre-processed by one or more machine learning models trained to detect anatomy in the video clip and determine whether heart and/or cardiovascular anatomy is present. For example, the one or more machine learning algorithms may be trained to determine if the video clips shows a heart, thorax and/or cardiovascular system. If it is determined that the video clips do not show a heart or other cardiovascular anatomy, or the thorax, such video clip may be discarded or otherwise ignored.

[0120] If a certain standard view is determined not to be present or if it is inconclusive whether the standard view is present in the image data, at optional block **310**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to log or otherwise note that a certain standard view is absent in the image data or if it is not clear whether the certain standard view is present or absent, then log or otherwise note that it is inconclusive whether the certain standard view is present. Further, one or more time points (e.g., time stamps) in the image data may be associated with the certain standard view being absent or inconclusive in the image data. At optional block **311**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to present a request for additional image data corresponding to the certain standard view.

[0121] Alternatively, if a certain standard view is determined to be present in the image data, at optional block **308**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to log or otherwise note that the certain standard view is present in the image data and may associate one or more time points (e.g., time stamps) in the image data with the certain standard view. A representative still frame showing the standard view may be selected from the video clip. For example, a still frame clearly showing the standard view may be selected from a one second video clip showing the standard view. Optionally, the standard view may be labeled with text. For example, textual indicators may be applied to each representative image for each standard view (e.g., **4**C, LVOT, 3V and 3VT).

[0122] Upon determining that a certain standard view is present and/or logging or otherwise noting that the certain standard view is present, if image data corresponding to that view is determined to include an abnormality, such abnormality may be identified and/or displayed as present. Prior to determining that a certain view is present, all abnormalities for such view will be identified and/or displayed as inconclusive. In another example, an indication of whether each abnormality and/or finding is present, absent, or inconclusive may be displayed or accessible once certain standard views are determined to be present. For example, once 4C, LVOT, and RVOT are determined to be present, an indication of whether each finding and/or abnormality is present, absent, or inconclusive may be displayed and/or otherwise accessible. While 4C, LVOT, and RVOT are used as examples, any other standard views may be selected and any number and/or combination of standard views may be selected. In yet another example, each finding and/or abnormality may correspond to a threshold value for determining whether such finding and/or abnormality is present and further may correspond to a heightened threshold value (e.g., larger than the threshold value used to determine whether such finding and/or abnormality is present), which if satisfied, may result in the presence of the finding and/or abnormality being immediately displayed and/or accessible not withstanding whether or not any standard views have been determined to be present.

[0123] At block **312**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to analyze the image data to determine a presence or absence of a certain morphological and/or flow abnormalities from the set of morphological and/or flow abnormalities. For example, the image data may be processed using the approach described above with respect to FIG. **3**A. Optionally, block **312** may be initiated after block **310** as well as after block **308**.

[0124] In yet another example, decision **307** and blocks **306**, **308**, **310**, and **311** may all be optional, and block **312** may be initiated immediately after block **306**. The image data analyzed at block **312** may be an entire video clip. For example, the video clip may be made up of multiple image frames and each frame of the video clip may be analyzed at block **312** to determine the presence or absence of morphological and/or flow abnormalities.

[0125] At decision **316**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to determine whether or not the morphological and/or flow abnormality is present or absent. If it is not clear whether the morphological and/or flow abnormality is present or absent, at block **314**, computer-executable

instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to log or otherwise mark the morphological and/or abnormality as inconclusive as it is not clear whether the abnormality is present or absent at one or more time points (e.g., time stamps) associated with the image data. Alternatively, if it determined that the morphological and/or flow abnormality is present or absent, at block **318**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to log or otherwise mark the morphological and/or flow abnormality as present or absent, as appropriate, and/or associate the presence or absence of such abnormality with one or more time points in the image data. If the morphological or flow abnormality is determined to be present, a representative still frame showing the morphological or flow abnormality may be selected from the video clip. For example, a still frame clearly showing the morphological or flow abnormality may be selected from a one second video clip. Optionally, the morphological or flow abnormality may be labeled with text.

[0126] At optional decision **320**, computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to determine whether additional views of the abnormality are required. For example, when an abnormality is determined to be present, it may be desirable to generate additional imaging to further analyze the abnormality. Conversely, when it is determined that an abnormality is absent, it may be desirable to generate additional images to further confirm that the abnormality is absent. Whether or not additional views are required may be dependent on the type of abnormality detected and may be predetermined (e.g., if a certain abnormality is detected then the system may automatically request certain additional views). If additional views are not required at decision **320**, then block **302** and/or **304** may be reinitiated. Alternatively, if additional views of the abnormality are required, then at optional block **322** computer-executable instructions stored on a memory of a device, such as a server and/or computer of an ultrasound system, may be executed to present a request for additional views of the abnormality and block **304** may be reinitiated. Where the image data analyzed at block **312** is the entire video clip, decision **320** and block **322** may be skipped after block **318**.

[0127] While various illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. The appended claims are intended to cover all such changes and modifications that fall within the true scope of the invention.

Claims

1. A computer implemented method for analysis of fetal ultrasound images corresponding to a patient, the method comprising: receiving image data corresponding to data generated by an ultrasound system, the image data comprising a plurality of frames forming one or more video clip and showing a portion of fetal anatomy; analyzing the image data using a classification model comprising a first neural network to generate a first output, the classification neural network adapted to extract features from the plurality of frames and generate the first output indicative of a likelihood of a presence of a first morphological abnormality; analyzing the image data using a keypoint detection model comprising a second neural network to generate a second output, the keypoint detection neural network adapted to extract features from the plurality of frames, extract feature maps from the plurality of frames, and generate the second output indicative of coordinates of a plurality of anatomical features corresponding to the portion of the fetal anatomy; analyzing the image data using a segmentation model comprising a third neural network to generate a third output, the segmentation neural network adapted to extract features from the plurality of frames, extract feature maps from the plurality of frames, and generate the third output indicative of contours of a plurality of anatomical features corresponding to the portion of the fetal anatomy; and determining a presence of at least one abnormality corresponding to the portion of fetal anatomy

based on one or more of the first output, the second output, or the third output.

2. The computer implemented method of claim 1, further comprising comparing the first output to a threshold value to determine that the first morphological abnormality is present, absent, or inconclusive.

3. The computer implemented method of claim 1, further comprising determining, based on the coordinates, one or more of a length value, area value, or angle value corresponding to at least one anatomical feature of the plurality of anatomical features.

4. The computer implemented method of claim 1, further comprising: comparing the third output to a threshold value to determine the third output satisfies the threshold value; determining that at least one anatomical feature of the plurality of anatomical features is present based on the third output satisfying the threshold value; and generating a binary mask for the at least one anatomic feature.

5. The computer implemented method of claim 1, wherein the first morphological abnormality is one of overriding artery, septal defect at the cardiac crux, or abnormal relationship of the outflow tracts.

6. The computer implemented method of claim 1, further comprising determining one of the following based on the second output: a location of one or more of a tricuspid valve, a mitral valve, a pulmonary valve, an aortic valve, an apex of a heart, a long axis of a heart, or an anteroposterior axis of a chest.

7. The computer implemented method of claim 6, further comprising calculating one or more of the following based the location of one or more of the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve: tricuspid valve to mitral valve annular size discrepancy, pulmonary valve to aortic valve annular size discrepancy, and cardiac axis deviation.

8. The computer implemented method of claim 6, further comprising calculating one or more of the following based the location of one or more of the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve: an enlarged cardiothoracic ratio or a right ventricular to left ventricular size discrepancy.

9. The computer implemented method of claim 1, further comprising determining, based on the third output, a contour of one or more of a left ventricle, a right ventricle, a heart, or a thorax.

10. The computer implemented method of claim 1, wherein determining a presence of at least one abnormality corresponding to the portion of fetal anatomy is further based on a gestational age corresponding to a fetus in the fetal ultrasound images.

11. A system for analysis of fetal ultrasound images, the system comprising: memory configured to store computer-executable instructions; and at least one computer processor configured to access memory and execute the computer-executable instructions to: receive image data corresponding to data generated by an ultrasound system, the image data comprising a plurality of frames forming one or more video clip and showing a portion of fetal anatomy; analyze the image data using a classification model comprising a first neural network to generate a first output, the classification neural network adapted to extract features from the plurality of frames and generate the first output indicative of a likelihood of a presence of a first morphological abnormality; analyze the image data using a keypoint detection model comprising a second neural network to generate a second output, the keypoint detection neural network adapted to extract features from the plurality of frames, extract feature maps from the plurality of frames, and generate the second output indicative of coordinates of a plurality of anatomical features corresponding to the portion of the fetal anatomy; analyze the image data using a segmentation model comprising a third neural network to generate a third output, the segmentation neural network adapted to extract features from the plurality of frames, extract feature maps from the plurality of frames, and generate the third output indicative of contours of a plurality of anatomical features corresponding to the portion of the fetal anatomy; and determine a presence of at least one abnormality corresponding to the portion of fetal anatomy based on one or more of the first output, the second output, or the third output.

12. The system of claim 11, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to compare the first output to a threshold value to determine that the first morphological abnormality is present, absent, or inconclusive.

13. The system of claim 11, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to determine, based on the coordinates, one or more of a length value, area value, or angle value corresponding to at least one anatomical feature of the plurality of anatomical features.

14. The system of claim 11, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to: compare the third output to a threshold value to determine the third output satisfies the threshold value; determine that at least one anatomical feature of the plurality of anatomical features is present based on the third output satisfying the threshold value; and generate a binary mask for the at least one anatomic feature.

15. The system of claim 11, wherein the first morphological abnormality is one of overriding artery, septal defect at the cardiac crux, or abnormal relationship of the outflow tracts.

16. The system of claim 11, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to determine one of the following based on the second output: a location of one or more of a tricuspid valve, a mitral valve, a pulmonary valve, an aortic valve, an apex of a heart, a long axis of a heart, or an anteroposterior axis of a chest.

17. The system of claim 16, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to calculate one or more of the following based the location of one or more of the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve: tricuspid valve to mitral valve annular size discrepancy, pulmonary valve to aortic valve annular size discrepancy, and cardiac axis deviation.

18. The system of claim 16, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to calculate one or more of the following based the location of one or more of the tricuspid valve, the mitral valve, the pulmonary valve, or the aortic valve: an enlarged cardiothoracic ratio or a right ventricular to left ventricular size discrepancy.

19. The system of claim 11, wherein the at least one computer processor is further configured to access memory and execute the computer-executable instructions to determine, based on the third output, a contour of one or more of a left ventricle, a right ventricle, a heart, or a thorax.

20. The system of claim 11, wherein determining a presence of at least one abnormality corresponding to the portion of fetal anatomy is further based on a gestational age corresponding to a fetus in the fetal ultrasound images.