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The Case for a Portable Open-Source 3D Ultrasound: *Issues, Benefits, and Challenges*

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***Abstract*— Ultrasound diagnostic imaging is an essential aspect of modern healthcare, but barriers such as cost, technical training, and access to medical facilities impede global adoption. To tackle these factors, the need for a portable open-source three-dimensional ultrasound system is discussed. Such a system, equipped with artificial intelligence, can provide unparalleled global accessibility to life-saving affordable medical diagnostic care as well as create copious amounts of data needed for training automated systems; however, it may also carry disadvantages. This paper assesses the considerations for and against an open-source approach and draws insights from successful open-source hardware projects in the past.**

Keywords*— *Open-source, Welfare, Ultrasound, Health, Medical Care, Health, Health and Poverty, Inequality, Medical Access, Mortality, Population Health, Quality of Life, Redistribution, Education and Inequality, Diagnostic imaging, Low-cost, Artificial intelligence, 3D

I. Introduction

Since 1990, maternal deaths worldwide have dropped by 45 percent [1], but every day nearly 800 women still die from causes related to pregnancy and childbirth [2]. 99 percent of these cases occur in developing countries [3]. Prenatal imaging is an effective tool in evaluating early risk factors to aid in the prevention of maternal mortality. However, limitations such as cost and access to training make ultrasound diagnostic imaging unavailable in remote and developing regions. The World Health Organization guidelines advise for the existence of one diagnostic imaging system per 50,000 people [4]. Despite this grave necessity, over 60 percent of the world's population lacks access to ultrasound imaging [5].

Ultrasound imaging has various uses in medicine, including pregnancy monitoring, diagnosing cancers, analyzing cardiovascular degeneration, examining orthopedic injuries, and identification of infections such as chronic obstructive pulmonary disease and liver cirrhosis. During high-precision medical procedures, inserting a catheter or gastrostomy tube into the body becomes easier under ultrasound guidance.

No one in a developed country today would consider a major medical diagnosis, such as cancer or cardiovascular disease (CVD), without imaging evidence. No one would attempt serious medical intervention such as surgery, without preoperational imaging. No one would undergo pregnancy and childbirth without ultrasound support. Yet, while the lack of X-Ray, CT (computed tomography) or MRI (magnetic resonance imaging) in developing countries can be explained due to capital expenditures and medical risk, the lack of ultrasound diagnostics is puzzling. Ultrasound imaging is safe, effective, and inexpensive- yet absent from many parts of the world.

We argue that a portable low-cost three-dimensional (3D) ultrasound system, specifically an open-source system, can provide unbounded opportunities for medical diagnostic technology by:

- Mitigating logistical complications and reducing the expense of accessing medical care in rural areas
- Leveraging Artificial Intelligence (AI) to facilitate image calibration, interpretation, processing, and diagnosis; reducing the dependency on trained staff
- Producing ample amounts of data that is sorely necessary for modern AI techniques to flourish, but is now available only to large organizations
- Creating an open platform that is not centrally controlled and therefore incentivizes and catalyzes continuous third-party innovation

In this paper, we discuss the unmet need for readily accessible diagnostic imaging, uses of ultrasound imaging, and implications of features such as portability, 3D imaging, AI, and open-source approach in increasing operationality and utility of ultrasound equipment. We also discuss ethical considerations and potential negative impacts of openly-accessible ultrasound imaging.

A. Accessible Medical Imaging Can Ease Global Health Problems

Limited access to medical facilities, equipment, and physicians has fueled inadequacies in standard patient care. One of the greatest threats to global public health is the lack of data to make well-informed health decisions. Few studies of ultrasound impact in low- and middle-income countries

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(LMICs) [6], have ever been performed and concrete data regarding ultrasound use and its availability around the world is scarce.

The 2008 study, *Impact of the Introduction of Ultrasound Services in a Limited Resource Setting: Rural Rwanda 2008,* (Fig. 1) highlights the impact of ultrasound services in limited-resource settings [7]. Diagnostic imaging systems were introduced at two district hospitals affiliated with Partners in Health, a United States non-governmental organization. Of the 345 scans performed, obstetrical ultrasound was the most frequent application. Evaluation of gestational age, fetal head position, and placental positioning were the most common findings. Additional uses included abdominal, cardiac, renal, pleural, procedural guidance, and vascular ultrasounds.

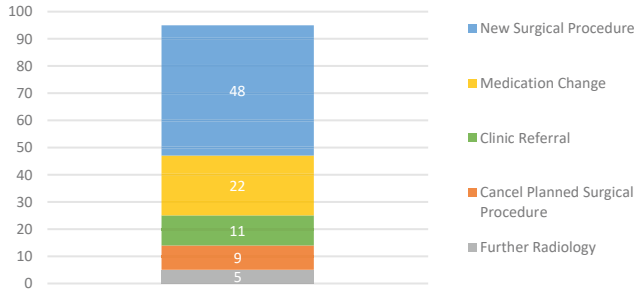


Fig. 1. *Changes in clinical management based on ultrasound findings. The use of ultrasound changed patient management in 102 of 242 of cases.* Source: Perry, Lora, and Robert Malkin. "Effectiveness of Medical Equipment Donations to Improve Health Systems: How Much Medical Equipment Is Broken in the Developing World?" Medical & Biological Engineering & Computing, vol. 49, no. 7, 2011, pp. 719–722., doi:10.1007/s11517-011-0786-3.

Access to medical imaging altered patient management outcomes in 42 percent of the cases evaluated. The most common change was to plan life-saving surgical procedures such as caesarian sections, biopsies, and minor surgeries. Public health interventions from non-governmental organizations resulted in a positive and sustainable outcome. The staff at the Rwanda clinics were non-radiologists lacking formal ultrasound training, but with guidance were able to autonomously perform imaging scans at 96 percent accuracy. The benefits of widespread diagnostic imaging, especially in obstetric care, are numerous.

B. How Medical Imaging Can Help Researchers Help Us

Mother and child mortality are one of the largest healthcare concerns of today; of the 8.2 million deaths of children under the age of five, approximately 3.3 million occur during the neonatal period (within the first month of life) [8]. Preterm babies are at a higher risk for neonatal mortality and long-term disabilities, costing the US healthcare system approximately $51,600 USD per infant, or over $26 billion USD each year [9, 10]. An open-source ultrasound can have a positive impact in generating copious amounts of data for academic research focused on addressing public health concerns.

Dr. Kristin Myer's Soft Tissues lab at Columbia University is using quantitative ultrasound imaging (QUS) to predict the risk of preterm birth in expectant mothers. Researchers aim to identify the anatomical and material factors that create cervical stress, tissue remodeling, and premature opening of the cervix, leading to potential complications in pregnancy. Finite element models are used to study the levels of excess mechanical load on the cervix and uterus which can potentially lead to premature rupture of the cervical lining, onsetting preterm birth.

Globally, prematurity is the leading cause of death in children under the age of five [11]. An estimated 15 million babies are born premature each year and those who survive can face a lifetime of disability [12]. QUS -based methods can also help detect and diagnose malignancies such as prostate and metastatic cancer [13]. In many cases, free and open access to medical imaging will prevent funding constraints from limiting cutting-edge research and aid in gathering critical information for researches, scientists, and medical experts.

II. The Main Factors Limiting Ultrasound Utilization

Cardiovascular (heart) disease is the number one cause of death in the world, and ultrasound is used to diagnose it. In 2012, there were 17.5 million cases of death from cardiovascular disease, with over 75 percent of fatalities occurring in developing countries [14]. In LMICs and among people in high-income regions with limited healthcare options, heart disease poses a major public health challenge. Premature disability and death can lead to negative economic implications. Over the period of 2011 to 2025, this impact is predicted at 21 million productive life years lost; or a cumulative economic loss output of approximately 3.76 trillion USD in LMICs [15].

A multitude of factors are responsible for missed opportunities to realize major gains in healthcare, including insufficient financial resources and populations inhabiting remote areas. This situation sheds light on the large-scale global health problem; we hypothesize that lack of medical care is a potential factor in the struggle for economic growth in LMICs. Higher-income countries can have 57 times as many ultrasound machines as developing countries do, sustaining a workforce with access to healthcare options.

Ultrasound is operator as well as equipment dependent, and difficulties in procuring ultrasound machinery, maintenance of broken equipment, and sourcing of trained medical personnel are major reasons for the deficiency of diagnostic imaging. We believe these barriers can be readily addressed with low-cost, openly accessible medical imaging.

A. Equipment Dependency Limits Ultrasound Use

The World Health Organization estimates that 80 percent of the medical equipment in the developing world is donated and only 10 to 30 percent of donated equipment ever becomes operational. A 2011 study examined inventory levels from 16 LMICs and concluded that an estimated 40 percent of donated health-care equipment is out of service (Fig. 2) compared to less than one percent in high-income regions [16].

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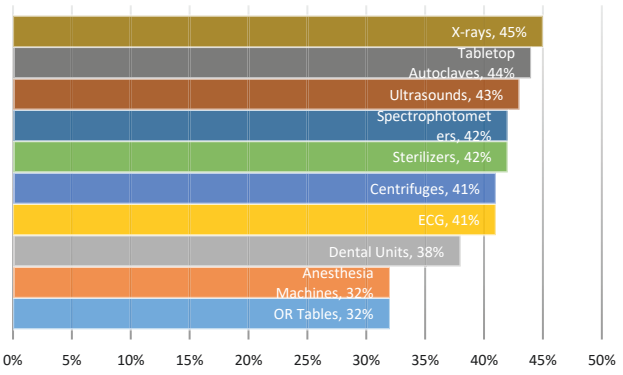


Fig. 2. *Percentage of out-of-service equipment by type. Based on a 2011 study examining inventory data from 15 countries in the Americas, Africa, and Asia.* Source: Perry, Lora, and Robert Malkin. "Effectiveness of Medical Equipment Donations to Improve Health Systems: How Much Medical Equipment Is Broken in the Developing World?" Medical & Biological Engineering & Computing, vol. 49, no. 7, 2011, pp. 719–722., doi:10.1007/s11517-011-0786-3. OR, operating room; ECG, electrocardiogram.

Additionally, there are also barriers preventing the use of fully functional equipment. Donated equipment may be incompatible with existing standards and systems, necessitating purchase and use of voltage converters. In most cases, sonographers must be present to operate the equipment. Nearly two-thirds of the global population struggles to access diagnostic imaging; of the equipment that is available, close to half is nonfunctional or defective, potentially leading to misdiagnosis and improper disease management.

B. *Operator Dependency Limits Ultrasound Use*

Since the global implementation of ultrasound technology in the 1980s, ultrasound has complemented or even replaced the need for imaging procedures such as X-ray, MRI, and echocardiogram. Ultrasound equipment has become compact, higher quality, less expensive, and easier to use, facilitating the growth of remote point-of-care ultrasound (PoCUS). The use of PoCUS by a broader range of physicians and allied health professionals has become widespread, including emergency medicine, cardiology, anesthesiology, rheumatology, obstetrics, neonatology, gynecology, gastroenterology, and other specialties. This increased utilization of medical imaging has further implications for education and training.

The operation of diagnostic ultrasound by individuals without proper training can increase the likelihood of unnecessary examinations and misdiagnosis. In many cases, the number of trained technicians available to perform an ultrasound scan is highly inadequate when considering population size. This can lead to a shortage of medical imaging options. In 2012, there were 3.180 trained physicians per 1000 population in France, 1.13 per 1000 in Peru, 0.20 per 1000 in Indonesia, and 0.04 per 1000 in Mozambique [17].

To better understand this disparity, we consider Shah, et al.'s 2015 study, *Perceived Barriers in the Use of Ultrasound in Developing Countries* (Fig. 3). When surveyed, health care providers working in 44 LMICs identified lack of training (59.9 percent), cost of machine acquisition and maintenance (50 percent), lack of maintenance (47.0 percent), and lack of equipment (45.5 percent) as their most common barriers to ultrasound use [18].

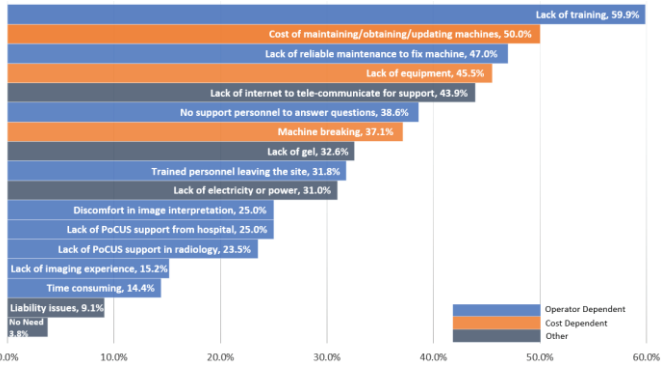


Fig. 3. *Percentage of respondents who have experienced this barrier to ultrasound use.* Based on Perceived barriers in the use of utlraosund in developing countries, a 2015 survery of 44 countries in Africa, South America, and Asia. Source: Shah, Sachita, et al. "Perceived Barriers in the Use of Ultrasound in Developing Countries." Critical Ultrasound Journal, vol. 7, no. 1, 2015, doi:10.1186/s13089-015-0028-2.

Worldwide, the need for training has grown in parallel to the demand for ultrasonography. The primary barrier to ultrasound imaging is the lack of widespread technical training programs. Solutions such as free and openly accessible online training modules and automated imaging software can help diminish the training gap and allow for facilitated sonogram interpretation. With the increased use of ultrasonography in medical settings, the need for education and training is clear.

Unlike X-ray-based modalities, no international and few national requirements or recommendations exist for the use of ultrasound [19]. Most countries do not have organizations overseeing ultrasound training and implementation. An open-source ultrasound modality partnered with training manuals and potentially an AI-based user interface, would make a global impact by facilitating consistent interpretation and uniform data gathering while providing universal access to imaging processing software. Open-access medical imaging could become a disruptive technology.

C. *The Advantages of 3D Imaging*

A sonographer's level of training and proficiency in imaging techniques can affect image quality. Three-dimensional ultrasound can help eliminate operator dependency in the medical imaging process. When distinguishing between malignant and benign tumors, the increased detail in a three-dimensional scan is highly preferred. Similarly, when diagnosing prenatal complications, three-dimensional visualization can help identify spatial complications. However, 3D commercial ultrasound systems that provide the best-in-market image quality and processing software can retail for up to $250,000 USD [20, 21].

The major reason for the increase in use of 3D ultrasound is related to the limitations of viewing anatomy. Conventional ultrasound images are two-dimensional (2D), yet the body's anatomy is three-dimensional. 3D ultrasound provides a more

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comprehensive, accurate and repeatable way of evaluating anatomic structures and disease entities than 2D ultrasound [22]. Generating brighter images (Fig. 4) with clearer volume and spatial relationships between anatomical structures leads to a higher diagnostic accuracy than with conventional 2D ultrasound imaging. The richness and redundancy in 3D data may reduce the amount of training required for sonographers and radiologists while increasing operator reliability.

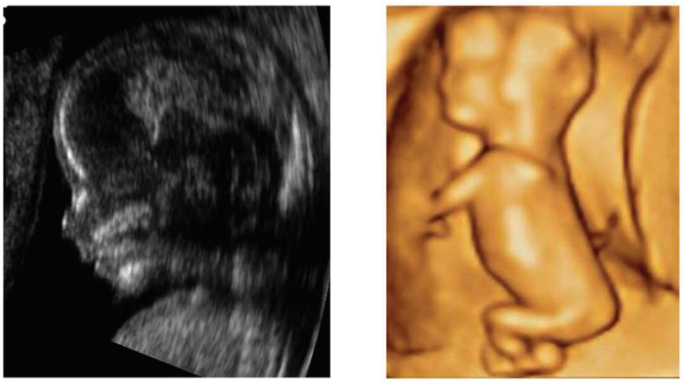


Fig. 4. *A fetus at 14 week's gestational age images in 2-Dimensional ultrasound (left) versus 3-Dimensional ultrasound (right).* Source: Wikipedia 2018.

2D imaging requires the clinician to sweep the ultrasound probe back and forth across the subject at specific orientations while visualizing the anatomy from multiple scans. In contrast, standard 3D imaging typically requires the acquisition of a single volume or sweep. Spatial information is gathered from examining image slices at varying angles and 3D visualization techniques such as volumetric reconstruction and surface rendering may be employed. Longitudinal 3D ultrasound scans can precisely assess size and location of tumors, cysts, and even distinguish blood vessels from lymph nodes. Its accuracy and repeatability make 3D ultrasound more suitable than 2D for monitoring the progression of a disease and its response to treatment [23].

A 3D ultrasound may carry disadvantages such as the time taken for the comprehensive 3D acquisition, the use of an external tracking device, and the possibility that the probe pressure may vary during the scan, leading to distortions in the image [24]. To ensure accurate data gathering during routine scans, the technician must scan with a smooth trajectory at an appropriate speed.

We hypothesize that it is possible to eliminate the need for precise manual scans while operating 3D ultrasounds. A portable open-source 3D ultrasound would have the ability to utilize established 3D reconstruction algorithms such as 3D simultaneous localization and mapping (SLAM) for image reconstruction. SLAM is an algorithm that stitches point clouds from sensors into a 3D map of an area or a volume. It is a key component in autonomous systems such as self-driving cars, robotic vacuum cleaners, and warehouse forklifts.

D. The Role of AI in Medicine

In 1950, Alan Turing published the landmark paper, *Computing Machinery and Intelligence*, which explored the mathematical feasibility of AI and suggested that machines could think [25]. The term "artificial intelligence" was officially established during the 1956 Dartmouth Summer Research Project on Artificial Intelligence conference. Subsequent investments from governmental organizations catalyzed the development of high-speed processing computers, fueling rapid growth of AI applications. In the 1970's, AI methods were being applied in fields such as life science and medicine [26]. Via increased availability of healthcare data and advancements in computing power, AI has assisted clinical decision making and even replaced human judgement in areas such as radiology [27].

The AI market has witnessed proliferated growth and is projected to create a nearly $150 billion USD savings in healthcare spending for the United States by the year 2026 [28] (Fig. 5). Meanwhile, the global AI market is expected to grow from $600 million in 2014 to $6.6 billion USD by 2021 at an annual rate of 40 percent [29]. This massive growth is enabling an era that is evolving to make better use of human-AI potential in medicine. AI tools can help alleviate the staff shortage in healthcare and provide workers with the necessary tools to enhance efficiency, while simultaneously increasing patient health and experience.

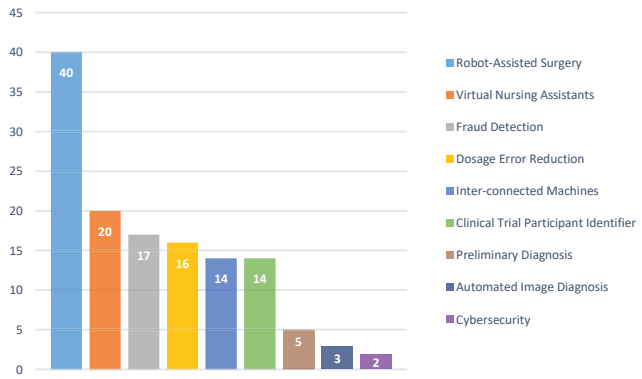


Fig. 5. *A projection of the impact in billions of dollars of the top 10 artificial intelligence applications by 2026*. The total combined value is $148 billion USD. Source: Data obtained from Accenture.

A team at Stanford University has trained AI using convolutional neural networks (CNNs) to classify skin cancers. By characterizing images of skin lesions as either benign or malignant cancer, the need for invasive biopsies [30] is reduced. Machine learning techniques are applied to 130,000 clinical images of over 2,000 diseases. This AI tool can significantly mitigate access, discomfort and, economic burden for cancer patients. The CNN achieves accuracy levels comparable to those of board-certified dermatologists. With the use of AI, medical phone applications will be able to extend the reach of physicians to provide diagnoses without patients accessing a medical facility. Readily available AI tools could also be used more frequently to facilitate early detection.

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Studies show that the application of AI in ultrasound can simplify sonogram interpretation and prevent misdiagnosis [31]. One current use of AI in ultrasound involves identification of a gestational sac or fetus's standard plane (i.e. the plane containing the largest cross-sectional area of a scanned region), a challenging task for trained sonographers [32]. The Samsung Medical Center study, *S-Detect™ in Breast Ultrasound: Initial Experience,* takes into consideration assessments of breast masses by a computer-aided diagnosis system using AI technology called S-Detect™ and compares results to those agreed upon by three breast dedicated radiologists with 7 to 14 years of experience [33].

Breast ultrasound examination requires a more systematic and standardized approach and assessments are highly operator dependent. Ultrasound results were interpreted by both radiologists and the computer automated system. Overall, S-Detect™ and radiologists showed excellent agreement on 91.2 percent of all diagnoses. However, both were prone to error. In two cases, S-Detect™ and doctors incorrectly classified fibroadenomas (a benign tumor) as malignant. The study concludes that S-Detect™ is an effective supporting tool in assessing and characterizing breast lesions, which is especially helpful for untrained radiologists. The accuracy of machine learning can be improved by increasing the dataset of breast abnormalities for CNNs to reference.

It is important to emphasize, however, that the use of AI in diagnostics is not merely about improving accuracy. In many cases, an automated diagnosis can substitute a lack of access to experts. Software enhancement tools are improving ultrasound image quality and facilitating autonomous detection of cancer and other diseases, reducing the dependency on trained ultrasonographers. With an open-source platform we can increase available training data to help AI systems become more accurate. The rise of machine learning ultrasound applications suggests that ultrasound imaging can eventually be standardized even for more challenging diagnostics. As AI applications gain more experience in the medical field, the process of continual learning will lead to higher precision and efficiency.

III. Potential Benefits of a Portable Open-Source 3D Ultrasound System

Ultrasound is a front-line diagnostic tool not only in pregnancy and obstetric care, but also in routine health monitoring and emergency care. The main advantage of a portable ultrasound is the flexibility of utilizing diagnostic imaging in varying settings and applications, enabling patient care anywhere and anytime.

In the next sections we will examine the role of ultrasound in health monitoring and discuss the benefits of deploying compact ultrasound systems as a means of improving patient care.

A. Ultrasound Use in Cardiovascular Disease Screening

CVD, a term describing ailments of the heart, is the leading cause of global mortality in developed and developing nations. Of the 15.2 million deaths worldwide in 2016, (Fig. 6 & Fig. 7) over 85 percent were attributable to heart attack and stroke [34]. Global access to medical imaging and treatment is highly inadequate; it is estimated that by 2030, 23.6 million people will die annually from CVD. With 80 percent of all CVD deaths occurring in low-resource regions, LMICs will be disproportionally affected by this increase [35].

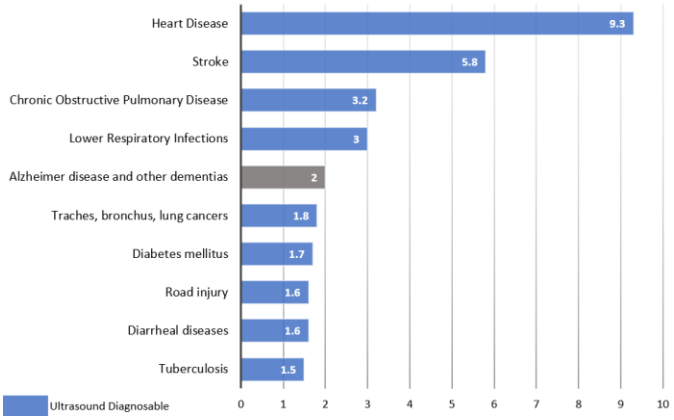


Fig. 6. *Top 10 global of causes of death (in millions).* Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2016. Geneva, World Health Organization: 2018.

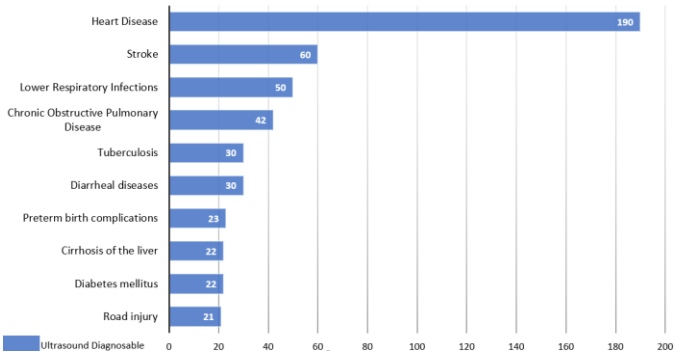


Fig. 7. *Top 10 causes of death in low-and middle-income countries (per 100,000 population).* Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2016. Geneva, World Health Organization: 2018.

In low-resource areas, most CVD deaths occur during peak productive decades of life, compared to later stages in more developed regions. Early detection is vital, and patients diagnosed at later stages in life are more susceptible to death. In a report titled *A Race Against Time* (Columbia University, 2003), it was estimated that by the year 2030, heart disease will be responsible for reducing over 30 million future years of productive life from five countries alone: Brazil, India, China, South Africa, and Mexico, versus just over 2 million in the Unites States and Portugal [36].

The use of diagnostic equipment, specifically compact ultrasound systems, is advantageous in diagnosing health issues in varying settings. In *Making an Impossible Mission Possible* (Kobal et al., 2004), a study based in Gambia, hand-carried, battery-powered ultrasounds were used by physicians to identify patients at a high risk of CVD [37]. Out of the 1997

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patients examined, 17 percent were diagnosed with hypertension (high blood pressure) and subsequently underwent echocardiography to identify risk of left ventricular hypertrophy, a marker indicative of high CVD risk. Left ventricular hypertrophy was identified in 65 percent of patients and preventative measures were taken. Compact ultrasound systems support clinicians in detecting the risk for and treatment of CVD in areas with limited access to medical imaging.

A similar study, *Focused Cardiac Ultrasound Screening for Rheumatic Heart Disease by Briefly Trained Health Workers: A Study of Diagnostic Accuracy* (Engelman, et al., 2016), was performed in Fiji to classify individuals with rheumatic heart disease [38]. Seven nurses with no prior diagnostic imaging experience performed focused cardiac ultrasound examinations using portable machines after having completed an 8-week training program (compared to the standard ultrasonography training length of 24 weeks). Approximately 2004 children between the ages of 5 and 15 were recruited for the study. The sensitivity and specificity of individual nurses during ultrasound scans ranged from 66.7 to 100 percent and 74 to 93.7 percent, respectively. This study reveals not only the importance of the use of ultrasound to reduce prevalence of cardiac disease, but also demonstrates the diagnostic capability of briefly trained nurses.

B. Ultrasound Use in Emergency Situations

Ultrasound is a front-line diagnostic tool in pregnancy and obstetric care, as well as in routine health monitoring and emergency care. Hand-held ultrasound supports rapid access to diagnostic imaging on-the-go and aids in situations such as daily patient management and triaging life-threatening injuries. Mass casualty incidents are defined as emergency situations that overwhelm local healthcare systems and require fast and effective triage of large numbers of patients [39]. These incidents typically occur in settings that are severely limited in resources and may lack trained personnel, shelter, sanitation, and electricity.

The Use of Portable Ultrasound Devices in Low- and Middle-Income Countries: A Systematic Review of the Literature (Becker et al., 2016) demonstrates that hand-carried ultrasounds have potential to affect clinical management in up to 70 percent of cases [40]. Diagnostic ultrasound imaging can improve triage effectiveness and allow for best course of action in emergency patient management. During triage, patient's injuries are evaluated to identify the most serious cases and provide rapid care. The role of focused assessment with sonography for trauma (FAST) in blunt abdominal trauma is well known, yet there are few studies on the use of FAST in military deployment. Unfortunately, pre-hospital triaging accuracy greatly depends on the abilities of the responders: while physician accuracy is high at 86.4 percent [41], emergency medical service personnel accuracy can range from 45 to 78 percent [42].

The Utility of Focused Assessment with Sonography for Trauma as a Triage Tool in Multiple-Casualty Incidents During the Second Lebanon War (Beck-Razi, et al., 2007) evaluates the effectiveness of FAST as a triage medium at a trauma center during the Second Lebanon War [43]. FAST was performed on 102 (36.3 percent) of the admitted patients upon suspicion of abdominal injuries. Ultrasound is considered the first-in-line modality, followed by more specific imaging tests if necessary. Upon the initial feedback from the FAST protocol, physicians may follow with a laparotomy, CT scan, or clinical observation (Fig. 8). The sensitivity, specificity, and accuracy rates of FAST remain relatively high with demonstrated rates of 75, 97.6, and 93.1 percent, respectively. As with any sonographic examination, operator experience plays an important role in accuracy.

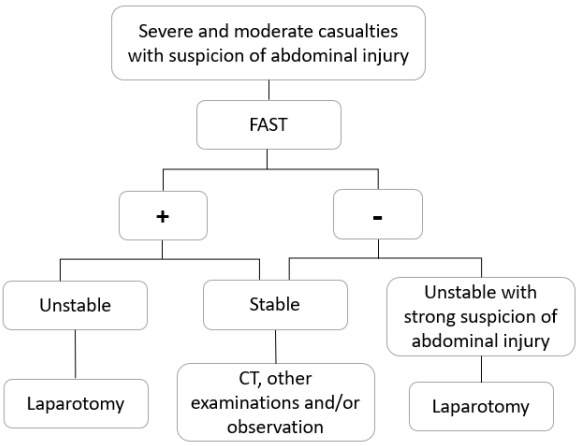


Fig. 8. *The FAST Protocol.* Severe and moderate casualties are the first to undergo FAST examination during continuous arrival. According to the results and the patient's hemodynamic stability, triage to laparotomy, CT, or clinical observation can be performed. Laparotomy is an emergency surgical incision in the abdomen. Source: Beck-Razi, Nira, et al. "The Utility of Focused Assessment with Sonography for Trauma as a Triage Tool in Multiple-Casualty Incidents During the Second Lebanon War." Journal of Ultrasound in Medicine, vol. 26, no. 9, 1 Sept. 2007, pp. 1149–1156., doi:10.7863/jum.2007.26.9.1149.

Sonographic Screening of Mass Casualties for Abdominal and Renal Injuries Following the 1988 Armenian Earthquake (Sarkisian et al., 1991) demonstrated that during the 1988 Armenian earthquake, trauma ultrasound could be performed quickly (an average four minutes per scan) and effectively on 400 patients [44]. As a result, 96 patients with clinically significant pathological conditions were identified and 16 were taken to an operating room. The utility of portable ultrasound was also evaluated when a 7.0 magnitude earthquake struck Haiti on January 12, 2010, killing an estimated 222,000 people and injuring 300,000 others. Access to portable ultrasound altered patient management outcomes were for 86 percent of trauma cases and 93 percent of non-trauma abdominal ultrasound [45]. On-scene use of FAST was effective as well. A simulation-based study reported that use of FAST for on-scene triage potentially identified seven percent of patients with delayed internal hemorrhage [46]. The effectiveness of trauma ultrasound suggests that portable ultrasound is an indispensable triage tool in mass casualty incidents.

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C. Ultrasound Use in Pregnancy Monitoring

Chrystelle Wedi, co-founder of the Ona Mtoto Wako (*See Your Baby*) initiative in the Democratic Republic of Congo details her experience travelling and speaking to women and girls in remote villages [47]. Wedi provides insight on technical and social-economic problems faced by inhabitants of rural areas when considering prenatal care. Due to remoteness of location, most people seek medical attention only after they begin suffering from an ailment and know that something is wrong. Being uniformed about potential life-threatening ailments leads to a lack of critical information to make important health decisions. Hospitals can schedule caesarian sections during the first and second trimesters, giving the families time to plan. Most complications during pregnancy are preventable or treatable. Unfortunately, because ultrasounds are not being performed during antenatal care, the need for a caesarian section is not discovered until the onset of labor, resulting in a high risk of maternal mortality.

Routine prenatal ultrasound scans are an indispensable tool in obstetric health and used to diagnose and facilitate prompt intervention. In the Philippines, the major causes of maternal and neonatal mortality are hemorrhaging and obstructed labor due to multiple gestations (twin pregnancies), fetal malpositioning, and placental implantation abnormalities, all of which are easily detectable with routine prenatal ultrasound scans [48]. However, women in low income groups and remote regions have struggled to gain access to prenatal care, making pregnancy and childbirth perilous.

In addition to improving maternal health, diagnostic imaging has been shown to reduce childhood mortality. Preterm babies are at a higher risk for neonatal mortality and long-term disabilities, often caused by birth defects. One percent of infants develop congenital anomalies (i.e., metabolic disorders) stemming from nutritional deficiencies and disease [49]. Diagnostic imaging allows for early discovery and possible treatment. Ultrasound can identify structural abnormalities and issues with developmental growth. For cases of serious life-altering abnormalities, early diagnosis would provide parents with option for an abortion to reduce suffering. Such cases are more prevalent in low-resource settings.

The impact that pregnancy and childbirth-related deaths has on LMICs versus high-income countries is dramatically different: while one out of seven women in Niger will die due to maternal complications, one out of 48,000 will die in Ireland [50]. In 2005 there were 536,000 global pregnancy-related deaths. The situation is most dire in Sub-Saharan Africa (201,000 deaths), and Southeast Asia (66,000 deaths), where one in every 160 women dies of pregnancy related causes, compared with only one in 3700 in high-income regions [51]. 99% of all maternal deaths occur in LMICs where the maternal mortality ratio can be up to 14 times higher (242 per 100,000 births).

Diagnosis of health problems through non-invasive obstetric ultrasound can improve progress towards the Millennium Development Goal 5 of reducing global neonatal and maternal mortality by 75 percent. There have been efforts to increase worldwide access to critical medical care. Between 2000 and 2015, maternal deaths have dropped by 37 percent, and under-five child mortality by 44 percent. However, the current situation remains inadequate and needs in obstetric and antenatal care are not being met.

In *Handheld Ultrasound to Avert Maternal and Neonatal Deaths in 2 Regions of the Philippines: An iBuntis® Intervention Study* (Dalmacion et al., 2018) additional evidence on the benefits of hand-held ultrasound is presented [52]. 6 doctors, 5 nurses, and 9 midwives from the two cities were selected for the program. Training was led by the President of the Philippine Society of Ultrasound in Obstetrics and Gynecology. All trainees were taught using mobile ultra-portable General Electric VScan ultrasounds which retail for $10,000 USD [53] and up (may be obtained at a discount if purchased refurbished or used). Ultrasound screening was performed on 460 women of which 145 (31.7 percent) were found to have obstetric abnormalities. Patients with high risk were further evaluated or referred to Emergency Maternal and Neonatal Care units.

In conclusion, the use of hand-held ultrasound prevented an estimated 6.3 percent maternal and 14.6 percent neonatal deaths. The impact of a certified training program on inexperienced ultrasound operators (non-radiologists) was evident: there was a positive agreement between trainees and professionals on 95 percent of all diagnoses. How did ultra-compact ultrasound compare to cart-based ultrasound? GE VScan portable system had a 99 percent accuracy rate when compared to standard ultrasound equipment that can be found in a doctor's office. PoCUS can successfully diagnose abnormal conditions which potentially lead to maternal and neonatal deaths.

Dalmacion et al. also observed that socio-cultural beliefs were critical barriers in prenatal health. Medical imaging technology is viewed as a taboo by some cultures who oppose the visualization of an unborn fetus. and Clinical data and knowledge for decision-making on childbirth and labor were superseded by cultural and social convictions. One such case is patient diagnosed with a breech pregnancy (malpositioned fetus) who refused to deliver at a hospital despite serious warnings of potential complications during childbirth.

IV. Global Ultrasound Market Trends

CVD is the leading cause of global mortality, being responsible for an estimated 17.9 million fatalities in 2016, representing 31% of all deaths [54]. The number of deaths caused by disease such as cardiovascular, respiratory, and abdominal disorders (most of which are ultrasound-diagnosable), has propelled the diagnostic imaging market. Ultrasound is the most relied-upon medical imaging modality in the world.

In 2017, global ultrasound revenues were $6.6 billion USD, with a 7.6 percent increase from 2016 [55]. GE Healthcare is

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currently the largest supplier of ultrasound diagnostic technology, followed by Philips Healthcare (Fig. 9).

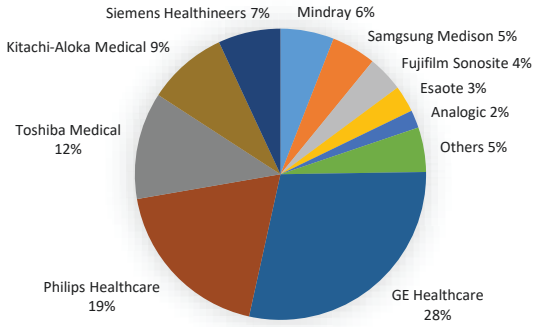


Fig. 9. *Global 2017 market shares for ultrasound equipment by supplier.* Source: IHS Market, Ultrasound Intelligence Service, 2017.

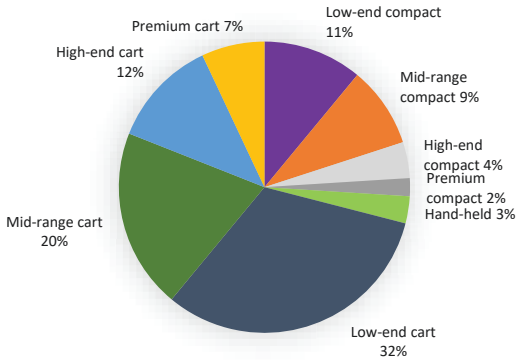


Fig. 10. *Global 2017 market shares for ultrasound equipment by type.* Source: IHS Market, Ultrasound Intelligence Service, 2017.

The global market is dominated by cart systems, accounting for 71 percent of total sales in 2017 (Fig. 10). High-end cart systems sales increased by 13 percent from prior year, these include state-of-the-art 3D and 4D imaging systems which are mainly procured by the United States and Asia. The average price of a cart-based ultrasound system is $115,000 USD, with low-end and premium systems retailing for $25,000 USD to $250,000 USD, respectively.

Price can be a serious limiting factor in enabling worldwide access to affordable diagnostic imaging. Most notably, the average price of cardiac ultrasound cart systems increased to $162,115 USD [56] in 2014, a 12 percent jump over prior year. The ultrasound market growth has catalyzed developments of new portable devices aimed at creating smart, user-friendly, and low-cost systems. This is particularly useful in low-resource settings that require a flexible and fast form of diagnostic imaging for the average user.

Portable (also known as compact) systems hold a 29 percent market share, which is significant considering their more recent introduction [57]. Most notably, hand-held ultrasound sales exhibited the most growth year over year, driven by the new introduction of products and the worldwide demand for point-of-care.

In resource-limited settings, PoCUS is less established and market growth has been understandably slower. This is largely due to the lack of education and training on PoCUS. The lower price of ultra-portable systems in the range of $8000-$10,000 USD [58] is ideal for point-of-care applications. Ultra-portable ultrasound systems provide benefits such as 1) a platform for training new users, 2) wireless connectivity which supports remote sharing of ultrasound scans, and 3) small size that can "fit in your pocket" and be transported by travelling nurses, midwives, physicians, and emergency response teams. With ultrasound machines getting smaller, better and more adaptable, ultrasound can reduce dependency on higher cost imaging modalities such as CT.

A. How Portable Ultrasounds Can Reduce Healthcare Costs

Historically, imaging tests such as ultrasonography, CT, and MRI are often used to improve diagnostic accuracy for the evaluation of a range of diseases. While CT scans offer high accuracy, they expose patients to ionizing radiation, which potentially increases the risk for developing cancer [59].

The increased utilization of ultrasound can potentially reduce dependency on higher-cost medical diagnostic imaging modalities, such as the CT scan. The study *Point-of-Care Ultrasound Integrated into a Staged Diagnostic Algorithm for Pediatric Appendicitis* (Doniger SJ and Kornblith A., 2018) hypothesizes that POCUS can have the same accuracy as radiology-performed ultrasound in diagnosing appendicitis in children. PoCUS exhibited a sensitivity of 93.8 and specificity of 87.5 percent, while cart-based ultrasound had a sensitivity of 81.25 and specificity of 100 percent. The standard cart-based performed ultrasound and PoCUS examinations had a positive alignment ($\kappa = 0.83$, $P < 0.0005$), yielding confidence in the findings of PoCUS. The use of point-of-care ultrasound yielded a significant reduction of 55 percent in future CT scan examinations. Furthermore, *Diagnostic Reliability of Pediatric Appendicitis Score, Ultrasound and Low-Dose Computed Tomography Scan in Children with Suspected Acute Appendicitis* (Sayed, Ashraf, et al., 2017) noted that in 33.7 percent of cases, the need for CT scan was avoided if ultrasound was used as the first-in-line imaging modality [60].

Whereas X-Ray and CT imaging carries health risks, and CT and MRI imaging require large investments in equipment, ultrasound technology is both safe and lower cost. Due to these factors, medical ultrasound is being leveraged as an effective alternative. However, ultrasound is largely operator dependent, potentially resulting in sensitivities and specificities varying widely. In addition, not all medical centers have 24/7 access to trained staff or ultrasound equipment, which can lead to delays in diagnosis and increased morbidity.

In rural areas of Morocco, women struggle to access basic prenatal care. To obtain routine ultrasound examinations during pregnancy, patients seek care at their nearest health house. Most of the locations do not have access to diagnostic imaging and patients are transported to regional clinics by hospital

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ambulance. Women living in rural areas must sometimes travel up to 30 miles for care, and upon onset of labor, have been known to walk up to 6 miles to deliver at the nearest health center or hospital. For the Moroccan government, the average cost of transport by ambulance is approximately $40 USD, plus $40 USD for each ultrasound examination [61].

Using portable ultrasound equipped paired with mobile technology can significantly decrease the cost and risk of transport. Portable systems are cost effective to run, at a fraction of one cent per diagnosis and can be accessed anywhere with an available internet connection. These mobile systems can support rapid diagnosis by providing digital transmission of sonograms to the primary physician who can evaluate the patient remotely and assess if they should embark on the lengthy trip to the clinic.

By bringing the "technology to the patient" via PoCUS in routine medical care, highly portable hand-held ultrasound devices can save more lives and further reduce diagnostic imaging expenditures. In the United States, more than 125 million ultrasound studies are performed annually, at an average cost of $800 USD each. Ultrasound diagnostic imaging has the potential to disrupt other imaging modalities which account for an additional 450 million studies per year in the US. The expanded use of hand-held portable ultrasound devices in point-of-care can yield a potential $50 billion USD annual savings [62]. Ultrasound's largest impact to healthcare is its ability to provide early stage disease diagnosis which can subsequently limit future expenditures and casualties.

V. The Case for a Portable Open-Source Ultrasound

The introduction of ultra-compact ultrasound systems is helping increase global access to lifesaving diagnostics care in areas such obstetrics and gynecology, cardiology and cancer detection. We hypothesize that the impact of free and open diagnostic imaging will be paramount in propelling desperately needed improvements to global public health. We propose the idea of a free and open-source ultrasound.

What is *open-source* and how does it distinguish from *low-cost*? The term *open-source* is commonly used when referring to computer software, though it can also apply to hardware systems. Linux is the most popular example of an open-source computer operating system. Source code may be used, modified and distributed, both commercially and non-commercially, as per terms of the license. However, open-source software is not necessarily free, and free software is not necessarily open-source. For example, a number of frameworks for Microsoft Windows™ are open-source, but source code is not free to readily redistribute.

Similarly, *closed* code is software offered only in a compiled form to ensure the source code is not published. Closed software can be distributed for free or it may be distributed under a licensing agreement to authorized users with private modification, copying, and republishing restrictions [63].

Like free technology, *low-cost* technology is potentially easier to acquire due to lower price points. Low-cost technology can be either closed or open-source. If open, there may still exist constraints on what can be done with the software and the restriction of access to the original source code.

Free and open-source software is software that can be classified as both free software and open-source. Open-source systems can be improved in design and functionality and will alter form and shape as they pass through the hands of developers. Open-source projects have become popular in varying industries such as business, marketing, and healthcare. These projects have catapulted technological developments while reducing the costs associated with purchasing these new technologies [64].

A. How an Open-Source Platform Helped Revolutionize 3D Printing

3D printing, also known as additive manufacturing (AM), is a technology that reconstructs essentially any object as a physical three-dimensional print. Fused deposition modeling, the most common type of 3D printing technology, uses molten thermoplastics to create durable and high precision parts. Since its introduction in the 1980s, 3D printing has thrived in applications ranging from mechanical engineering and materials science, to chemistry and medicine.

AM technology, created for large-scale industrial applications, was limited to commercial use due to high costs of ownership, significant equipment size, and proprietary nature. In the 2000s, over 20 years after the conception of 3D printing, this technology was openly released to the public, sparking the worldwide "3D Printing Revolution." Significant reductions in price transcended AM technology from commercial to consumer markets as it became a disruptive technology supporting rapid prototyping, customization and low-cost manufacturing.

In 2005, Cornell University's *Fab@Home* project and University of Bath's *RepRap* project were the world's first open-source do-it-yourself (DIY) 3D printers. These projects re-envisioned the commercial 3D printer to create a versatile, low-cost, open-source, and "hackable" printers at a time when all systems were proprietary. In 2008, after the expiration of a critical patent on fused deposition modeling technology, MakerBot launched. The company introduced 3D printing to the masses by creating user-friendly and low-cost printers.

Prices have continued to drop; compared to $150,000 USD for a 3D printer in 2005, we can now purchase basic printers for under $1000 USD[65]. The price of 3D printers is projected to continue to decline through 2019 at an annualized rate of 6.1 percent, while sales continue to grow due to heightened affordability and versatility [66]. Per Fig. 11, the global 3D printing market is projected to reach $21 billion USD by 2021 [67].

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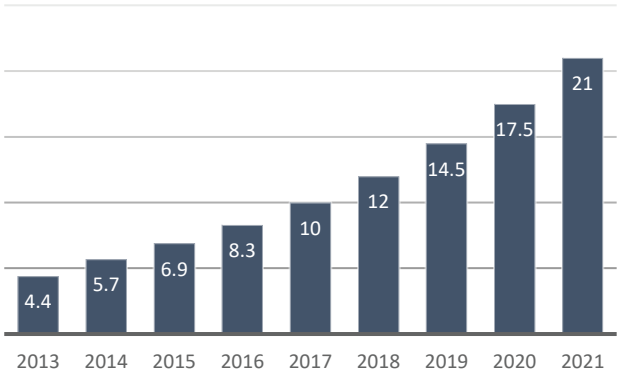


Fig. 11. *Global 3D printing market size from 2013 to 2021 (in billion U.S. dollars).* Source: Statista 2018.

As more users become exposed to 3D printing, suddenly a larger customer base began to arise. Business for both commercial and low-cost machines began to increase, and the technology rapidly spread. Open-source 3D printing became a disruptive technology that substantially lowered the cost of procuring a 3D printer while significantly increasing the consumer market size. We hypothesize that open-source ultrasound technology could have a similar impact, reducing economic barriers to life-saving medical diagnostic imaging while spurring innovation and technology development.

B. New Disruptive Ultrasound Technologies Under Development

After the sinking of the Titanic in 1912 and with the onset of World War I, sound navigation and ranging (sonar) technology was developed. Navigation via underwater echolocation enabled the tracking and identification of dangers such as icebergs and enemy submarines. By 1956, clinical ultrasound was introduced to obstetrics medicine as a form of "medical sonar." From the mid-sixties and onward, rapid technological advancements in materials science and electrical engineering facilitated the advent of commercial systems. The pairing of the microchip with increased processing power helped create more compact, cart-based, ultrasound machines. We witnessed a significant size reduction considering that the first medical ultrasound was as large as a refrigerator.

Rapid growth soon followed, and ultrasound medical imaging spread to high-income regions. However, only recently have fundamental changes in technology led to significant size and price reductions. For the first time since the launch of clinical ultrasound in 1956, ample options for ultrasound imaging exist for under $10,000 USD. Fig. 12 provides an overview of today's most affordable medical imaging technologies. Low-cost portable ultrasound systems have gained popularity and reliability; at present, they account for nearly 30 percent of the global ultrasound market.

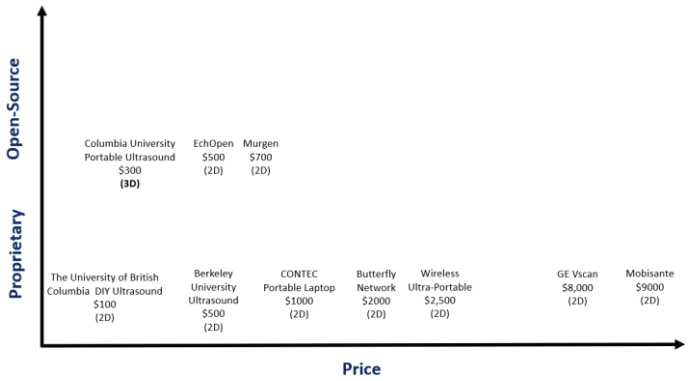


Fig. 12. *A landscape of existing open-source and proprietary portable ultrasound systems in 2018.*

Standard 2D ultrasound machines such as Mobisante and GE VScan can be purchased for $8,000 to $9,000 USD [68]. Butterfly Network has released the first "ultrasound-on-a-chip" personal ultrasound, eliminating the need for specialized piezoelectric ceramics and further reducing the price and complexity of ultrasound technology. In 2017, the company received FDA clearance for their hand-held PoCUS. In 2019, their highly anticipated product started to retail at $1,999 USD plus user license fees. Similarly, the University of British Columbia has fabricated a $100 USD transducer which consists of nanoscale polymer-resin vibrating drums [69]. The prototype is ultra-compact and, in the future, could be further developed to perform functions such as live continuous monitoring of the heart. While these technologies provide alternatives to higher-cost commercial systems, they are either proprietary or not simple to replicate by novices.

The Murgen project led by the independent maker Luc Jonveaux, has had success in developing a full ultrasound system by "hacking" into a standard medical ultrasound transducer and developing open hardware that controls the transducer to generate sonogram images, all at around $700 USD in materials cost [70]. This consists of a set of modules that provide ultrasound image processing and hardware control. Echomods (also known as EchOpen) is the second iteration of this Arduino based development kit and reduces the materials expense to approximately $500 USD [71].

Although budget-friendly systems considerably reduce the cost of acquiring an ultrasound, DIY and open-source projects can eliminate almost every barrier to diagnostic imaging. These include price, lack of proficiency in sonogram interpretation (limited training), and difficulty reaching medical facilities.

C. Our Technology

The *Columbia University Open-Source Portable Ultrasound* project has drawn inspiration from the impact of the open-source 3D printer (V.A) which has drastically reduced the price of additive manufacturing technology and enabled widespread use. An open community of users who build and continually improve upon technology can foster an environment of collaborative development and spark future advancements in the field of medical diagnostic imaging.

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Techniques such as QUS can become rapidly available to more users in the field of cancer research.

We aim to provide users with access to hardware and software to build a complete hand-held ultrasound system at home for less than $300 USD in materials cost. No experience is required, and the assembly instructions are simple. This system would be capable of generating 3-dimensional ultrasound images. Our hand-held ultrasound device can be created with typical software and hardware tools available in a public "makerspace" where users can print, assemble, and test their newly constructed medical imaging transducer probes. We assume that users 1) have access to mobile applications and a 3D printer, 2) have no formal technical training, and 3) can purchase the electrical and mechanical components needed to build the hand-held system. There is no continued cost to utilizing our ultrasound besides the initial materials cost, which is conservative because most of the hardware is 3D printed.

To support the efficient integration of our device in economically underdeveloped regions, we must take into consideration that the sonographer may be inexperienced. 3D imaging has been proven to help untrained operators capture and interpret sonograms with greater ease (II.C). Cart-based ultrasound systems that provide the best-in-market 3-dimensional image quality and processing software can retail for up to $250,000 USD. While we are not a state-of-the-art system, we can promise a reliable 3D imaging system, a great improvement from standard 2-dimensional imaging modalities. AI techniques will further facilitate calibration and interpretation of ultrasound data (II.D). Sonograms can then be shared wirelessly with physicians and healthcare providers, potentially eliminating the need for a physical office visit which for many is a long, expensive, and complicated journey. Our mission at Columbia University is to develop an open-source portable medical ultrasound that can address the needs of global users.

VI. Challenges of Implementing an Open-Source Ultrasound

Implementation barriers to widespread medical imaging include economic limitations, a lack of trained personnel, cultural resistance, and an inadequate number of medical infrastructures. An open-source ultrasound carries additional risks for female feticide, misdiagnosis, and reduced data privacy. We hypothesize that these dangers are mitigated by the potential benefits.

A. The Growing Problem of Female Feticide

126 million girls are believed to be "missing" around the world [72]. Gender-biased sex selection has led to *female feticide*, the selective abortion of female fetuses. In India, nearly one million pregnancies are terminated every year for the purpose of sex selection [73]. In general, sex selection can occur either during pregnancy via prenatal gender screening, abortion, or following birth, via infanticide. While infanticide, the deliberate killing of young children, has a long history, feticide is relatively new, surfacing with the advent of ultrasound technology in the mid-1980s. Although there have been global efforts to improve prenatal care for women, leading to subsequent reductions in maternal mortality rates, these advancements have been offset by the increased numbers of sex-selective abortions. While there are numerous positive applications for ultrasound, the combination of this technology with prior social inclinations has prompted sex-specific abortions.

In the absence of external influences, the standard sex ratio (SRB) for humans is 106 male births to 100 female births. In 1980, before the introduction of ultrasound technology, the birth rate in China was 108 males to 100 females. By the year 2000, there were 120 males to 100 females in China [74]. Because of the large population in China, this translates to a sizeable disparity: the number of males under 20 years of age currently exceeds the number of females by almost 32 million. These highly skewed sex ratios have destructive implications on society. Due to the surplus of men from predominantly lower socioeconomic status who will never marry, there is increased risk of violence against women including rape, abduction, and human trafficking. Female feticide has created social instability and fueled a modern-day war on women.

China and India have the highest populations in the world, at 2.7 billion people as of 2018 [75]. There are an estimated 80 million missing girls in these two counties alone [76]. A deep-rooted preference for sons may be to blame for the current dilemma. In China, the one-child policy has undoubtedly contributed to this imbalance. China existed as a predominantly agrarian society for centuries and as a result, placed a higher value on the role of the male laborer who remains in the family as a financially contributing member. In India, sons may offer their parents the prospects of social and economic stability through financial support, providing security during old age, and saving them the burden of paying a dowry for marriage (money or property gifted to the groom's family). The introduction of new medical technology can increase pre-existing disparities in society and potentially lead to harmful public health practices. Cultural beliefs and not the technology itself may be responsible for the inequalities.

Medical imaging is not the only method for sex identification but is considered the least invasive. Amniocentesis, Noninvasive Prenatal Testing (NIPT), and Chorionic Villus Sampling are blood tests that screen for chromosomal and genetic characteristics including gender [77]. NIPT was introduced in 2011 and is rapidly becoming available throughout the United States, Western Europe, the Middle East, Southeast Asia, Latin America, and Africa [78]. NIPT can return accurate fetal diagnosis in the first trimester of pregnancy (as early as 7 weeks) and results can be obtained in 2 weeks. The cost of NIPT examinations range between $800-2000 USD in the Unites States and $500-1500 USD [79] around the world. NIPT is a relatively new technology, and prices are expected to decline as popularity increases.

Historically, LMICs have had difficulties regulating new reproductive technologies. Prenatal sex detection methods have been misused, allowing for the selective abortions of female

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offspring to proliferate. While China and India both forbid gender screening, weak law enforcement has failed to fully curb this practice. Ultrasound for prenatal sex-determination can be illegally performed in China for as little as $2.60 USD [80]. In India, $150 USD will cover an illegal ultrasound and abortion procedure. As alternative gender diagnostic tools begin to arise, the relative contribution of ultrasound imaging to the feticide problem is expected to diminish. Technologies such as In Vitro Fertilization, Pre-Implantation Genetic Diagnosis, Pre-Implantation Genetic Screening, and sperm-sorting have emerged as the next challenge.

The impact of existing cultural prejudices can still be seen today as an impeding factor to the adoption of widespread and efficient care. Culturally supported predisposition towards male offspring, along with expanded options for gender screening, can potentially create a larger imbalance of SRB. There is no way to regulate the use of an open-source ultrasound and female feticide is likely to continue in regions where is it culturally accepted. After the introduction of ultrasound in South Korea, the SRB increased from 109 to 115 between 1985 and 1994 [81]. Strict governmental measures were implemented and the SRB stabilized to 105.3 male births per 100 female births. Change is possible via public education and law enforcement.

B. *The Potential for Misdiagnosis*

When used appropriately, ultrasound medical imaging is a powerful life-saving tool that can improve the quality of life for mothers and newborns. Ultrasonography aids physicians in the evaluation, diagnosis and treatment of medical illnesses. It is especially relied upon by doctors during high-precision procedures such as ultrasound guided biopsies and is the most widely used imaging modality for the diagnosis abdominal abnormalities. However, as with any medical diagnosis, these can be prone to error. A significant portion of mistakes during routine ultrasound scans are caused by unreliable medical equipment, the presence of sonographic imaging artifacts, unfavorable anatomic variants, or improper preparation of the patient for the examination.

Misdiagnosis in ultrasound diagnostic imaging results from inappropriate techniques or erroneous interpretation of images obtained by sonographers. The widespread use of ultrasonography by untrained operators leads to increased misinterpretation and erroneous diagnosis. 3D imaging can be leveraged to optimize results and reduce interpreter errors, decreasing future risk of misdiagnosis (II.C). The richness and redundancy in 3D data may also reduce the amount of training required for sonographers and radiologists, while simultaneously increasing their reliability.

We believe that an open-source portable ultrasound coupled with 3D SLAM and AI software can ultimately address the main barrier to ultrasonic imaging, i.e., training. Complete ultrasound scan automation will reduce the need for professional experience and expand the user base of potential operators (II.D). To reach this point, considerable amounts of data will need to be collected for training machine learning algorithms in image interpretation and disease analysis. Due to the proprietary nature of current ultrasound systems, data collection is slow and expensive. An open-source portable ultrasound is an ideal data-gathering platform, although, for some users, this may raise privacy considerations.

C. *Open-Access Data Yields Privacy Concerns*

Open-access systems can facilitate fast and efficient data collection due to being low-cost and universally accessible. However, the lack of control over personal information has the potential to yield data privacy and security concerns. This issue becomes pronounced when considering an open-source ultrasound, where encryption and privacy measures may be circumvented. If privacy is a concern, and the user can afford it, proprietary technology may provide more peace of mind. Open-source technology should be acquired at the discretion of the end-user.

Conversely, open-access systems may even lead to increased security. The organic nature of open technology means that users will add value by the numbers. Per Linus' law, "given enough eyeballs, all bugs are shallow [82]." The more "eyeballs," or users managing the software, the harder it is for a security threat to go unnoticed. Since the customer can play the role of both the user and developer, issues such as bugs can be quickly found and resolved. While an increased user base can be beneficial, a potential drawback is that it may become difficult to streamline or manage the modification process. However, some may say that no software code, whether open or private, is truly safe and secure. However, a notable case in which an open-source computer operating system is more secure than proprietary system is that of Linux vs. Windows.

The *cBioPortal for Cancer Genomics* is an open-source portal that shares cancer genomics and clinical data with scientists, biologists and medical practitioners to centralize vital information that supports pathways for cancer research. The cBioPortal is an open-access platform with a user-friendly interface that enables interactive visualization and analysis of large-scale genomics data down to the patient level. Project source code is available on GitHub (an online- low-cost development platform) and is openly maintained by organizations including the Children's Hospital of Philadelphia, the Memorial Sloan Kettering Cancer Center, and The Hyve, a Netherlands based open-source bioinformatics company [83]. Open-access medical software is becoming a standard in healthcare, helping optimize information management, communication, and patient care in areas such as medical information systems, imaging and visualization, mobile device integration, and disease management.

While open-source software may carry privacy concerns, its widespread use in healthcare solidifies its reliability in maintaining patient information safe. To support future AI-based medical applications that utilize machine learning and image recognition techniques, a large dataset is necessary for training the algorithm. Multiple users will need to allow for personal information and sonograms images to be stored and analyzed. There is a clear global demand for open, reliable and flexible technology; however, these systems exist almost

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exclusively in high-income regions. At Columbia University we aim to introduce the use of an open-source, AI-based medical imaging system to areas in which social and economic issues have hindered the adoption of widespread diagnostic technology.

VII. Conclusion

Nearly 50 percent of the world's population—more than 3 billion people—survive on less than $2.50 USD a day [84]. These economic limitations often mean that the cost of crucial medical imaging remains out of reach. As of 2014, 46 percent of the global population is living in rural areas, or an estimated 3.3 billion people [85]. Worldwide, those living in remote regions suffer untimely or total lack of access to healthcare services. Due to factors such as a growing elderly population, the increase in cases of chronic diseases (i.e. heart disease), and growing focus on public health, we believe that the need for diagnostic medical imaging will continue to rise.

Our mission at Columbia University is to develop a 3D portable open-source ultrasound that is simple to construct, and others can innovate and improve on. We hypothesize that broad accessibility to ultrasound imaging can revolutionize healthcare in developing nations and generate data necessary for training AI- based mobile diagnostic tools. These tools will have the capacity to detect and diagnose numerous medical conditions ranging from premature labor to cardiovascular and orthopedic malignancies, while minimizing dependency on professionally trained staff to operate equipment.

The use of 3D imaging and AI can alleviate the difficulty of sonogram image interpretation for users who are not professionally trained sonographers. Moreover, a single 3D scan is more compact to store, transmit, and analyze than a lengthy series of 2D scans. Due to current pricing models, 3D ultrasound modalities are highly exclusive. In addition to saving lives, a portable open-source 3D ultrasound can significantly reduce healthcare expenditures attributed with diagnosing and treating a condition.

Compact PoCUS are easier for sonographers, physicians, nurses and midwives to transport and are also more affordable. This makes ultrasound image-capturing convenient in places where it was not previously available due to lack of infrastructure or economic feasibility. In the case of mass-casualty incidents, healthcare providers must efficiently triage to ensure the maximum number of patients can be treated. Compact ultrasound allows for FAST modalities to be implemented, which can improve triage accuracies and allow for best course of treatment in emergency patient management. Additionally, mobile networks make it possible for portable systems to transmit clinical information to physicians.

Our technology will aid in providing essential knowledge to physicians, engineers, and medical experts. As an open-source technology, we are dependent on a community of users who via continuous development can create personalized ultrasound systems that support specific needs in medically underserved areas. Open-source software is available for the public to use, modify, and improve from its original form.

In summary, we believe an open-source portable 3D ultrasound system can achieve the following goals:

- Mitigate logistical complications and reduce the expense of accessing medical care in rural areas
- Utilize AI to facilitate automated calibration, interpretation, and diagnostics; hence, reducing dependency on trained staff
- Incentivize software developers to develop internet accessible platforms for 2D and 3D visualization applications on smartphones and laptops
- Increase open-data sets for training AI and machine learning modules for research and patient care

The *Columbia University Open-Source Portable Ultrasound* project is driven by a growing interest in intelligent, affordable, and complete point-of-care diagnostic imaging. We plan to introduce a portable open-source DIY medical ultrasound that addresses the needs of global users. Our technology will be the first-ever imaging system that generates 3D sonograms for under $300 USD in materials cost, paving the way for ultra-affordable modalities to enter the ultrasound market.

Acknowledgments

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