Setting: A Case Study in Obstetric Ultrasound

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OD1 Abstract

Despite the rapid development of AI models in med-002 ical image analysis, their validation in real world 003 clinical settings remains limited. Models are often 004 developed without continuous feedback from clini-005 006 cians, which can lead to a lack of alignment with the actual needs. To address this, we introduce a generic 007 framework designed for deploying and testing image-008 based AI models early in such settings. Using this 009 framework, we deployed a trained model for fetal 010 ultrasound standard plane detection and evaluated 011 it in real-time sessions with both novice and expert 012 users. Feedback from these sessions revealed that 013 while the model offers potential benefits to medical 014 practitioners, the need for navigational guidance 015 was identified as a key area for improvement. These 016 findings underscore the importance of early testing 017 of AI models in real-world settings, leading to in-018 sights that can guide the refinement of the model 019 and system based on actual user feedback. 020

021 1 Introduction

The clinical community is eagerly anticipating the 022 validation of AI in real-world clinical settings [1]. 023 024 This is distinct from retrospective validation using previously recorded videos [2]. For many imaging 025 modalities, dynamic decision-making is required not 026 only for image recognition (i.e. "what am I looking 027 at?") but also for image acquisition (i.e. "where 028 to look at in the first place?"). Furthermore, AI 029 systems are anticipated to face more practical chal-030 lenges in real-world clinical settings [3–5]. Lessons 031 learned from case studies studying the deployment 032 of AI tools for clinical applications highlight that 033 well-performing AI models may fail for unexpected 034 reasons in the real world. For instance, Beede et 035 al. [6] studied the deployment of a diabetic retinopa-036 thy detection system with >90% sensitivity and 037 specificity in the lab but faced severe ungradability 038 issues in a real-world setting. Their system refused 039 to grade 21% of the images citing quality issues, 040 although the images were acceptable to human read-041 ers, introducing unnecessary delay in a busy clinic. 042 This underscores that the actual utility and value of 043 an AI model remain unclear until it is tested under 044 real-world conditions. 045

046 Real-world clinical deployment is challenging.

First, the success of an AI tool in the clinic strongly 047 depends on how well it integrates with the clinical 048 workflow [7]. However, researchers are often not 049 allowed to deploy developmental work directly into 050 a medical device in the clinic for security reasons, 051 effectively creating an upper bound on how well-052 integrated the deployment can be. Second, existing 053 deployment tools focus on making the inferencing 054 pipeline efficient and streamlined, while research 055 code is often messy. These factors lead to overhead, 056 discouraging AI researchers from deploying their 057 models early in their development process. However, 058 we advocate for testing deep learning models in the 059 clinical setting as early as possible. If things should 060 fail, they should fail early. 061

In this paper, we introduce a framework for the 062 deployment of dynamical image-based AI systems 063 from research in a clinical setting. As a case study, 064 we illustrate our framework in the setting of fetal 065 ultrasound standard plane detection, where despite 066 active development of AI methods [8–11], actual 067 deployment in the real world is rarely seen. We 068 aim to be as integrated into the clinical workflow 069 as possible, expecting only the HDMI output from 070 the medical device. We discuss the constraints and 071 present our design solution, aiming to lower the en-072 try barrier of deploying and testing machine learning 073 models directly from research, without the burden 074 of making it efficient or optimized. We aim to speed 075 up the development cycle, gain initial user feedback, 076 refine development goals, and iterate. We describe 077 how, using our designed solution, we deployed an 078 explainable AI model for fetal ultrasound standard 079 plane detection, and invited clinical practitioners to 080 use the system as they scan their patients. Finally, 081 we also report our findings from interviews with clin-082 ical practitioners using our deployed system. This 083 study highlights a significant step towards bridging 084 the gap between research and practice in the field 085 of medical image analysis. 086

2 Method

2.1 Design challenges & requirements 088

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Designing a generic framework for deploying imagebased AI systems in a clinical setting presents several challenges and requirements. These include: 091

Device Output The system should not expect any 092

output from the medical device other than a video
feed via an HDMI cable. This is because any other
form of output may not generalize across different
medical devices.

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Prediction Latency The system should aim to 097 098 generate predictions at minimal latency. This is different from processing retrospective videos, which 099 favors processing large amount of data simultane-100 ously by batch inferencing. In a live supporting 101 system, video frames from the past become irrele-102 vant as time progresses, and therefore the system 103 should focus on responding to new video frames as 104 quickly as possible to provide real-time feedback. 105

Local Processing The system should be able to
run the entire processing pipeline locally, since data
security is crucial for many clinical applications.
Furthermore, this approach incurs a lower learning
overhead for researchers than a more complicated
workflow, such as a remote-server-edge-client architecture.

Wireless Display The system should have a mechanism for showing the live results on a wirelesslyconnected display device. Wired connections are not
always possible in the room setting of a clinic.

Video Recording The system should optionally
support video recording in parallel to the prediction process. This means that while the AI model is
making predictions in real-time, the system should simultaneously be able to record the video feed, which
is helpful for further development of the prototype
model.

Physical Setup The physical setup should be as
small and stealthy as possible, so that it does not
introduce any obstructions in a busy clinic.

Software Compatibility On the software level,
the framework should be able to accommodate research code, which is typically chaotic by nature.
Ease-of-use should be prioritized over computational
efficiency.

132 2.2 Design solution

Our design solution, as illustrated in Figure 1, is a robust and flexible framework that leverages a variety of technologies to capture and process realtime video streams from medical devices. Code is available at http://ANON-REPO-URL/

HDMI-to-USB Converter Box We use this device to capture the real-time video stream from the
medical device. The converter box feeds the video
stream to a small computation server and appears
as a USB webcam device on the server. This setup
allows us to use common software packages such as
OpenCV to capture and process the video stream.



Figure 1. System architecture. Live video is streamed from the scanner to the server, where all processing steps are executed within respective containers. Results are subsequently rendered on a webpage, which is accessible wirelessly from tablets.

Computation Server The server is responsible 145 for all computation needs of the deployment. This 146 server can be CPU-only to satisfy economical considerations or security restrictions of the clinical 148 authority, or equipped with a GPU to meet the 149 computational needs of the researchers. 150

Docker Containers Within the server, we achieve 151 our design requirements with the use of Docker containers [12]. These containers perform various tasks: 153

- Video Frame Broadcaster This container 154 grabs video frames from the converter box via 155 OpenCV and broadcasts them through a websocket. 157
- Recorder This container listens to the websocket and records the video, saving it into an mp4 file for retrospective AI development activity. 161
- Webpage Server This container also listens 162 to the websocket, coordinates prediction on 163 the live video stream, and hosts a webpage for 164 displaying results. It acts as a prediction task 165 manager/router, sending latest video frames to 166 the inference engine for model predictions, and 167 displaying results to the clinician (see Figure 2) 168 upon receiving response from the inference en-169 gine. 170
- Inference Engine This container encapsulates all the code needed to runs the model 172 prediction. 173

Docker Compose Manages the lifecycle (start, 174 restart, etc.) of the containers.

Wireless Router Connects display devices and 176 the server.

Tablets Display inference results accessible via a178webpage hosted by the server.179

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Our design solution is underpinned by a number 180 of key principles and considerations, which we will 181 discuss next: 182

2.2.1**Containerization & System Stability** 183

One of the primary benefits of our design is the use 184 of containerization. This approach ensures that a 185 failure at the component level, such as a runtime 186 error in the AI inference engine, does not shut down 187 the entire system. This means that even if one part 188 of the system encounters an issue, other components, 189 190 like video recording, continue to function normally. Furthermore, the containerized environment allows 191 for the execution of research code in an isolated 192 setting, making the system much more tolerant to 193 the inherent messiness of research code. The use of 194 Docker Compose as an orchestration tool allows the 195 system to auto-restart failed inference engines. 196

2.2.2Environment Isolation & Model De-197 ployment 198

Containerization also inherently provides the benefit 199 of environment isolation. This means models devel-200 oped with different dependencies can be deployed 201 on the same machine without conflicting with each 202 other. It is not necessary for the model to be ex-203 ported in a deploy-specialized format (e.g., ONNX, 204 TorchScript), since the original research code can 205 206 be executed within the isolated environment. This flexibility simplifies the deployment process and ac-207 celerates the transition from research to clinic. 208

2.2.3Advanced Inferencing Pipeline & 209 Workflow Management 210

For advanced inferencing pipelines that involve pre-211 212 dictions with multiple models, more inference engine containers can be added. The pipeline can be man-213 ually programmed into the webpage server applica-214 tion. We chose not to orchestrate such workflows 215 with existing workflow management software (e.g., 216 Apache Airflow), which, while optimized for produc-217 tion environments, introduces unnecessary overhead 218 for researchers wanting to test their prototype mod-219 els in the clinic. 220

2.2.4**Distributed Execution & Performance** 221 Optimization 222

For advanced use cases, containerization also allows 223 execution of components among distributed com-224 putational units. For example, latency-insensitive, 225 computationally heavy workloads can be executed on 226 a remote GPU server. For slow, compute-intensive 227 models, it is possible to modify the web server appli-228 cation to only perform inference when the ultrasound 229

mizes system performance and ensures efficient use of computational resources. 232

operator has frozen the screen. This approach opti-

User Feedback & Result Display 2.2.5233

By displaying the result via a simple web applica-234 tion, we can easily stream results to multiple clients 235 simultaneously. This allows researchers to collect 236 user feedback from multiple target users, such as 237 clinical operators and patients, providing insights 238 for system improvement. 239

3 Experiment

Using our framework, we deploy an AI model for 241 fetal ultrasound standard plane detection. We first 242 examine the additional latency introduced by this 243 setup compared to running the model directly with-244 out containerization (see subsection 3.2). Then, 245 we conduct a pilot study with clinicians using our 246 system in a real-world clinical setting (see subsec-247 tion 3.3). This helps in guiding both downstream 248 technical development and future full-blown random-249 ized control trails. 250

Fetal Ultrasound Standard Plane 3.1251 Detection 252

Standard obstetric trimester scans involve capturing 253 ultrasound images of the fetal head, stomach, and 254 femur [13]. The accuracy of this task is crucial as 255 it impacts the downstream task of fetal weight esti-256 mation [14], which directly influences the accurate 257 monitoring of fetal growth. 258

We chose to approach the standard plane detec-259 tion problem with PCBM, a hierarchical variant 260 of the concept bottleneck model [15] developed by 261 Lin et al. [16] for fetal ultrasound scan quality as-262 sessment. It approaches the problem by emulating 263 the step-by-step decision-making process of experts, 264 starting with visual concepts from image segmenta-265 tion and then applying property concepts directly 266 tied to the task. 267

Compared to standard black-box approaches, this 268 method is explainable, providing transparency in 269 its decision-making process, which arguably allows 270 for a better understanding and trust in the model's 271 predictions. Instead of predicting whether or not 272 an image is of a standard plane, PCBM offers ad-273 ditional explanation to what anatomical landmarks 274 are present or missing (see Figure 2). 275

To determine the validity of these claims, we de-276 cided to deploy a trained PCBM model in the clinic. 277 We aim to determine whether the model's explain-278 ability provides any additional value as a computer-279 aided detection (CAD) tool. More importantly, we 280 want to establish whether such a tool fits well in the 281



Figure 2. (Left) Setup at the clinic. The tablet was placed next to the scanner, while the remaining equipment was placed on a table. (Right) Screenshot of displayed prediction. A video recording is provided in the supplementary material.

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clinical workflow, bringing benefits that are actuallyappreciated by medical workers.

284 3.2 Equipment

Following our framework as illustrated in Figure 1, 285 we selected Magewell USB Capture Plus HDMI 286 box as our HDMI-to-USB converter, TP-Link 287 802.11ac router (model number: TL-WR902AC) 288 as our WiFi router, and two Microsoft Surface 289 tablets as our **display devices**. We first measured 290 the duration required to process one video frame, 291 292 using three different computational devices as the server: a workstation (i7-7800X, Quadro P5000, 293 TITAN V, 128GB RAM), a laptop (i7-10750H, RTX 294 2070 Super, 16GB RAM), and a mini PC (Intel 295 NUC12WSKi7, i7-1260P, 32GB RAM). We also de-296 termined the extra latency introduced by our frame-297 work as compared to running the native research 298 code directly (see Table 1). This was to understand 299 the trade-off between the deployment ease offered 300 by containerization and the potential increase in 301 latency. 302

For our deployment, we selected the mini PC as our server to remain compliant with safety standards [17]. This was a requirement set by our deployment hospital to ensure the safety of both the patients and the medical practitioners. A photo of the setup in the clinic is shown in Figure 2.

309 3.3 Clinical sessions

We deployed the system at ANON HOSPITAL and recruited two volunteer patients in their mid-third trimester with ANON IRB's approval. We invited six novice participants (P1-P6), all senior undergraduate students enrolled in a medical program, to use our system while scanning the patients. P1 & P2 were given all explanations as predicted by 316 PCBM. P3 & P4 were only told whether a cur-317 rent image is a standard plane, close to a standard 318 plane, or at a completely unknown plane. P5 & P6 319 were control users without any guidance from our 320 system. We observed the participants during the 321 scan and interviewed them afterward to gather their 322 feedback about our system. In separate sessions, 323 we also invited an obstetrician (P7) and an expe-324 rienced sonographer (P8) to use our tool, allowing 325 us to gain valuable insights from a professional per-326 spective about our system. These sessions provide 327 an early evaluation of PCBM's performance in real 328 clinical settings before committing to a large-scale 329 randomized control trial study. 330

Results 331

4.0.1 Level of Integration into Clinical 332 Workflow 333

Almost all participants expressed a desire for the 334 prediction results to be displayed directly on the ul-335 trasound machine. However, most participants were 336 able to accept the current setup as a viable solu-337 tion for testing purposes without being disruptive to 338 their workflow. Meanwhile, the novice participants 339 (P1-P4) specifically requested a higher frame rate. 340 They expressed that a higher frame rate would allow 341 them to move the ultrasound probe faster without 342 the system lagging behind. 343

4.0.2 Usefulness of the Additional Explana- 344 tion Provided by PCBM 345

P1 found the explanation on whether a specific 346 anatomical landmark is visible helpful, while P2 347 took a neutral stance. Without the explanation, P3 348 NLDL

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machine	Workstation			Laptop		Mini PC
	CPU	P5000	TITAN_V	CPU	RTX_{2070S}	CPU
native	1.00 ± 0.04	0.25 ± 0.04	0.34 ± 0.04	2.69 ± 0.56	0.39 ± 0.20	1.19 ± 0.09
framework	1.06 ± 0.04	0.31 ± 0.04	0.40 ± 0.05	2.75 ± 0.56	0.45 ± 0.21	1.23 ± 0.10
difference	0.06 ± 0.02	0.06 ± 0.02	0.05 ± 0.01	0.06 ± 0.02	0.06 ± 0.02	0.03 ± 0.01

 Table 1. Time taken (in seconds) to process one video frame across different computational machines by running native code vs. using our framework.

and P5 found it challenging to identify what was missing from an image before it could be considered a standard plane image

351 a standard plane image.

3524.0.3Usefulness of the Tool in Helping a353Novice User to Take High Quality Fe-354tal Ultrasound Standard Plane Images

P1-P4 commented that the tool has helped indicating whether they are looking at a standard plane,
while P5 wished for similar guidance. However, P1P4 had difficulty in identifying which plane they were
currently looking at. They adapted the strategy of
blindly scanning around until the tool indicated that
they were at one of the standard planes.

362 4.0.4 Additional Findings

P1, P3 & P4 expressed their wish for more naviga-363 tional support. Following their strategy, the tool 364 showed signs that they were near a standard plane 365 every now and then, but without navigational guid-366 ance, they did not know where they should move 367 the probe to get closer to the standard plane. They 368 acknowledged that a higher frame rate might be 369 helpful, but ultimately it would be ideal if the tool 370 could tell them the direction they should move the 371 probe if they wanted to reach a certain standard 372 plane. This was especially the case for the femur, 373 which had to be taken from a challenging sagittal 374 view. 375

On the other hand, our interview with P7 sug-376 gested that users who are already familiar with the 377 task may have a different use case for our tool. In-378 stead of relying on the tool for navigational guid-379 ance, the expert used the tool for confirmation 380 of thoughts. During the session, P7 took multi-381 ple screenshots whenever an image appeared like 382 a standard plane image. After the session, P7 ran 383 through the screenshots while looking at the model 384 predictions, checking through the explanations from 385 PCBM, and picked the best images for reporting. 386 Meanwhile, P8 tended to rely on self-judgement 387 rather than relying on feedback from PCBM. How-388 ever, P8 commented that our predictions are gen-389 erally accurate, and acknowledged that the system 390 could be valuable for inexperienced users. 391

This feedback was instrumental for us in understanding the different applicability of an AI tool in

a real-world setting with different types of clinical 394 users. 395

5 Discussion & Conclusion 396

We have introduced a generic framework designed to 397 deploy image-based AI models in real-world clinical 398 settings, which focuses on research code compati-399 bility and clinical workflow integration. Using this 400 framework, we have successfully deployed a model 401 for fetal ultrasound standard plane detection in a 402 clinical environment, and evaluated its performance 403 in real-time sessions with both novice and expert 404 users. The feedback gathered from these sessions 405 has provided valuable insights into the model's per-406 formance, its integration into the clinical workflow, 407 and its potential benefits to medical practitioners. 408

Our findings from the interviews show that the 409 deployed PCBM model works well as a feedback tool. 410 However, if the intended purpose is to guide a novice 411 user in taking better standard plane images, the tool 412 would be an even better fit for the clinical workflow 413 if it could provide navigational guidance. Zooming 414 out to a bigger picture, this also emphasizes that in 415 ultrasound, image acquisition is the major part of 416 the challenge, which calls for different solutions than 417 what the medical image analysis community typi-418 cally focuses on [18, 19]. These findings underscore 419 the importance of a framework that supports early 420 deployment and testing of research models in real-421 world settings: Early deployment serves the crucial 422 purpose of guiding the refinement and development 423 of the continued technical research towards solving 424 actually relevant clinical problems. 425

Leveraging our experience in this deployment, we 426 hope to demonstrate the importance of early de-427 ployment of AI models. Early deployment leads 428 to insights that are otherwise undiscovered, while 429 the developmental works proceed in an undesired 430 direction. This approach allows for the refinement of 431 the model and system based on real-world feedback, 432 ultimately leading to a tool that is more effective 433 and beneficial in a clinical setting. 434

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