Evaluation of a cardiac troponin process flow at the chest pain center with the shortest turnaround time

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Abstract

Background: Early diagnosis of myocardial infarction is crucial in chest pain management and cardiac troponin (cTn) test is an important step in it. Process improvement to shorten the test turnaround time (TAT) may improve patients’ outcomes. The cTn test at chest pain center (CPC) of Zhongshan Hospital had the shortest TAT ever reported, but its process flow was not fully evaluated.

Methods: We performed a stepwise evaluation of CPC cTn TAT and explored the potential factor that might cause delay. The performance of CPC cTn test was also compared with cTn test and human chorionic gonadotropin (HCG) test ordered from emergency department (ED).

Results: At least 95% of CPC cTn tests were completed in 60 min, while 62% in 30 min. The medians of monthly order-to-collect time, collect-to-received time, and received-to-result time were ~7 min, ~3 min, and ~13 min, respectively. The samples collected at the bedside had longer collect-to-received time than the ones collected at the blood draw site next to the laboratory. Compared to ED cTn test and ED HCG test, CPC cTn test took less time in each step. A combination of the sample type switch and the centrifugation time reduction contributed the most to the shortening of TAT, which was reflected in the received-to-result time.

Conclusions: The current process flow of CPC cTn test satisfied the requirements of chest pain management, giving an example of how to implement process improvement for emergency medicine to shorten TAT of laboratory tests.
1 | INTRODUCTION

Ischemic injury is a key cause of death and other adverse events in patients suffering myocardial infarction (MI). Reopening the obstructed artery via percutaneous coronary intervention (PCI) may effectively eliminate ischemia. A lot of efforts have been made to shorten the time from the patient seeking emergency care to inflation of the catheter balloon, which is also called door-to-balloon time, and duration of ischemia. One of them is the establishment of chest pain centers (CPCs), where specified processes are implemented to facilitate diagnosis and treatment for MI patients. In China, the establishment and accreditation of CPCs have started since 2011.

An accurate diagnosis of MI, which includes evaluation of cardiac biomarker, is the rate-limiting step in the management of chest pain. Nowadays, cardiac troponin (cTn) has become the primary cardiac biomarker in the management of MI and the central in the definition of non-ST-elevation MI (NSTEMI). The recommended cTn delivery turnaround time (TAT) at a CPC or an emergency department (ED) for chest pain is 60 min, to offer timely treatments to NSTEMI patients and to minimize door-to-balloon time, which is essential for the very high-risk patients. Meanwhile, a short cTn TAT also helps to minimize patient length of stay at ED and to ease crowding. However, it is a challenge for a clinical laboratory to achieve the TAT goal.

Although point-of-care testing, which may reduce assay TAT, is a recommended replacement, its reliability and expense still could not satisfy clinicians, and laboratory testing remains the preferred option. Therefore, several studies have investigated how process improvement may help to reduce laboratory TAT for cTn tests. Their improvements included barcoding, floorplan design, sample processing priority and so on, and the shortest monthly order-to-result time (median) is around 50 min reportedly. At Zhongshan Hospital, the establishment of CPC was completed in 2017, and previous studies were used for reference in the determination of the laboratory testing processes for cTn. A monthly review in 2020 showed that most of CPC cTn tests at Zhongshan Hospital were reported to patients in 50 min, which was much better than previous reports, meeting the requirements in the clinical guidance documents.

In this study, we made a systematic evaluation of CPC cTn TAT at Zhongshan Hospital. The performance of CPC cTn was also compared to that of ED cTn, which was ordered for a heart disease patient without chest pain, and ED human chorionic gonadotropin (HCG), which had a similar process flow with previous cTn (before establishment of CPC), to investigate how process improvements shortened CPC cTn TAT. The findings may give ideas on the further improvements of laboratory testing and chest pain management processes, for both Zhongshan Hospital and other medical institutions.

2 | MATERIALS AND METHODS

2.1 | The establishment of CPC

Before 2017, the patients with chest pain were admitted at ED of Zhongshan Hospital and treated following similar process flows of other patients. In 2017, to ensure that a patient suffering from a heart attack could be quickly identified and admitted for further services, Zhongshan Hospital established CPC based on ED. CPC and ED shared the spaces, instruments and laboratory. However, CPC only took care of individuals with chest pain and, had specified instruments and procedures for cTn test to reduce TAT. CPC of Zhongshan Hospital provided services since 2018.

The final process flow of CPC cTn test was a combination of stepwise process improvements. The improvements included (1) waiving physician assessment, (2) prioritizing order module, (3) waiving prior payment, (4) increasing blood sampling priority, (5) changing the sample type, (6) receiving samples immediately, (7) using an individual centrifuge, (8) shortening centrifugation time, (9) applying automatic numbering, (10) using rapid testing reagents, and (11) applying auto-verification, which could be explained by a comparison among CPC cTn test, ED cTn test, ED HCG test, and previous cTn test (Table 1).

2.2 | Study design

This study was to evaluate the cTn TAT at CPC after around 2 years of operation and identify opportunities for further improvement. The order-to-result time of CPC cTn was a key metric in evaluating TAT. Based on the order-to-result time of each CPC cTn sample, we calculated and evaluated the monthly on-time percentages. The evaluation also included stepwise TAT analysis and comparison with tests at ED. Zhongshan Hospital Research Ethics Committee approved this study (Ethics certificate number, B2021-524R) and waived informed consents from patients.

2.3 | Laboratory settings

Emergency department of Zhongshan Hospital had its own laboratory, where CPC tests were also performed, and its patient blood draw site was next to the laboratory. The entrance, cashier, patient blood draw site, and laboratory were all on the ground floor of ED. All the immunoassay tests, including cTn and HCG, were performed on Roche E411 analyzer (made in Germany). CPC cTn test had an individual centrifuge, whereas ED cTn and HCG tests shared a centrifuge with other tests. CPC and ED cTn samples were analyzed using 9-min electrochemiluminescence cardiac troponin T (cTnT) reagents.
Meanwhile, ED HCG samples were analyzed using 18-min electrochemiluminescence HCG reagents.

### 2.4 Data collection and analysis

#### 2.4.1 Data

The order, collection, received, and result time of each sample were stored at the Network Center of Zhongshan Hospital. Time data generated from CPC cTn test, ED cTn test, and ED HCG test between February 2018 and May 2020 were retrieved. Samples were grouped by month and, order-to-collect time, collect-to-received time, and received-to-result time of each sample were calculated. According to order-to-collect time, collect-to-received time, and received-to-result time, samples with outlier values were eliminated.

#### 2.4.2 On-time percentage

The order-to-result time of each CPC cTn sample was calculated. Four standards, 30, 40, 50, and 60 min, were used to evaluate the monthly order-to-result on-time percentages. The correlation among monthly on-time percentages and sample size was also evaluated.

#### 2.4.3 Stepwise CPC cTn TAT

Monthly data distribution of order-to-collect time, collect-to-result time, collect-to-received time, and received-to-result time was analyzed.

#### 2.4.4 Identification of the delay-causing factor

Since monthly data distribution of collect-to-received time appeared as bimodal shapes in the diagram, a cut-off line, showing the trough between two peaks, was determined. The samples were divided into two groups according to the cut-off (samples without collection location information were not included in the analysis). The monthly bedside sample amount and lab sample (sample collected at the patient blood draw site next to the laboratory) amount was compared between the two groups.

#### 2.4.5 Effects of the delay-causing factor

The samples were divided into laboratory samples and bedside samples. The collect-to-received time and order-to-collect time were compared between the two sample groups.
2.4.6 | Stepwise evaluation of process improvements

The monthly order-to-collect time, collect-to-received time and received-to-result time of cTn (it also used rapid testing reagents, but ED process flow) and HCG (its process flow and reagent types were similar to those of previous cTn) at ED were compared with those of cTn at CPC, respectively.

2.5 | Statistics

The diagram creation and outlier value identification were performed using GraphPad Prism software. The correlation among monthly on-time percentages and sample size was analyzed using Spearman’s correlation efficient. Categorical variables were analyzed using the Chi-square test. A p-value smaller than 0.05 was considered as statistically significant.

3 | RESULTS

3.1 | An overview of CPC cTn TAT

Twenty thousand, one hundred forty-three samples were included in this study. The smallest monthly sample size was 389, and the largest one was 1274. For each month, at least 95% of samples were completed (order-to-result) in 60 min, 91% in 50 min, 84% in 40 min, and 62% in 30 min (Figure 1). In another word, the median of monthly order-to-result time of CPC cTn was consistently below 30 min. The monthly sample size curve did not coincide with each monthly on-time percentage curve and on-time percentages were not correlated with sample size, suggesting that patient volume didn’t challenge the CPC cTn testing performance (Figure S1).

3.2 | Time cost in each step

According to the patient involvement, the order-to-result process could be divided into the patient-dependent order-to-collect step and the patient-independent collect-to-result step. The median of monthly order-to-collect time ranged from 4.55 min to 8.09 min, whereas the median of monthly collect-to-result time ranged from 16.53 min to 17.95 min (Figure 2). Interestingly, compared to the order-to-collect time, whose distribution was symmetric or near symmetric, the collect-to-result time had data distribution of an overt bimodal shape, indicating that there were some factors separating samples into two distinct groups and prolonging the collect-to-report time (Figure 2).

To further investigate whether the collect-to-received step or the received-to-report step contributed to the prolonged collect-to-report time, their data distributions were analyzed. More obvious bimodal shapes appeared in the diagram for collect-to-received time, rather than that for received-to-result time (Figure 3). The cut-off line, which showed the trough between two peaks, represented 140 s (Figure 3). These results suggested that factors in the collect-to-received step separated samples.

3.3 | Sampling location factor in CPC cTn test

The collect-to-received time was the sample transportation time. Since some chest pain patients were not able to walk to the patient blood draw site next to the laboratory, nurses had to draw their blood at the bedside and transport samples to the lab, which took a longer time. According to the collect-to-received time, samples were divided into two groups, above the cut-off line and below the cut-off line. The chi-square test results indicated that most of the patients with a prolonged collect-to-received time were sampled at the bedside (Table 2).

The samples collected at the bedside were compared to those collected next to the laboratory (lab) via analyzing the location-specific collect-to-received time. In either group only one peak was detected in the distribution of each monthly collect-to-received time, and the medians of bedside-specific collect-to-received time were 3–4 min longer (Figure 4, top). The medians of bedside-specific order-to-collect time were also, to some extent, longer, probably because of material preparation for blood sampling at the bedside (Figure 4, bottom).

3.4 | Comparison with ED tests

The order-to-collect time for CPC cTn test was the shortest among 3 tests, indicating that removal of payment and waiting for blood
The patient-dependent and independent TAT metrics. The order-to-collect time is patient-dependent, whereas the collect-to-result time is patient-independent. Each dot represented a sample and bars represented median with interquartile range.

Compared to ED HCG test, whose samples were mostly collected at the patient blood draw site, CPC cTn test had a reduced collect-to-received time (reduction ranged from 1.14 min to 7.66 min), showing the importance of immediate reception (Figure 5, middle). Meanwhile, the collect-to-received time for ED cTn test was much longer than that for ED HCG test (8.80–12.92 min longer), which was probably caused by more samples collected at the bedside or longer transportation time (Figure 5, middle).

The most significant reduction occurred in the received-to-result time. The differences between ED cTn and ED HCG tests ranged from 3.33 min to 8.97 min, showing the contribution of 9-min rapid testing reagents (Figure 5, bottom). The maximum reduction from ED cTn test to CPC cTn test was 25.00 min, while the minimum was 20.29 min, indicating the importance of sample type change, short centrifugation time and automatic numbering (Figure 5, bottom). The sample type change eliminated 10-min standing for clotting (Table 1). A smaller sample volume of the E411 analyzer allowed 1-min centrifugation to generate enough plasma (on the top layer) for instrumental analysis. In addition, the specified centrifuge and automatic number significantly reduced the waiting time.

**4 | DISCUSSION**

The reduction of cTn TAT is always an important goal to achieve in emergency medicine. With the clinical application of high-sensitivity
### TABLE 2 Location factor of prolonged collect-to-received time

| Month | Location   | Total | <140s | ≥140s | p Value | Month | Location   | Total | <140s | ≥140s | p Value |
|-------|------------|-------|-------|-------|---------|-------|------------|-------|-------|-------|---------|
| 18.02 | Lab        | 314   | 216   | 98    | <0.0001 | 19.04 | Lab        | 374   | 359   | 15    | <0.0001 |
|       | Bedside    | 382   | 10    | 372   |          |       | Bedside    | 429   | 10    | 419   |          |
| 18.03 | Lab        | 228   | 219   | 9     | <0.0001 | 19.05 | Lab        | 286   | 272   | 14    | <0.0001 |
|       | Bedside    | 591   | 18    | 573   |          |       | Bedside    | 470   | 23    | 447   |          |
| 18.04 | Lab        | 132   | 122   | 10    | <0.0001 | 19.06 | Lab        | 354   | 332   | 22    | <0.0001 |
|       | Bedside    | 322   | 5     | 317   |          |       | Bedside    | 436   | 12    | 424   |          |
| 18.05 | Lab        | 149   | 141   | 8     | <0.0001 | 19.07 | Lab        | 332   | 319   | 13    | <0.0001 |
|       | Bedside    | 278   | 9     | 269   |          |       | Bedside    | 446   | 11    | 435   |          |
| 18.06 | Lab        | 181   | 169   | 12    | <0.0001 | 19.08 | Lab        | 265   | 256   | 9     | <0.0001 |
|       | Bedside    | 291   | 17    | 274   |          |       | Bedside    | 420   | 16    | 404   |          |
| 18.07 | Lab        | 184   | 174   | 10    | <0.0001 | 19.09 | Lab        | 349   | 336   | 13    | <0.0001 |
|       | Bedside    | 294   | 7     | 287   |          |       | Bedside    | 360   | 10    | 350   |          |
| 18.08 | Lab        | 153   | 148   | 5     | <0.0001 | 19.10 | Lab        | 348   | 332   | 16    | <0.0001 |
|       | Bedside    | 255   | 10    | 245   |          |       | Bedside    | 352   | 12    | 340   |          |
| 18.09 | Lab        | 183   | 176   | 7     | <0.0001 | 19.11 | Lab        | 447   | 429   | 18    | <0.0001 |
|       | Bedside    | 348   | 16    | 332   |          |       | Bedside    | 512   | 14    | 498   |          |
| 18.10 | Lab        | 150   | 141   | 9     | <0.0001 | 19.12 | Lab        | 537   | 520   | 17    | <0.0001 |
|       | Bedside    | 239   | 8     | 231   |          |       | Bedside    | 712   | 14    | 698   |          |
| 18.11 | Lab        | 326   | 317   | 9     | <0.0001 | 20.01 | Lab        | 352   | 337   | 15    | <0.0001 |
|       | Bedside    | 649   | 20    | 629   |          |       | Bedside    | 530   | 18    | 512   |          |
| 18.12 | Lab        | 462   | 449   | 13    | <0.0001 | 20.02 | Lab        | 192   | 183   | 9     | <0.0001 |
|       | Bedside    | 559   | 19    | 540   |          |       | Bedside    | 194   | 7     | 187   |          |
| 19.01 | Lab        | 363   | 351   | 12    | <0.0001 | 20.03 | Lab        | 185   | 176   | 9     | <0.0001 |
|       | Bedside    | 435   | 13    | 422   |          |       | Bedside    | 339   | 10    | 329   |          |
| 19.02 | Lab        | 313   | 302   | 11    | <0.0001 | 20.04 | Lab        | 301   | 296   | 5     | <0.0001 |
|       | Bedside    | 450   | 16    | 434   |          |       | Bedside    | 406   | 19    | 387   |          |
| 19.03 | Lab        | 413   | 407   | 6     | <0.0001 | 20.05 | Lab        | 305   | 295   | 10    | <0.0001 |
|       | Bedside    | 646   | 18    | 628   |          |       | Bedside    | 390   | 8     | 382   |          |

**FIGURE 4** The contribution of location factor to TAT metrics. Each dot represented a sample and bars represented median with interquartile range.
cTn tests, more and more strategies have been developed to maximize the value of cTn testing. In 2015 European Society of Cardiology guidelines, a 0/1-h algorithm of cTn results was recommended for earlier diagnosis of NSTEMI. Similar algorithms were proposed by several other studies and, in all these studies, the increase of cTn results between two sequential tests may give a hint of NSTEMI earlier than a traditional one-time cut-off. In principle, a patient taking two serial cTn tests should stay at ED/CPC for 2 h with a cTn TAT of 60 min, whereas the length of stay is 1.5 h with a TAT of 30 min. The 25% reduction of the length of stay indicates that the use of cTn algorithms adds an economic value to the time control of cTn testing.

Lean methodology is a way to optimize the efficiency of a system via eliminating the unnecessary waste of people, resources, efforts and so on. During the establishment of CPC at Zhongshan Hospital, the process flow of cTn testing was determined according to the principles of lean methodology, thereby effectively controlling the TAT. In this study, a stepwise evaluation gives us an insight into the performance of each step and opportunities for further improvement. From more to less, the time was spent on the received-to-result step, the order-to-collect step and the collect-to-received step successively, which is consistent with other studies (Figures 2 and 3). Meanwhile, the order-to-collect step had the widest quartile range, while the received-to-result step had the narrowest one, indicating that the sample analysis at the laboratory was optimized significantly and the order-to-collect step should be further explored. Considering the entrance and the patient blood draw site were on the same floor and the walk time between them was about 2 min, a possible explanation for the delayed sample collection is that patients wasted some time in finding the blood draw site. Another possibility is that some patients took electrocardiography, another key examination for MI, before blood draw. More signposts and education for patients may help to improve this situation. The location factor identified in this study suggests that the floorplan of ED still could be optimized and a short distance between the patient observation room and the laboratory might reduce the transportation time for bedside samples (Figure 4 and Table 2).

A key measure to shorten cTn TAT at CPC of Zhongshan Hospital is the combination of a sample type switch and a centrifugation time reduction. Since the manufacturer informed that, for its cTn tests, plasma had similar performance with serum in early diagnosis of MI, we switched the sample type to plasma to eliminate 10-min clotting time (Table 1). Moreover, considering the E411 analyzer draws the plasma from the top and the required sample volume is 50 µl, one-min centrifugation could remove most of the blood cells on the top layer and generate a sufficient volume of plasma for the instrumental analysis. As a result, the queuing and processing time for centrifugation decreased from 10–20 min to 1–2 min, without clinical concerns on the assay performance. A previous study has suggested
the use of whole blood and a hematocrit-based conversion equation to remove the centrifugation step. However, whole blood is not a recommended sample type and our procedure is more suitable for the E411 analyzer.

There were still some limitations in this study. Firstly, the process improvements were implemented simultaneously, rather than progressively. Hence, we could not evaluate the process improvements step by step to find out the valueless attempts. Secondly, the time data for cTn test before 2017 could not be retrieved and the replacement, ED HCG test, did not fully reflect its performance. Thirdly, the contributions of sampling location factor were influenced by floorplan and the floorplan for each hospital was unique. All these should be investigated in further studies.

ACKNOWLEDGEMENTS
This study was supported by the National Natural Science Foundation of China (81772263, 81972000, 82000275, 81902139), the Constructing Project of Clinical Key Disciplines in Shanghai (SHSLCZ2DZK03302), the Key Medical and Health Projects of Xiamen (YDZX201935020000002), Shanghai Medical Key Specialty (ZK2019B28), Specialized Fund for the Clinical Researches of Zhongshan Hospital affiliated Fudan University (2018ZSLC05, 2020ZSLC54), Scientific Research Fund by Zhongshan Hospital (418), the Project funded by China Postdoctoral Science Foundation (2019M651370) and Shanghai Post-doctoral Excellence Program (2018166).

CONFLICT OF INTEREST
All authors report no conflict of interest.

AUTHOR CONTRIBUTIONS
HW, XW, KW, and WG conceptualized and designed the study. KW and WJ acquired the data. HW, XW, KW, XD, and BP analyzed and interpreted the data. HW and XW drafted the manuscript. HW, BT, BP, BW, and WG revised the manuscript. HW, BW, BP, and WG acquired funding.

DATA AVAILABILITY STATEMENT
All the data are included in this manuscript.

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**SUPPORTING INFORMATION**

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**How to cite this article:** Wang H, Wang X, Wang K, et al. Evaluation of a cardiac troponin process flow at the chest pain center with the shortest turnaround time. *J Clin Lab Anal*. 2022;36:e24335. doi:10.1002/jcla.24335