

Quality Improvement by Offline-Online Hybrid Kidney Transplantation Waiting List Clinic in the New Normal in Srinagarind Hospital

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Objective: Recent Coronavirus disease (COVID-19) outbreak has made restricted non-COVID-19 disease care to limit viral spreading, and the kidney transplant waitlist clinic has offered an offline-online-hybrid-kidney transplantation waiting list clinic. The quality outcomes were compared between the new and the conventional service.

Materials and Methods: A retrospective review was done with data of the hybrid clinic, which opened from January to April 2021, and the conventional clinic, which explored from 2018 to 2020. The percentage of passing the peri-operative health evaluation, PRA (panel reactive antibody) test records, and monthly serum sample records were assessed.

Results: There were 823 cases on the list with 637 active cases. The passing of peri-operative health evaluation increased from 68.8%, 81.4%, and 76.4% in 2018 to 2020 to 100% in early 2021. The percentage of PRA test records and serum sample records of transplant candidates increased from less than 50% in the conventional clinic service to 82% and 93.9%, consecutively in the hybrid clinic service. The hybrid clinic significantly improved the PRA test records ($p < 0.001$), the serum sample records rates ($p < 0.001$), and the passing health check rate when compared to the median performance of the three years of the conventional clinic ($p = 0.027$).

Conclusion: During the pandemic, the hybrid kidney transplantation waiting list clinic supports kidney transplant candidates by maintaining qualification in the organ allocation system and improve the passing of peri-operative health assessment.

Keywords: Online waiting list clinic; Waiting list during the pandemic; KT waiting list in the pandemic; Hybrid waiting list clinic; Offline-online service in waitlist

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Organ transplantation is the most cost-effective renal replacement therapy (RRT) because it has given a better quality of life and longevity than chronic dialysis⁽¹⁾. However, donated organs are in shortage while the waiting lists of patients keep increasing in number^(2,3). The rising of transplant candidates on the waiting list is also evidenced in Thailand, which more than six thousand cases in 2018⁽⁴⁾.

The kidney transplantation program in the Faculty

of Medicine, Khon Kaen University (KKU), has provided organ transplant service for northeastern Thailand since 1990 and acts in concert with its Organ Transplant Coordinator (OTC) team. Most cases are deceased kidney donor type. Hence, a waiting list maintenance service is a vital part and has the potential to grow with the rapidly increasing rate of end-stage kidney disease.

The World Health Organization (WHO), after the significant expansion of the SARS-CoV-2 virus, declared the state of a pandemic by coronavirus 2019 disease (COVID-19) on March 11, 2020⁽⁵⁾. The COVID-19 outbreak has triggered the lockdown of populations worldwide, strongly affecting daily life, as well as most health systems, which have been confronted with the management of both infected patients and routine non-COVID-19 patient care^(6,7). In response to the recent COVID-19 pandemic, many specialty healthcare providers have transitioned from physical review to telemedicine review to minimize patients' and staffs' movement as a strategy to reduce the risk of transmission^(6,7). As other parts of healthcare service, kidney transplantation and waiting list clinic have been affected by the COVID-19 pandemic, which leads to reducing or temporary closing organ transplantation services and

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restriction of the onsite visit of chronic disease care. In our program, kidney transplantation activity was withheld and re-opened many times since the first wave of the pandemic in March 2020. However, after the country has controlled the first wave of the pandemic, we found that transplant candidates on the waitlist loss their continuity from the waitlist clinic follow-up. Many transplant candidates reflected that they found the uncertainty of coming back to the clinic after the locked-down city and the kidney transplant was re-opened. Transplant candidates lose their eligibility because could not maintain qualification that required by the national allocation system. Thus, we decided to keep opening waiting list clinic, even announcing the temporary closing of organ donation and transplant activities in the second and third wave of COVID-19 to lessen the loss of connection of transplant candidates and maintain continuous health assessment. To comply with the outbreak regulatory control, we have considered telehealth as an alternative for the service. Lots of literature has shown advantages of telehealth but in organ transplant especially transplant waiting lists, only a few studies^(8,9). Introducing telehealth and web-based submission with video conference can improve waitlist evaluation, time-saving, and reduced travel-related costs in USA study^(10,11). Telehealth service can save traveling time and cost in post-kidney transplant patients from single-center Australia⁽¹²⁾. However, there is a lack of evidence that telehealth can be effective in our setting in transplant waitlists in the country. After a trial of the new normal service, a retrospective study was created to evaluate the efficacy of the offline-online-hybrid-kidney transplantation waiting list clinic compared to the previous one.

Materials and Methods

Ethics approval

The Human Research Ethics Committee of Khon Kaen University reviewed and approved the study per the Helsinki Declaration and the Good Clinical Practice Guidelines (HE641279).

Setting

Our center's organ transplant operation was temporarily suspended from April 1, 2020, to May 1, 2020, and from April 3, 2021, to May 12, 2021, because of the first wave and the tremendous third wave COVID-19 pandemic in Thailand. During the second wave of the pandemic, the situation in the Northeast of Thailand was more controllable. Our waitlist clinic had re-opened with multiple safety measures such as temperature and history screening in the out-patient department front desk, social distancing, and swab test with quarantine in a high-risk one.

After the second wave of the Covid-19 pandemic in Thailand, which started around December 2020, our Organ Transplantation Unit provided the hybrid clinic service from January 1, 2021 until now. Thus, the quality outcomes of waitlist maintenance before the hybrid clinic (conventional waitlist clinic) and after the hybrid clinic (online and onsite visits combination) implementation can be compared by

timing sequence, as shown in Figure 1.

The subjects in the study were enrolled from the inclusion criteria, including 1) all transplant candidates in routine service during the start of January 2018 to the end of April 2021, 2) the age in the range 18 to 65 years old, and 3) both currently active and inactive waiting list cases who already had registered in the national database of the Thai Red Cross Organ Donation Centre. The subjects would be excluded if 1) loss to follow-up with our waitlist team more than a year, 2) the transplant candidates who opted-out from the list due to their personal reasons or moving out from the Northeast region, 3) discontinuation of serum sample sending to the KKU Blood Transfusion Center, and 4) discontinuation of PRA test records from the KKU Blood Transfusion Center database.

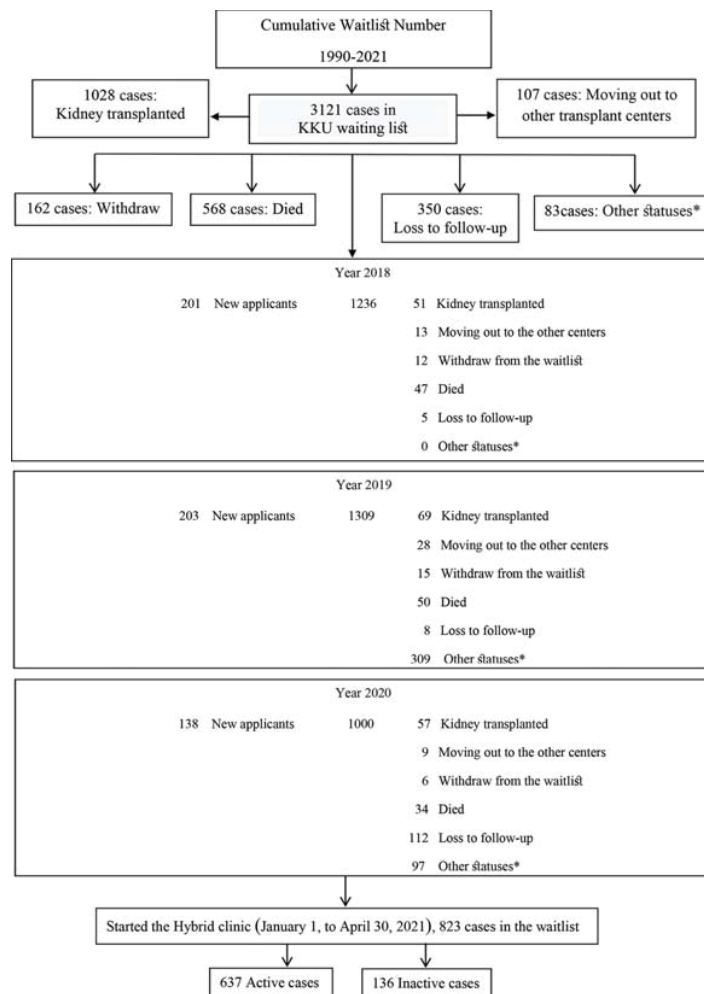
While transplant candidate registered cases must be maintained in the waiting list clinic in the transplant center, there are new ESRD cases that come to apply for our waitlist. However, by waitlist data cleaning and before handling quality and validated data into KKU waiting list- online database in 2020, loss of contact, withdrawal cases, or non-compliance transplant candidates have been removed from the list. As a result, we can explore the actual number of cases and cost-effectively operate the database.

The conventional waiting list clinic

In the conventional clinic, transplant candidates regularly visit every 3 to 4 months with their health record form filled with essential laboratory results from their dialysis unit. The waitlist nephrologists check the health record form and define the health status of transplant candidates after seeing them in person. Waiting list nurses in the clinic give advice, more details of personal health information, and documents before candidates discharge from the service. The transplant candidates bring back the health record form to their local dialysis unit team if any problems require intervention. Suppose the candidate has a serious problem that is contraindicated for the transplant operation. In that case, the status will define "inactive", and transplant candidates should not come to visit when they get notified about potential donors from the OTC. The transplant candidate who has the problem solved can contact the waitlist clinic office and see the waitlist nephrologists to validate the status into "active". Before 2020, our unit required the officer to input the health status into a static file recorded securely in Organ Transplant Unit.

The hybrid waiting list clinic

In the hybrid clinic service, the full-time waiting list coordinator contacts back to transplant candidates via a phone call and screening health information by using a telemedicine health record form. Every week, the waitlist nephrologists check the telemedicine health record forms collected from many candidates by the waiting list coordinator. And then define essential problems if an onsite visit or intervention from the local dialysis unit is needed. The waiting list coordinator informs back to the candidates and the



Other statuses* = Status that transplant candidates were maintained in the waitlist in the national database of the Thai Red Cross Organ Donation Centre. Still, they have had one of the conditions as following, 1) lacked communication to the KKKU waitlist team not more than a year and were waited to respond by official mail, 2) unavailable to contact by phone call, 3) did not come to visit the KKKU waitlist clinic, 4) loss to follow-up during the pandemic

Figure 1. The study flow represents the accumulative number of transplant candidates before enrollment and clinical outcomes during the year on the waitlist.

local dialysis unit via the phone call or secure online chat system depending on candidates preferable. In this way, giving advice, personal health information, and appointment documents can send via an online chat system with synchronous or asynchronous telemedicine mode.

Design, outcomes and statistical analysis

This retrospective cohort study compared efficacy between the conventional service, which was explored from 2018 to 2020, and new normal service by offline-online

hybrid waiting list clinic, which opened from January to April 2021. Descriptive data are presented as the percentage. The comparison of quality outcomes between the conventional and the hybrid clinics was analyzed by the Chi-square test and Fisher's exact test. A p-value of less than 0.05 was considered significant. All statistical analyses were performed using computer software (Stata, version 10.1 (StataCorp, College Station, TX, USA)).

The study was approved by Khon Kaen University Ethics committee in human research as the study

number HE641279. The manuscript is written as described in The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

Results

Demographic data

From KKKU WL online database, there were 3,121 cases totally in conventional clinics since the service opening in 1990. One thousand twenty-eight cases had kidney transplanted, 107 cases moved to list in other transplant centers, 162 cases withdrew from the list, 568 cases died during the wait on the list, 350 cases opted out due to loss to follow-up, and 83 cases were removed from the list for various reasons (Figure 1).

Finally, 823 cases were confirmed, remaining on the list with 637 active and 136 inactive (not ready to get the operation clinically) cases. Baseline demographic data can be extracted from the hybrid clinic patients. 58.2% of males and nearly half of all candidates were at age 46 to 65 years old (Table 1). Chronic hemodialysis is the majority mode of long-term RRT, as shown in two-third of candidates. Candidates in blood group O and group B were the most common on this waitlist.

The Ministry of Public Health provides a service plan (SP) strategy in areas 7, 8, 9, and 10 for the northeastern region (Figure 2). The majority of transplant candidates were contributed from Surin province, which nearly 10% (Figure 2), and SP8 plus SP9 contributed around two-third of the list. The lowest part was SP10 that included the lowest two provinces, which were Sisaket and Ubon Ratchathani.

Table 1. Demographic data of the kidney transplant candidates waiting list in the hybrid clinic service

	Number	%
Total subjects	823	100
Gender		
Male	478	58.20
Female	345	41.90
Age range		
19 to 30 years old	135	16.40
31 to 45 years old	287	34.80
46 to 65 years old	401	48.70
Treatment		
HD	538	65.30
CAPD	285	34.60
Blood group		
A	173	21.00
AB	29	3.50
B	293	35.60
O	328	39.80

Quality outcomes

To begin with, the percentage of PRA test records and serum sample records of transplant candidates showed less than 50% in the conventional clinic service and 82% and 93.9%, consecutively in the hybrid clinic service (Figure 3). The hybrid clinic significantly improved the PRA test records ($p<0.001$) and the serum sample records rates ($p<0.001$) when compared to the median performance of the conventional clinic (Table 2).

Furthermore, the percentage of candidates passing health checks when visiting the transplant center for evaluation before kidney transplanted has shown in Figure 3. In our center, we usually require only the two finalists of the most compatible candidates to come to visit at a time for one kidney. In comparison, the third and the fourth compatible transplant candidates would get activated and come to visit when either one or both two finalists has a possibility to fail. As we notice in early 2021, there was 100% of the transplant candidates passing health check at pre-operative assessment compared to 68.8% in 2018 and 81.4% in 2019, which described the conventional clinic service in the pre-COVID-19 period and 76.4 % in 2020, which represented the conventional clinic service during COVID-19 pandemic. Overall, the hybrid clinic significantly increased the passing health check rate when compared to the median of the three years conventional clinic ($p=0.027$) (Table 2) and showed a trend when compared to the conventional clinic during the pandemic ($p=0.038$) (Table 2).

Discussion

The study shows that the offline-online-hybrid-kidney transplantation waiting list clinic can maintain or even improve the efficacy of the service compared to the conventional service in terms of percentage of passing perioperative health evaluation, PRA test, and serum sample record.

The results showed a positive impact of online contribution in our healthcare setting as from publications^(8-12,15,19). The hybrid clinic provides safety for healthcare personnel and transplant candidates in the pandemic by remotely gain information about candidates' health status online, thus aid in deciding if there is a need to intervene at the onsite visit⁽⁸⁻¹²⁾. Asynchronous telemedicine allows the waiting list coordinator to manage multiple transplant candidates in a 'virtual clinic' simultaneously and keep connecting with the local dialysis unit easily by store-and-forward communication⁽¹³⁾. There was only a large kidney transplant waiting list study from the USA that showed improve waitlist evaluation, time-saving, and reduced travel-related costs when telehealth with web-based submission and video conferencing were deployed^(10,11). A recent well-design prospective study has been launched for telemedicine-based follow-up care in post-kidney transplant in Germany⁽¹⁴⁾, and outcomes soon should benefit all organ transplants. We believe that there are possible to find the same trend of cost- and time-saving outcomes in our setting, but we focus on testing quality outcomes first in

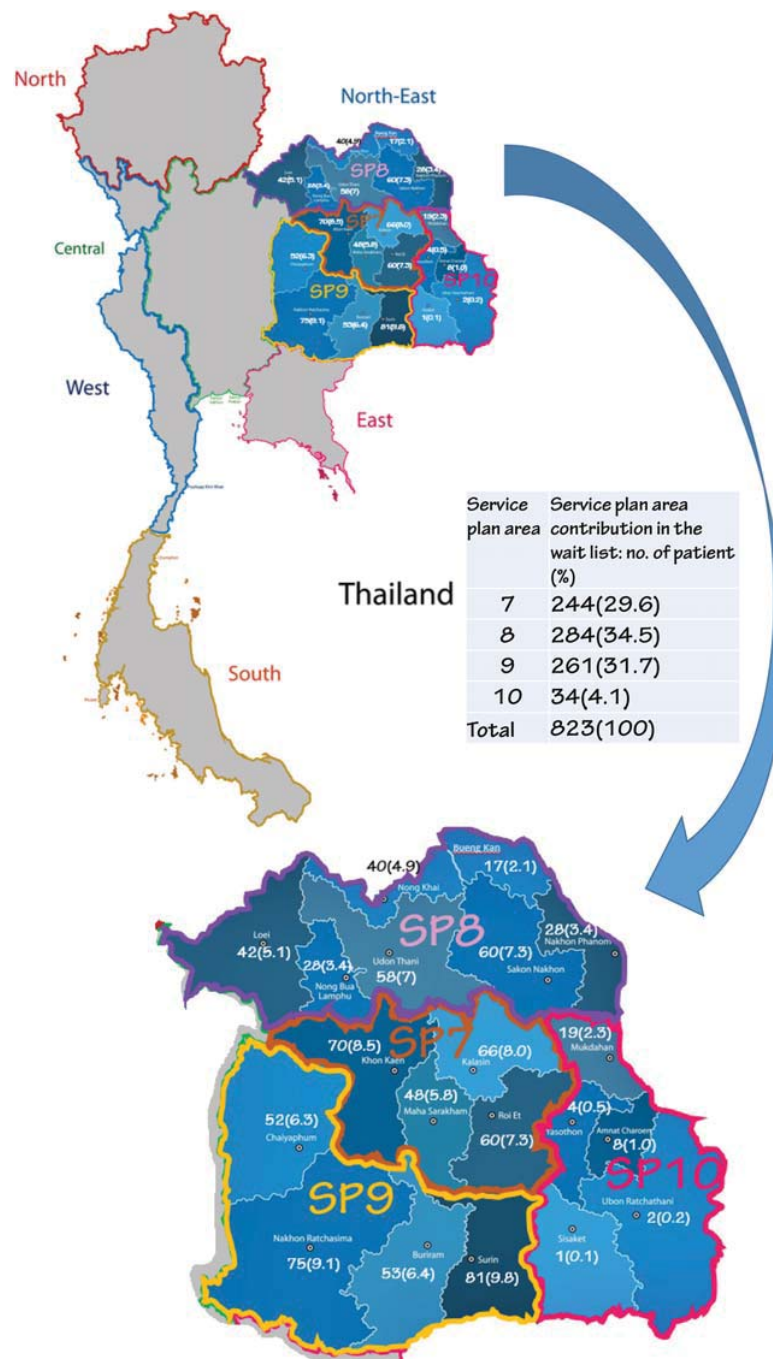
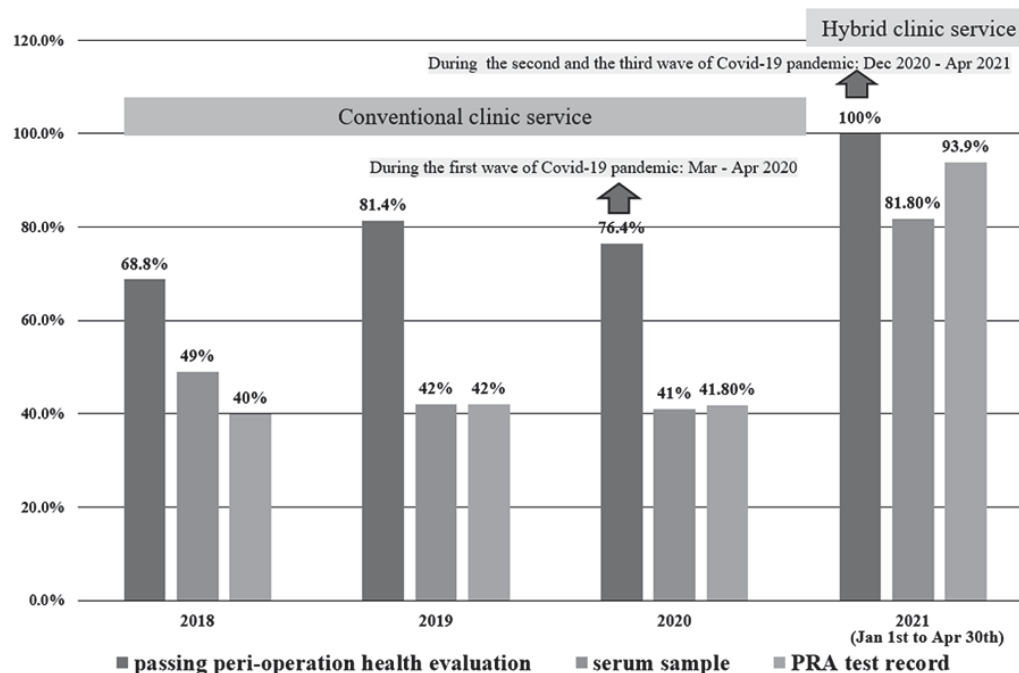


Figure 2. Number and percentage of transplant candidates in our waiting list by provincial areas and service plan areas.

this study before going further.

Besides continuous remote waitlist candidates

monitoring, multiple factors influence our facilities' service quality and outcomes, including online database collaboration,



* Passing perioperative health evaluation is calculated from the yearly number of transplant candidates who were passing perioperative health check divided by the yearly number of transplant candidates who visit as the potential recipient after the call

Figure 3. Comparison between the conventional clinic and the hybrid clinic in the passing of perioperative health evaluation*, the percentage of PRA test records and serum sample records of kidney transplant candidates, yearly.

Table 2. The comparison of quality outcomes by Chi-square test and Fisher's exact test between the conventional (median value of 3 years) and the hybrid clinics at the upper part of the table. The comparison of quality outcomes by Chi-square test and Fisher's exact test during the pandemic between the conventional (2020) and the hybrid (2021) clinics at the lower part of the table

Quality outcomes between the conventional and the hybrid clinics	2018 to 2020	2021	Chi-square test	p-value
PRA test records, n (%)	1,461 (41.2)*	772 (93.8)	739.30	<0.001
Serum sample records, n (%)	1,564 (44.1)*	673 (81.7)	379.06	<0.001
Passing peri-operation health evaluation, n (%)	245 (75.6)*	15 (100)	Fisher's exact test	0.027
Quality outcomes between the conventional and the hybrid clinics during the year of pandemic (2020 vs. 2021)	2020	2021	Chi-square test	p-value
PRA test records, n (%)	418 (41.8)	772 (93.9)	538.64	<0.001
Serum sample records, n (%)	410 (41)	673 (81.7)	311.24	<0.001
Passing peri-operation health evaluation, n (%)	78 (76.4)	15 (100)	Fisher's exact test	0.038

* = Median value of the years 2018 to 2020

healthcare networking with regional dialysis units, and maintaining onsite visits for a problem case.

To begin with, a waiting list-online database can help for data gathering, reduce operating costs, and share patients' information securely among the multidisciplinary team, including transplant nephrologist, OTC, transplant surgeon, and the Blood Transfusion Center teams contribute to the service.

Having access to this database 24 hour a day from anywhere can become a huge advantage for deceased donor organ transplant teams in time-sensitive working hours. When combining this tool with the hybrid clinic, transplant candidates' health status can be updated in real-time and ready to use for clinician decision-making. Without a real-time updated online database, the process of changing health status back and forth and details of problems for each transplant candidate can be delayed and cause many problems in the process of deceased donor organ allocation and perioperative period.

Moreover, healthcare networking with dialysis units is crucial and greatly beneficial for transplant candidates. From the process of hybrid clinic service, the waiting list coordinator is indispensable in making an online connection with regional dialysis units to coordinate and recruit transplant candidates' clinical data. Future development of well-built telehealth can reduce candidates' traveling cost burden. Many transplant candidates from other SP areas, such as SP8 (Figure 1), contribute to our waitlist more than our area (SP7). As one can notice from geographical distance around northeastern Thailand as the Figure 1, KKU of Khon Kaen province is in a central area of the region. This location is far more challenging to access by transplant candidates traveling from the marginal area than other country regions.

In addition, the telemedicine health record form is designed to assist health checking by the waiting list coordinator nurse. This tool supports the maintenance of the hybrid clinic with less contact, an isolated working environment, less time-consuming for waitlist nephrologists to see all transplant candidates and skip an unnecessary onsite visit⁽¹⁵⁾. However, we cannot refuse that the onsite visit is still essential for a problem case. With local dialysis unit's engagement, contagious risk of exposure screening can be done in advance, and COVID-19 Real-time RT-PCR (reverse transcription-polymerase chain reaction) testing can be set up if needed.

Basic outcome indicating quality management

Perioperative health evaluation represents two-part of patients' care, current care and underlying comorbidities. Some acute problem is inevitable and prevents the candidate from kidney transplantation, but most comorbidities are manageable and preventable in advance by the effective waiting list system. For this reason, we put the passing of perioperative health evaluation as an indicator of effective service.

PRA test records and serum sample records directly indicate candidates' compliance and waiting list clinic

efficiency. Data management and information technology system in the back office should be done securely and on a real-time basis for assuring timely check of PRA at least twice a year and a monthly serum sample for each candidate. Those are the minimum requirement of the Thai Red Cross Organ Donation Centre.

PRA is crucial as one part of scoring in the national kidney allocation system. Updated PRA value comes up with accurate individual immunologic risk profiling and supports transparency and equality in the allocation system^(16,17). Our center provides the PRA testing by the KKU Blood Transfusion Center for our candidates and sending all validated data to the national allocation center. The storage of candidate serum samples in the KKU Blood Transfusion Center is essential. The first half would be sent to the Thai Red Cross Organ Donation Centre to match the potential donor promptly. The second half would be reserved for PRA testing in the pandemic when transplant candidates cannot come onsite to give a blood test.

Limitations

There are many limitations to this retrospective analysis and online implementation. As the study design was an observational study and lacked a controlled group, the improvement of compliance outcomes might be considered because of subjects aware of being observed in the study (the Hawthorne effect). However, it was a retrospective cohort that during the hybrid clinic initial implementation, all subjects, the waiting list coordinator nurse, and associated physicians did not know in advance that they would be in the research. On the other hand, it has to accept subjects' selection bias by retrospective cohort nature because the conventional clinic and the hybrid clinic groups reached their outcomes already before analysis. The majority of subjects in the hybrid clinic were those who had experienced the conventional clinic by the time sequence. With the time and service constraints during the pandemic, we cannot leave the conventional service as the control group ethically.

The generalizability and reproducibility of the hybrid clinic might be possible only in the setting of full-time waiting list coordinator availability and an easily accessible online database.

From the waiting list coordinator's point of view, online tools application into the population in various knowledge levels is not comfortable at initial. Many obstacles can be revealed, such as outdated transplant candidates' contact numbers, making a new connection with chronic dialysis patients, and explaining new services.

Additionally, telehealth needs everyone to have available access. Even asynchronous telehealth is flexible, and no need to have real-time interaction, but some candidates are not pleasant for the first time of contact. Those have many reasons, such as not having a smartphone, not feeling comfortable with technology, and do not want to get interrupted during daytime job hours. Patient and provider satisfaction in using the technology will need to be evaluated, and response can enhance both the patient and provider

experience.

Furthermore, this online communication is not a new thing in Thai society. However, there is a lack of official regulation for remote telehealth data transit in an official healthcare setting. There is a lack of enforcement of privacy and security safeguards in the country. Healthcare providers can use telehealth services to provide all services in their professional judgment, especially when pressed by a national public health emergency. On the one hand, medical personnel might feel free to use various software as availability or personal experience without notice of data security and encryption level. There is a risk of a sensitive data breach, especially personal healthcare information. On the other hand, there is a lack of backup law and government policy for health provider protection. Many transplant candidates might not accept or rely on the stranger calls in the first contact and lead to a time-consuming case approach for the waiting list coordinator. After the pandemic subsided, our healthcare community might have an opportunity to establish the next level of data privacy standard⁽¹⁸⁾.

For another thing, our telehealthcare costs have never been studied. The recent economic analysis showed that telehealth is cost-saving for the health system with a breakeven point that can be less than a year or later depending on application modes, whether store-and-forward or videoconference services. The breakeven point is the point after which the initial investment is recouped, and the cost savings have become a reality⁽¹⁹⁾. Nonetheless, different settings and different infrastructure platforms might cost different outcomes in our facilities.

Finally, data cleaning might be a big issue in our center. We can observe that subjects in the conventional waitlist clinic were in a larger group due to unclear data of the active status. In contrast, the hybrid clinic group was in a smaller, data-cleaner group and included a small number of newly registered cases during the pandemic. Therefore, the main quality outcomes comparison focuses on a percentage more than an absolute number of patients, which is incomparable.

Conclusion

The study sheds light on the next service step with the online implementation that a coming of the COVID-19 pandemic has forced. By collaborating with the full-time waiting list coordinator nurse, waiting list-online database, regional dialysis unit networking, and onsite visit preparing as needed, the effective hybrid service is possible in resource-limited settings. Hybrid of conventional and digital cares for kidney transplantation waiting list clinic helps maintain quality and reduce the onsite clinic visit while complying with social distancing, quarantine, and isolation during the pandemic. A further prospective analysis in the post-COVID pandemic period might yield better follow-up protocols and be more cost-effective in the near future.

What is already known on this topic?

Telemedicine helps for reducing traveling time,

mailing time of documents, and costs in transplant center visits for transplant candidates and post kidney transplant patients in developed countries.

What this study adds?

The collaboration of online communication and onsite hospital visit as the hybrid service in transplant waiting lists can improve access by maintaining the qualification of transplant candidates both clinically and immunologically to kidney transplantation. During the COVID-19 pandemic, compulsory social distancing, the lack of curative therapy for the virus, and prompt vaccination have driven telemedicine the most effective and safest connecting system among kidney transplant candidates, dialysis units, transplant coordinators, and the transplant center. The implication of online healthcare communication into developing society with varying technology diffusion in our population can be effectively combined with different technologies from the old fashion to a new one.

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Potential conflicts of interest

The authors declare no conflict of interest.

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