Assessment of Quality Management System for Clinical Nutrition in Jiangsu

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Research Article

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Abstract

Objective: To critically evaluate the Quality Management System (QMS) for Clinical Nutrition (CN) in Jiangsu. Monitor its performance in quality assessment as well as human resource management from nutrition aspect. Investigate the appliance and development of Artificial Intelligence (AI) in medical quality control.

Data Source: The study source of this research was all the staffs of 70 Clinical Nutrition Department (CND) of the tertiary hospitals in Jiangsu Province, China. These departments are all members of the Quality Management System of Clinical Nutrition in Jiangsu (QMSNJ).

Methods: An online survey was conducted on all 341 employees within all these CNDs based on the staff information from the surveyed medical institutions. The questionnaire contains 5 aspects, while data analysis and AI evaluation were focused on human resource information.

Results: 330 questionnaires were collected with the respondent rate of 96.77%. The QMS for CN has been build up for CNDs in Jiangsu, which achieved its target in human resource improvements, especially among dietitians. The increasing number of participated departments (42.8%) and the significant growth of dietitians (p=0.02, t=-0.42) are all expressions of the advancements of QMSNJ.

Conclusion: As the rst innovation of an online platform for QM in Jiangsu, JPCNMP has been successfully implemented among QMS from this research. This multidimensional electronic system can help QMSNJ and CND achieve quality assessment from various aspects, so as to realize the continuous improvement of clinical nutrition. The instrument of online platform, as well as AI technology for quality assessment is worth to be recommended and promoted in the future.

Summary

What is known on this topic:

1. An electronic system that automatically collects medical information can realize timely monitoring of patient health, improve the effectiveness and accuracy of medical treatment.
2. To our knowledge, the application of AI into medical service quality assessment has merely been evaluated, especially for CND in china.
3. From the perspective of medical ethics, patient safety is the core before any other factors within health science, which belongs to the responsibility of Quality Management System within medical institutions.

What this study adds:

1. This is the first evaluation of the online QM platform after its implementation in daily disciplinary management among the QMS in china.
2. A clearer forecast of AI in medical quality assessment and disciplinary construction was achieved, while some modifications are recommended in human resource management to improve its efficiency and accuracy.

3. This analysis is emphasizing on the human resource approuvement after the designation and application of QMS.

Background

From the perspective of medical ethics, patient safety is the core before any other factors within health science. As the application of health science, medical services are inseparable from the safety of patients’ lives and medical ethics. Scope of its practice is composed of statutory and individual components, includes codes of ethics (eg, health institution, department director, and/or other national organizations) and other resources. As the Quality Management Center of Clinical Nutrition in Jiangsu (QMCNJ), it is the system for tertiary hospitals. Their quality assessment comes from the reported data of all CND among these hospitals, such as human and material resource, professional practice, foodservice operation, patient’s satisfaction, and nutrition education presentation for hospital and community. All of the required information is scheduled based on the Revised 2016 Standards of Construction and Management of Clinical Nutrition Department in Jiangsu, reflects advances in CND practice during the past 6 years and replaces the 2010 Standards.

Within this information era, most of the current information is network-based, as well as the data of healthcare. An electronic system that automatically collects medical information can realize timely monitoring of patient health, improve the effectiveness and accuracy of medical treatment. From a medical quality perspective, a reliance intelligent management system can improve data curation, reduce human resource costs, and contribute to facilitating continuous improvement. As one of the inventions in the information era, AI shows its strong adaptability to the network-based health-care system. It can be introduced into clinical behavior detection accurately and automatically, and of great significance for reducing the incidence of treatment errors and ensuring patients safety. However, the amount of digital data has increased dramatically after the appliance of online system. A crucial consequence is that data management has become more complex, which has increased the necessity for methods that are able to deal with the quality assessment of digital information. From the perspective of QM and the discipline development of a medical specialty, such as CN, the specific indicators and the application evaluation of AI are important to achieving quality control goals.

To our knowledge, the application of AI into medical service quality assessment has merely been evaluated, especially for CND. There existed a unified platform for all the QM centers of various medical specialties set up by the Jiangsu Provincial Health Commission (JPHC). After its broken-down in October 2017, the QMCNJ became the first center to independently develop and promote the application of its Clinical Nutrition Management Platform (JPCNMP,
This platform does not require any software installation, just enter the web and fill in the activated account password to complete the login and start data reporting, which makes related information collection more convenient. It was officially launched in the QMSNJ in 2019 and successfully promoted to 70 CND within the quality control system. They are required to fill in relevant information regularly in accordance with the regulations of “Strengthening the Management of Provincial Medical Quality Management System” formulated by JPHC, which has revised in September 2020. Since the stable application of this platform for two years, its effect in QM required to be validated. At the same time, the application value of AI and the development of the CND in Jiangsu can also be clarified.

Methods

1. Subjects

An online questionnaire was designed for employees in 70 CND of the tertiary hospitals in Jiangsu Province, which are all members of QMSNJ. There are 341 staffs in total based on the human resource information from the surveyed medical institutions. The questionnaire contains 5 aspects: hospital information, personal profile, education in QM, scientific research achievements, and nutrition education presentation though internet.

2. Survey recruitment and data collection

Before distribution, the survey and methods were approved by the QMCNJ and JPHC. The data were collected through an online survey (ID: 97003762) through the free-access platform “Wen Juan Xing” (https://www.wjx.cn/wjx/design/previewmobile.aspx?activity=97003762&s=1). One specific code was requested to fill the questionnaire. An electronic reminder was sent by QMCNJ to the secretary of these 70 CND through SMS, email, JPCNMP and WeChat. The deadline for completing this survey is Nov. 14, 2020.

3. Ethics

Institutional ethics approval was obtained for this study from Ethics Committee of First Affiliated Hospital with Nanjing Medical University. This survey presents no risks to the participants, neither did it involve any therapeutic intervention. All the personal information within the questionnaire was designed to verify the authenticity of the feedback. After screening valid questionnaires, all personal information would not be included in the statistical analysis. As the result, there is no risk of additional use or disclosure of private information. Key informants were assured that confidentiality would be maintained and that findings would be presented in an anonymous fashion.

4. Data analysis

Because information about the CND’s human resource and service requirements of related hospitals could be automatically captured through the JPCNMP and the Hospital Information System (HIS), the risk of error caused by manual filling should be avoided. Therefore, these two pieces of information belong to the most easily obtained and most accurate data for CND’s status assessment. Also, it is the foundation for
this research. All of these information was gathered on Nov. 14, 2020. This original data is online-accessible for the QMCNJ from the link “https://www.wjx.cn/report/97003762.aspx”.

Only completed questionnaires will be included in the data analysis. An overall description was performed to summarize the demographic and professional characteristics of the valid study sample. The current construction of the CND and their human resource has been clarified with this description. Comparing it with the corresponding data when the online management system was not activated, which is documented in the survey “Current Status of the CND among tertiary hospitals in Jiangsu Province” conducted by our research team in 2018, a preliminary evaluation result of the progress of the quality control was obtained.

The in-depth quality assessment of each participant in the QMSNJ was declared with the gathered information. Because the JPCNMP maintained in the trial operation stage in 2018, it has not been uniformly applied in the entire QMSNJ. Therefore, a natural time grouping was formed according to the dates when the two surveys were completed. In 2018, the 49 CND that did not use AI tools for QM was the control group, and the corresponding CND that was maturely used AI tools for management in 2020 was the observation group. The list of QMSNJ in 2018 was used to filter valid information. Some new departments applied to participate in the quality control system within this period and their information in 2018 was un-surveyed, so they cannot be compared. Another criterion is the consistency between “Numbers of Colleges in your Department” in the "Hospital Information" and the number of documented staffs of the CND in their HIS system. It is used to verify the authenticity of the feedback. The questionnaire was considered valid while these two data matched. An paired sample t-Test was conducted to determine differences between their situation before and after the application of JPCNMP.

5. Statistical method

SPSS Statistics 22.0 (SPSS, Inc, an IBM Company, Chicago, IL) was used to describe the results; statistical significance was set at $p \leq 0.05$ as shown in the “Table 1 Online Survey for Members of QMSNJ in 2020".
Table 1
Online Survey for Members of QMSNJ in 2020

**Hospital Information**
- Name of your Medical Institution
- The Category of your Institution
- The Specialty Category of your Clinical Nutrition Department (CND)
- Numbers of Colleges in your Department

**Personal Profile**
- Your Name
- Your Gender
- Your Position
- Your Title

- Are you a certified physician?
- Are you a registered dietitian (RD)?
- Are you a certified nurse?

**Education in QM**
- Did you notice the 2020 QMSNJ Training?
- Did you participated in the 2020 QMSNJ Training?
- Date of the 2020 QMSNJ Training
- Content of the 2020 QMSNJ Training

**Scientific Research Achievements**
(From 2018 to 2020)
- List of your current researches
- List of your published research papers
- List of your published monographs
- List of your certified copyrights

**Medical Service though Internet**
(From 2018 to 2020)
- Whether you have taken part in your department’s online medical service?
- The website of your department’s online medical service
- The frequency of your department’s online medical service
- Numbers of the patients in your department’s online medical service
- Whether you have carried out online medical service on your own?
- The website of your own online medical service
Online Survey for members of QMSNJ in 2020

<table>
<thead>
<tr>
<th>The frequency of your own online medical service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numbers of the patients in your own online medical service</td>
</tr>
<tr>
<td>Have you participated in any nutrition education presentation online?</td>
</tr>
<tr>
<td>Numbers of your online nutrition education presentation</td>
</tr>
<tr>
<td>Your online nutrition education video URL</td>
</tr>
</tbody>
</table>

Result

1. Proportion of valid feedback

Based on the staff information from the surveyed medical institutions’ HIS, there are 341 employees within all these CND. On November 1st, once the survey was delivered to each participant, they were provided 14 days to complete. All of the collected questionnaires were screened according to the rubrics of valid conditions. With a respondent rate of 96.77%, a total of 330 valid questionnaires were counted.

2. Overall description of QCSNJ

There are 70 departments in this QM system in 2020, which has raised 42.8% after 2018 (49). From the department’s human resource aspect, the total number of employees in all these CND has increased from 313 to 341 (8.95%) as shown in the “Figure 1. Staff composition of CND in 2018” and the “Figure 2. Staff composition of CND in 2020”.

3. Human resource in CND

According to the 330 valid responders, they were mainly clinicians (158, 46.33%), followed by dietitians (104, 30.49%) and nurses (84, 24.63%) as shown in the “Figure 2. Staff composition of CND in 2020”. As the Registered Dietitian/Registered Dietitian Nutritionist (RD/RDN) was certificated by the Chinese Nutrition Society (CNS) after 2016, which is still not an employment requirement for the professionals involved in CND for now, the number of RD/RDNs from this survey was 92 (26.98% compared to 330). Among these populations, 45 clinicians, 35 dietitians and 12 nurses have earned the RD/RDN certification.

4. Progress of management in CND

There are 49 departments that participated in the 2018 survey, which provided the basis of this comparison. As shown in the “Table 2. Comparation of staffs in CND between 2018 and 2020 (Paired sample t-test)”, except for one CND provided different staff numbers with its hospital’s HIS, the remaining 48 CND were all included in this part of analysis. The only significant increase was observed in the number of dietitians within two years, while the other changes were not apparent at the same time.
Table 2
Comparation of staffs in CND between 2018 and 2020 (Paired sample t-test)

<table>
<thead>
<tr>
<th>Year</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>P</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Staff</td>
<td>2018</td>
<td>6.50</td>
<td>4.02</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>6.29</td>
<td>2.80</td>
<td></td>
</tr>
<tr>
<td>Total Clinician</td>
<td>2018</td>
<td>2.81</td>
<td>2.13</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>2.92</td>
<td>1.78</td>
<td></td>
</tr>
<tr>
<td>Total Dietitian</td>
<td>2018</td>
<td>1.90</td>
<td>1.54</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>2.31</td>
<td>1.65</td>
<td></td>
</tr>
<tr>
<td>Total Nurse</td>
<td>2018</td>
<td>1.33</td>
<td>1.11</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>1.08</td>
<td>1.09</td>
<td></td>
</tr>
</tbody>
</table>

Considering the changes in general medical requirements within these two years, which could be observed through the data of hospital beds through HIS, we chose the ratio of professionals in CND to hospital beds as another evaluation index. As shown in the “Table 3. Ratios between professionals to hospital beds between 2018 and 2020”, this ratio belongs to one of the criteria issued by JPHC for hospital accreditation. Similar to the insignificant resource development in CND, the ratio of various professionals to hospital beds (total staff, clinician, dietitian) was not noticeable. Only the ratio between nurse and hospital beds indicated a significant decrease within these two years.

Table 3
Ratios between professionals to hospital beds between 2018 and 2020

<table>
<thead>
<tr>
<th>Year</th>
<th>Mean ($\times 10^{-2}$)</th>
<th>Standard Deviation ($\times 10^{-2}$)</th>
<th>P</th>
<th>T ($\times 10^{-3}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Staff</td>
<td>2018</td>
<td>0.40</td>
<td>0.20</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>0.36</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>Clinician</td>
<td>2018</td>
<td>0.18</td>
<td>0.10</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>0.17</td>
<td>0.10</td>
<td></td>
</tr>
<tr>
<td>Dietitian</td>
<td>2018</td>
<td>0.12</td>
<td>0.09</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>0.12</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td>2018</td>
<td>0.09</td>
<td>0.09</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>0.07</td>
<td>0.08</td>
<td></td>
</tr>
</tbody>
</table>
Discussion

The significant growth in the human resource as well as in the number of CND involved in the QM system in Jiangsu provided a promising development of professionals within the nutrition area. After the illustration of staff shortage in 2018, the QMCNJ has focused on its improvement together with all quality control system departments. This progress certified that the importance of CNM in healthcare services had been concentrated by health institutions, department managers, and other national organizations such as JPHC. The ratio criteria between CND professionals to hospital beds issued by JPHC for hospital accreditation is 1:200 (0.50 × 10^{-2}). Compared with the mean value from this research (0.36 × 10^{-2}), the CND is still in need of implementation for human resource and should make more effort or resource management.

The increasing number of departments that participated in QMSNJ brought their staff into the QM system of CN, which led to an increased total amount of human resources. However, most of this growth was resulted from the hired clinicians and nurses instead of dietitians. The dietitians in Jiangsu decreased from 113 to 104, while the clinicians increased by 13 and nurses increased by 29. This led to a shrink of the professionals who were graduated from nutrition majors and desired to provide nutrition-related medical services. Based on the human resource profile from surveyed hospitals and the documentation in JPCNMP, most of the clinicians employed in CND were educated as physicians, such as gastroenterologists or endocrinologists. As a result, though the hospital, the human resource department, and the CND director realized the importance of CNM and desired to improve its staff resource, the CND was still in lack of certified dietitians. This vagueness may be induced by the late development of CN in China. The certification of RD/RDNs was officially organized by the CNS in the past five years. Compared to the lack of RD/RDNs throughout the province two years before, there were 92 now accounted for 26.98% in total, while 38.04% are from nutrition majors. Though it is still less ideal than the proportion of RD/RDN in the US CNM (98.6%), it had achieved breakthroughs within this time period.

The advancement of CND`s staff resource might be mainly related to the expansion of QMSNJ, which has proved the QMCNJ has achieved initial results in the QM of human resource engaged in CN in Jiangsu in recent years. However, judging from the comparison of the personnel situation of the 48 original CNDs, which had been involved in the 2018 QMSNJ and participated in the last construction survey, the number of their dietitians has increased significantly (p = 0.02, t=-0.42). Simultaneously, the number of clinicians in relevant departments is the same, and the number of nurses has shown a decreasing trend without statistical significance. From the perspective of balancing the CN resources and health service requirements, which could be illustrated by the professional ratio in CND to hospital beds, the dissertation was only observed in nurse number (p = 0.05, t = 0.19). At the same time, no obvious change has been found in the clinician, nor the dietitian. These results confirmed that the medical institution and the department`s director had realized the importance of a solid foundation of professional staff to improve the quality of specialist work and ensure patient safety. These 48 CND have continuously increased their emphasis on CNM, while QMCNJ has indicated in promoting the RD/RDN resource within clinical trial by improving CND professionalism. Within the “Education in QM” part of this questionnaire, 327 out of 330
employees took part in the QM training held through the online platform JPCNMP by QMCNJ in 2020. In the exam after the course, the passing rate of trainees was 99.20%.

The expansion of the organization of QMCNJ has been proved through this research and the rising focus on CNM and human resource management by medical institutions and health commission. All of these signs of progresses are inseparable from the introduction of AI instruments. With the implementation of the specialized online platform JPCNMP after 2019, a real-time quality assessment of CND’s daily work could be observed both by themselves and by QMCNJ. The platform functions involve quality assessment, information communication, personnel education, and training, etc. Through the login interface of the CND, the department director and the secretary can browse its historical QM data, grasp the current status and trends of its medical service quality, as well as the department management quality. Relevant problems will be exposed, and adjustments can be implemented in time. Through the login interface of QMCNJ, the center specialists can browse each department’s data within QMSNJ. JPCNMP system has installed automatic warnings for departments and quality control centers of abnormal information, such as inconsistencies, missing values, outliers, and similarities. It provides a great advantage for QMCNJ to adjust its QM methods based on the current status of CND and quality assessment throughout Jiangsu and to apply for management policies to the JPHC.

Apart from data collection and quality assessment, JPCNMP is convenient for QMCNJ to publish the latest QM guidelines, the QM progress of CNDs in Jiangsu, and the frontier QM research trends, etc. It is effectively saving the resource consumption caused by traditional forms such as paper information filling and on-site supervision with the application of this AI technology. Consistent with the trend of the information technology revolution of our era, AI provides an automated method and various rules that are able to deal with the quality assessment of big data for healthcare. Its advantages have been reported in multidiscipline, such as geothermal systems, medical centers, clinical laboratories, as well as medical QM. The JPCNMP provides a freely available, open-source tool in data collection for CND of QMSNJ, which achieves the goal of intelligent management. The part of artificial is still in need of QMCNJ to achieve data curation and evaluation. As a result, QMCNJ highlights the importance of the QM data quality assessment by developing and continuously revising the index evaluation standards since its foundation in 2010. Similar to any data analysis service, the most crucial process of JPCNMP is the data quality assessment, which is related to the evaluation of data metrics, the organizational structure of the data, and the overall information management. Rather than the initial QM system requires artificial analysis of quality control data, it will be more accurate and reliable if an automated framework to effectively manages the quality of JPCNMP’s data in the future.

Conclusion

This research has certificated that the QM system for CN has been build up for CNDs within QMSNJ, which achieved its target in human resource improvements, especially among RD/RDNs in Jiangsu. The increasing number of participated departments in the quality control system, the significant growth of dietitians within the original 48 CNDs, the promotion of professional management of RD/RDNs are all
expressions of the advancements of QMSNJ. The processing of AI into quality assessment should be suggested with our achievements, while more effort is required for a brighter future. As the foundation of medical ethics, patient safety could only be guaranteed by a rigorous and standardized QMS. It is essential for not only nutrition but also other medical specialties to provide safe, timely, person-centered quality care and health service.

**Suggestion**

There are three suggestions concluded from this research for future development. Firstly, the Standards of Construction and Management of Clinical Nutrition Department in Jiangsu must be revised to reflect advances in CNM practice during the past five years and replaces the 2016 revision. A specific standard of professional performance for RD/RDNs should be included as guarantee the quality of human resources in nutrition fields. Secondly, it is essential to providing life-long learning and professional development opportunity for RD/RDNs. The three levels of proficiency\(^1\) (novice, advanced beginner, competent, proficient, and expert) during the acquisition and development of knowledge and skills should be introduced to QMSNJ. It not only attracts high-quality talents, encourages professional development and achieves individual professional goals, but also optimizes the quality of human resources of CND at the same time. Thirdly, the automated information capture has been clarified to be suitable for the internet-based and medical quality control. The AI technology of JPCNMP should keep improving its intelligence part by the alliance with other management systems, such as HIS workflow or other advanced human resource management system. Therefore, the professional development of employees could be suggested by both the quality management organization and the medical institution as well.

**Abbreviations**

1. QMS: Quality Management System
2. CN: Clinical Nutrition
3. AI: Artificial Intelligence
4. CND: Clinical Nutrition Department
5. QMSNJ: Quality Management System of Clinical Nutrition in Jiangsu
6. QMCNJ: Quality Management Center of Clinical Nutrition in Jiangsu
7. CNM: Clinical Nutrition Management
8. JPCNMP: Jiangsu Province Clinical Nutrition Management Platform
9. HIS: Hospital Information System
10. JPHC: Jiangsu Provincial Health Commission
11. RD: Registered Dietitian
12. RDN: Registered Dietitian Nutritionist
13. CNS: Chinese Nutrition Society

\(^1\)
Declarations

Ethics approval and consent to participate:

Institutional ethics approval was obtained for this study from Ethics Committee of First Affiliated Hospital with Nanjing Medical University. This survey presents no risks to the participants, neither did it involve any therapeutic intervention. All the personal information within the questionnaire was designed to verify the authenticity of the feedback. As the result, First Affiliated Hospital with Nanjing Medical University provided the “Exception to Written Evidence of Consent” for this research as shown in the “Figure 3. Exception to Written Evidence of Consent”. This experiment were performed in accordance with “Standards of Construction and Management of Clinical Nutrition Department in Jiangsu” within QMSNJ. After screening valid questionnaires, all personal information would not be included in the statistical analysis. As the result, there is no risk of additional use or disclosure of private information. Key informants were assured that confidentiality would be maintained and that findings would be presented in an anonymous fashion.

Consent for publication:

No conflict of interest exists in the submission of this manuscript, and manuscript is approved by all authors for publication. I would like to declare on behalf of my co-authors that the work described was original research that has not been published previously, and not under consideration for publication elsewhere, in whole or in part. All the authors listed have approved the manuscript that is enclosed.

Availability of data and material:

All the data included in this research are available in a public, open access repository.

Competing interests:

The authors have declared no financial/commercial conflict of interest.

Funding:

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Author’s contributions:

Jin Wang is the sectary of Quality Control Center of Clinical Nutrition in Jiangsu, who was the leader of all the researchers included and was responsible for decision making, research design and manuscript.
writing. As the corresponding writer and specialist of human resource management, Chen Pan participated in the research design and responsible for organization of the survey and analyzed the results. Xianghua Ma is the director of Quality Control Center of Clinical Nutrition in Jiangsu. All authors read and approved the final manuscript.

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Thanks to all the colleagues of the Quality Control Center of Clinical Nutrition in Jiangsu, the colleagues of the Nutrition Department, and the colleagues of the Human Resource Department of The First Affiliated Hospital of Nanjing Medical University. Thanks to all the hospitals that participated in this research. Thanks to all of our research team and their families with all their support led this submission and achievement.

References


**Figures**

![Figure 1](image)

Staff composition of CND in 2018
Figure 2

Staff composition of CND in 2020

2020

Clinicians, 158, 45.66%

Dietitians, 104, 30.06%

Nurses, 84, 24.28%
## Exception to Written Evidence of Consent

<table>
<thead>
<tr>
<th>Title of the Trial Project</th>
<th>Assessment of Quality Management System for Clinical Nutrition in Jiangsu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Management</td>
</tr>
<tr>
<td>Institution</td>
<td>Hosted by</td>
</tr>
<tr>
<td>Jiangsu Province Hospital / First Affiliated Hospital with Nanjing Medical University</td>
<td>Jiangsu Province Hospital / First Affiliated Hospital with Nanjing Medical University</td>
</tr>
</tbody>
</table>

Oral consent with a waiver of the requirement for documentation could be allowed. This requires an oral consent process that uses a IRB approved written script, which contains the basic elements of informed consent. The script must be read to the participant in the presence of a witness.

### 1. Research belongs to the cases:

- [ ] The informed consent will pose an undue threat to the privacy of the participants. This provides the only record of the participants' real identity and research, which belongs to the main risk of disclosure of identity or personal privacy in the study.

- [x] The protocols are clearly below minimal risk\(^1\). There is no requirement of any signed documentation for the same operation or procedure in the same case without “research”, such as interview.

  *Researcher Statement: this research presents no risks to the participants. All of our participants will not be identifiable from the data collected. The research does not involve any therapeutic intervention.*

### 2. Waiver of Consent must be contained:

- [ ] The script must be read to the participant in the presence of a witness.

- [x] The participant will either verbally agree or not agree to participate in the study.

- [ ] The informed consent activities must be secure documented and the records should be kept.

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\(^1\) Minimal Risk: an estimate of the amount of risks is not greater than the risk of daily living, or normal physical or psychological testing.

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**Figure 3**

Exception to Written Evidence of Consent