

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Minutes
March 27, 2018
Conference Call

Jeffrey Orlowski, MS, CPTC, Chair
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Introduction

The Membership and Professional Standards Committee (MPSC) met via Citrix GoToTraining and teleconference on March 27, 2018, to discuss the following agenda item:

1. Modifications to OPTN Bylaws, Appendix L

The following is a summary of the Committee's discussions.

1. Modifications to OPTN Bylaws Appendix L

The MPSC sponsored a proposal entitled, "Appendix L Revisions" that the OPTN distributed for public comment from January 22 - March 23, 2018. During its March 27 teleconference, the MPSC reviewed the feedback it received in response to this proposal. The following summarizes the comments and the MPSC's response to these comments.

Individual Comments

- The overwhelming number of comments received through the OPTN website and at OPTN/UNOS regional meetings indicated support for the changes presented in the proposal. Through the OPTN website and OPTN/UNOS regional meetings, this proposal received 113 individual comments- 106 of these indicated that they "supported" or "strongly supported" the proposed changes; the remaining seven expressed that they were "neutral" on the proposed changes.

MPSC Response: The MPSC appreciates respondents taking the time to review the proposal and express their support.

- Included in the individual responses were a few specific comments and recommendations for the MPSC to consider. The MPSC reviewed and responded to these additional considerations individually:
 - One commenter who expressed strong support for the proposal added, "While I agree with allowing the MPSC to more frequently offer Deferred Disposition, I am concerned with offering the member multiple Deferred Disposition periods. I think a limit should be set as to how many (or total time) there should be before an action is taken. Otherwise you might have a program on perpetual Deferred Disposition. In the format of the informal discussions, interviews and hearings, the proposal details the minimum amount of time for presenting information. I agree with this, but suggest that a maximum time be set as well. Otherwise you might have a filibuster situation."

MPSC Response: The MPSC appreciates the response and considered these recommendations while developing this proposal. The MPSC ultimately decided against upper limits in these situations to allow the MPSC to tailor its reviews to the circumstances of any given case. It will be the MPSC's and MPSC Chair's responsibility

to set appropriate limits to avoid “filibuster situations,” “perpetual Deferred Disposition,” and other unproductive conditions during MPSC and member interactions.

- One commenter who expressed support for the proposal added, “I would remind the MPSC that center performance criteria in D.12.A were discussed by the MPSC in about 2013 and were to be reviewed within 2 or 3 years to decide if too many centers were being determined to be 'under-performers'. Many peer review publications in the last few years show this is the case and that this large number of 'flagged' programs results in decreased transplantation rates throughout this country.”

MPSC Response: The MPSC appreciates this feedback. The MPSC did not consider substantive changes to OPTN Bylaws D.12.A. as a part of this proposal. The MPSC limited changes to D.12.A. to those that are required to align the section with substantive Appendix L changes. That being said, the MPSC continues to monitor the effectiveness of member performance screening criteria. Recent efforts to address member performance reviews include an MPSC-sponsored proposal during the summer 2016 public comment cycle that addressed OPTN Bylaws D.12.A. (the MPSC ultimately did not present this proposal for the OPTN/UNOS Board of Directors' consideration due to public comment feedback), an operational rule for kidney transplant program outcome reviews that excludes programs from review if they did not meet the expected thresholds due to transplants involving a kidney from a donor with a KDPI of 85 or greater and a recipient with an EPTS score greater than 80, and the Collaborative Innovation and Improvement Network (COIIN) project.

- One commenter recognized improvement of OPTN Bylaws Appendix L and the processes described in the proposal; however, the commenter believes that the proposal still includes significant flaws and provided additional recommendations for the Committee to consider.
 - “One additional detail that the drafters may wish to consider is the requirement that an official list of issues be maintained by committee staff so that an agreed upon set of facts and/or an agreed upon resolution of a specific issue can be deleted from the list. This may sound too perfunctory and obvious, but I have witnessed numerous occasions in which a member has been led to believe that a specific issue has been resolved, only to see the issue resurrected in a subsequent portion of the review process in a manner that leads to significant frustration and a sense of having been dealt with unfairly.”

MPSC Response: The MPSC appreciates the commenter's response and additional consideration. The MPSC agrees that clear and ongoing communication with the member during the review process is critical. The MPSC also agrees that a tool to track the MPSC's concerns and the member's progress towards satisfactorily resolving the issue would be useful for both parties.

It is worth noting that MPSC reviews are dynamic; the MPSC may change its assessment of whether a member has satisfactorily addressed an issue as additional information becomes available. Similarly, the scope of a review may expand if the MPSC's review reveals additional significant issues that need to be addressed. The MPSC does not intend for the tool to be used in a way that prohibits the MPSC from thoroughly evaluating and assessing the situation. However, the MPSC acknowledges that a tracking tool would be particularly helpful in situations where the MPSC's concerns or the scope of the review change over time.

The MPSC is committed to developing and implementing the requested issue tracking tool quickly, but the MPSC does not believe it is necessary or appropriate to include this level of detail in the proposal. The MPSC already uses similar operational tools such as surveys and templates, none of which are referenced in the current Bylaws or the proposal. The MPSC believes incorporating this level of operational detail in the Bylaws is unnecessary and could limit the MPSC's ability to create, modify, or discontinue use of these tools in a timely manner when appropriate.

- "I am hopeful that the drafters' warning that the proposed revisions are meant to emphasize reliability and predictability in the processes rather than an explicit set of detailed procedures is referring specifically to the revised provisions regarding Hearings. The drafters may feel as if it is critical for the MPSC Chair and others to reserve the right to conduct a Hearing that is tailored to the specific facts and issues that comprise a specific review process. But I am concerned that the proposed revisions will ultimately prove unsatisfactory if the current processes of 'direct testimony' and 'cross examination' and notions of 'burden of proof' are allowed to continue to dominate...I would urge the drafters to consider setting forth additional procedural safeguards aimed at ensuring a non-time pressured, thorough and comprehensive exchange of views in the Hearing setting that reflect those priorities as explicitly as the revisions provide in the informal discussion and Interview phases."

MPSC Response: The Committee appreciates the commenter's assessment of the hearing process and these additional considerations.

By allowing multiple informal discussions, multiple interviews and a greater likelihood for Deferred Disposition, the proposal provides increased opportunities for the MPSC and the member to thoroughly discuss issues in a non-time pressured setting. The MPSC hopes that these opportunities will reduce the number of hearings, if not avoid them entirely. However, if a hearing is still necessary, the MPSC believes that certain formalities of a hearing are appropriate. For example, the MPSC believes members and the MPSC should continue to have the right to be represented by an attorney. However, the MPSC agrees that other aspects of the current hearing process, such as the direct witness testimony and cross examination, may not be the most effective or efficient way to conduct every hearing. The proposed hearing language does not require that these aspects of the hearing process remain going forward. The MPSC is dedicated to constantly reviewing the format of the hearing process and, under the framework proposed in the Bylaws, the MPSC can implement changes to the hearing process in the future.

The MPSC believes the proposed hearing language establishes an appropriate minimum framework for hearings that can be adapted as needed. The MPSC did not identify "additional procedural safeguards" to introduce into the proposal at this time, but the MPSC is happy to consider suggestions the commenter or others may have to improve the hearing process.

Regional Meeting Comments

- All 11 OPTN/UNOS regions unanimously supported the proposal. Discussion at the regional meetings yielded a few specific comments and recommendations for the MPSC to consider. The MPSC expressed its appreciation for the support provided at the regional meetings, and responded to the additional considerations individually:

- At the Region 1 meeting, members expressed concerns that the proposed flexibility may increase the burden on MPSC members with a drastically higher work load.

MPSC Response: The MPSC appreciates Region 1's support and these concerns. The MPSC understands that these changes may lead to more work for the MPSC in some instances. However, the MPSC believes that these changes will yield more meaningful interactions with members. Additionally, the proposal includes considerations that will simplify these processes for the MPSC and members (e.g., ability to have interviews via teleconference).

- At the Region 3 meeting, members suggested it would be beneficial to require that two MPSC members have content expertise during informal discussions.

MPSC Response: Subject matter experts are commonly present on the MPSC, and the MPSC will always work to include experts on all of its reviews. Informal discussions are intended to be information gathering conversations among peers. The MPSC is concerned that this perspective may be lost if larger panels are needed to conduct the informal discussion, and with the inclusion of additional experts outside of the MPSC. Nothing in the proposal prohibits the MPSC from obtaining additional expertise for informal discussions if necessary, and the MPSC has done so in the past, even when not required by the Bylaws. However, the MPSC felt requiring at least two subject matter experts for every informal discussion may limit the MPSC's ability to quickly hold a discussion with a member for a seemingly straightforward issue, such as clarifying the MPSC's concerns described in a letter or further explaining why the MPSC requested specific information. With this perspective, and for the sake of maintaining member confidentiality, the MPSC did not support Bylaws changes that may potentially require prematurely asking experts outside the committee to interact with members during informal discussions. The proposal continues to require at least two subject matter experts participate in interviews and hearings.

- At the Region 8 meeting, members also added that reviewers need expertise in the matter under review.

MPSC Response: The MPSC agrees that expertise is critical, and the MPSC has traditionally worked to make sure that appropriate expertise is a part of every review. Proposed changes to Appendix L formalize the expectation for subject matter experts, and how that experience is obtained if not directly from the MPSC. The MPSC did not propose including this level of detail in the Bylaws for informal discussions with respects to the informal nature of these interactions and member confidentiality, as noted above.

- Region 8 also requested that the MPSC remove inquiries from required paperwork about topics not related to the matter under review. For example, requests for information about the number of nutritionists or information about social workers may not pertain to performance-related reviews. The member stated that these additional questions create extra burden for the members.

MPSC Response: The MPSC carefully considers every request asked of members during a review. Inquiries about topics that may seem unrelated to the matter under review are not arbitrary. Such inquiries are intended to give the MPSC a greater perspective of the member's operations as it works through the review.

- Region 9 expressed its support but has concerns that the MPSC remains a punitive body and lessons learned are not shared with the transplant community.

MPSC Response: The MPSC acknowledges the perception by some that the peer review process is punitive, and it routinely evaluates ways to appropriately address that perception. Monitoring will always be an MPSC responsibility; however, the MPSC hopes that the proposed changes to Appendix L will allow the MPSC to conduct reviews in a more effective and efficient manner and will provide members a greater opportunity to demonstrate effective quality improvement practices before the MPSC takes an action.

As for sharing lessons learned, the MPSC frequently presents updates from the past year at annual meetings, and it discusses potential educational topics that can be shared with the community at the end of each in-person meeting. The MPSC has made a number of referrals to the OPTN/UNOS Operations and Safety Committee's Patient Safety Advisory Group that have resulted in educational offerings. Nevertheless, the MPSC understands that there is an ongoing interest in lessons learned through MPSC reviews. The MPSC is working with the UNOS Member Quality Department to find additional ways to share this information with the community, and within the bounds of confidential medical peer review under which the MPSC functions.

Transplant Society Comments

- The MPSC received public comment feedback on the proposal from the American Society of Transplantation (AST), the Association of Organ Procurement Organizations (AOPO), the American Society of Histocompatibility and Immunogenetics (ASHI) and the American Society of Transplant Surgeons (ASTS). AST, AOPO, and ASHI expressed support for the proposal. ASTS applauded the MPSC's efforts, but expressed a number of concerns with the proposal. The MPSC stated its appreciation for societies' review and the feedback provided. The MPSC discussed each of the concerns posed by ASTS, and responded as follows:

- "We doubt that the new proposal will be viewed by our membership as a significant advance, as it falls short of our membership expectations of real regulatory relief that would help advance the field."

MPSC Response- The MPSC appreciates the members' desire for decreased regulation. While the proposal does not reduce the number of OPTN Policy and Bylaw requirements, the MPSC believes the proposal does represent a significant improvement over the current Bylaws, and will allow the OPTN to conduct reviews in a more effective and efficient manner.

- "Of particular concern is the subjectivity of determining imminent threat to the health of the public, particularly in a discipline as complex as transplantation."

MPSC Response- Language in the proposal regarding the MPSC's review of potentially "urgent and severe risks to patient health and public safety" is currently in the Bylaws, and stems from obligations established by the Final Rule. The Final Rule requires that the OPTN Board of Directors, "shall advise the Secretary of the results of any reviews

and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which...indicate a risk to the health of patients or to the public safety.” The MPSC appreciates the desire for greater detail around these assessments but believes that these Bylaws should be consistent with language in the Final Rule. Additionally, the MPSC agreed that it wouldn’t be reasonable to write Bylaws that include every possible consideration and scenario that may prompt a review due to patient health and public safety concerns.

- “Similar to the original version, it is clearly stated (now multiple times in the new document) that the burden of proof is on the program to 'prove that the MPSC's recommendation lacks substantial basis or the conclusions drawn are arbitrary, unreasonable, or capricious.' This is an extremely high bar for any Transplant Center and, at its root, is unfair because the MPSC acts as the investigator and prosecutor in making the allegation and then acts as judge and jury, rendering the recommendation for punishment.”

MPSC Response: The MPSC is empathetic to this point but is unclear on appropriate post-public comment changes to address the concern. As noted in the comment, this standard is included in the current Bylaws and not changed with this proposal. The MPSC also noted other reviews in the medical field where the burden of proof lies with the group or individual under review.

The proposal does not include any reference to burden of proof during an informal discussion, an interview, or a hearing. Instead, the proposed language suggests that the member is expected to satisfactorily address concerns the MPSC communicated to the member in advance of the interaction. Language regarding the member’s burden of proof appears in the proposal in Section L. 11. (Appearances before the Board of Directors). The MPSC continues to believe it is appropriate to prove to the Board of Directors’ satisfaction that the MPSC recommendation lacks substantial basis or that the MPSC’s conclusions are arbitrary, unreasonable, or capricious, if the member does not want the Board of Directors to approve the MPSC’s recommendation. To improve fairness and transparency in the Board of Directors review process, the proposal allows the member to be present when the MPSC makes its recommendation to the Board of Directors.

- **L.5. Investigation of Potential Noncompliance with OPTN Obligations-** “At present, any written correspondence between the MPSC and the program may or may not detail the nature of the exact violation/noncompliance. We feel that the OPTN should clearly state the nature of the potential non-compliance to be investigated. The member may then provide the most relevant information to the OPTN related to any questions of non-compliance with membership requirements or professional standards. In addition, this level of detail should be restated on each correspondence thereafter. This will alleviate any confusion by the program as to why the correspondence is occurring in the first place.”

MPSC Response: The MPSC appreciates this comment and will continue to work on ways to reduce member confusion when interacting the Committee. Initial correspondences between UNOS staff and members may not specify a particular policy or bylaw requirement as these communications are a means to gather information to determine whether any potential noncompliance occurred and, if necessary, obtain appropriate information for the MPSC’s review. Once the MPSC has reviewed the

matter, the Committee specifies in its communications which OPTN Obligations are the focus of the review. This process will continue with these proposed Bylaws changes. The proposal also requires the MPSC to clearly communicate any issues the MPSC would like the member to address when offering the member an informal discussion, an interview, or a hearing.

- **L.8. Informal Discussions-** “Any correspondence between a program and the MPSC, either written, by phone, or in person, should be considered 'formal.' This should be relabeled to reflect the seriousness of the situation. Perhaps 'Initial' discussion.”

MPSC Response: The MPSC debated what to call this MPSC and member interaction before distributing the proposal for public comment. The Committee ultimately reached consensus around “informal discussion” to underscore the conversational and information sharing nature intended for these discussions. The Committee appreciates that these are serious conversations and the perspective that labeling them as “informal” could be seen as a misnomer; however, the Committee does not believe that the “informal discussion” label is misleading or problematic for members. This perspective is based on previous informal discussions conducted by the MPSC, follow-up with members that have participated in an informal discussion, and no other feedback provided during public comment that raised this concern.

In reviewing this suggestion, the MPSC spent some time considering alternative labels for these MPSC and member interactions. The MPSC considered the suggestion from ASTS to call these interactions “initial discussions” but the Committee thought this would be more confusing as the proposed informal discussions are not always the initial step of an MPSC and member interaction. Committee members brainstormed other suggestions, but ultimately, the Committee agreed to proceed with labeling these interactions as “informal discussions.”

- **L.8.D. Informal Discussion Format-** “Depending on the exact nature of the potential violation/noncompliance, 10 minutes is likely not enough time to adequately cover a specific case in question, program policy/procedure, and/or administrative issue being discussed.”

MPSC Response- The minimum time proposed is based on the amount of time currently provided to members. Prior to developing this proposal, UNOS Member Quality staff surveyed members who have participated in informal discussions with the MPSC. Survey responses indicated that members felt the amount of time to present information was sufficient. Additionally, these proposed Bylaws reflect lower limits for member and MPSC interactions. The MPSC appreciates that the complexity of some situations may require additional time to have a complete discussion. In those circumstances, the MPSC will allow members the time needed to thoroughly review all the relevant information. The Committee’s primary goal is to obtain a complete picture of the member’s situation, and it will work with the member to set appropriate time frames to achieve this goal.

- **L.9.C. Interview Format-** “This section is especially troubling with regard to potentially complex surgical cases such as heart transplant, high MELD liver transplant, and/or dual organ cases. In our opinion, 2 experts may not be adequate. Furthermore, the current document assumes this expertise will be present within the OPTN committees itself. While that may be true for some unknown fraction of cases, the current revision leaves no room for the program to provide its own experts, in addition to OPTN, which may help clarify and/or reinforce certain clinical standards of practice, surgical decision-making, and the current state of a given discipline. Giving programs the ability to have an outside clinician, with a robust practice, the opportunity to review specific issues would be extremely helpful in certain circumstances regardless of the ultimate outcome. As result, we feel that the OPTN should consider a policy where members can bring their own experts forward in either interviews or hearings.”

L.10.C. Hearing Format- Again, given the seriousness of any potential violation/noncompliance, the current document stops short of what is needed. See above. However, this issue now becomes extremely important as the process progresses. At the level of a hearing, in addition to legal representation, a program may not be able to adequately defend its position to the MPSC if the appropriate amount of experience with the matter is not present.

MPSC Response- Members may currently consult or bring their own experts when interacting with the MPSC. Members are not limited in how they may present information or expertise for the MPSC’s consideration. The proposal does not change this. Members interacting with the MPSC are welcome to use any experts that may be helpful to clarify details surrounding any matter that the MPSC is reviewing. To clarify this, the MPSC will work to update the toolkit that supplements these proposed changes and that will be available for members. The toolkit will be updated to specify that members may use additional experts as necessary to convey and clarify for the MPSC all the critical information pertaining to the member’s case.

- **L.11.D. Board of Directors Appearances Format-** In general, it is concerning that waiving a right to a hearing automatically waives the right to appear before the Board of Directors. More importantly, the order of the proceedings in front of the Board of Directors becomes important for the program in question. Given that the burden of proof is on the program, the MPSC chair should be first to present the information stating and reinforcing the noncompliance against a program. Forcing a program to present information first, followed by the MPSC, puts the program at a sizable disadvantage.

MPSC Response- The MPSC feels strongly that it is necessary for the MPSC to conduct a thorough review, including any interviews and hearings, before the MPSC forwards an adverse action recommendation to the Board of Directors. Previous instances where the member has bypassed the MPSC and proceeded directly to the Board of Directors has resulted in confusion and dissatisfaction with the process for not only the member, but also for the MPSC and the Board of Directors. The MPSC believes that requiring members to complete the MPSC review process will increase the likelihood that the MPSC and the member will resolve the issue without involving the Board of Directors. The MPSC also believes, if it is still necessary after the hearing to forward a matter to

the Board of Directors, that the MPSC review process will ensure the Board of Directors has all the necessary information to make a decision.

Regarding the presenting order at a Board of Directors appearance, the Committee discussed making changes to the proposed Bylaws but ultimately decided not to. The proposed Bylaws allow both the member and the MPSC to be present during the other's presentation, and during any questions that the Board of Directors has for the member or the MPSC. The MPSC believes these improvements allow for greater transparency for the MPSC and the member, and allows for the Board of Directors to reach greater clarity by asking questions of both parties simultaneously

- **L.12.A. Deferred Disposition** - Again, this puts all programs at a distinct disadvantage. At the very least, a program should have the right to a 'Formal Discussion' with the MPSC which outlines (in detail) the reasons for not offering or ending a Deferred Disposition period.

MPSC Response- The current Bylaws allow the MPSC to offer the member a Deferred Disposition period, but puts a number of limits on when the MPSC may do so. These limits have resulted in the MPSC rarely being able to take this action. One aim of this proposal was to allow the MPSC more latitude to offer members a Deferred Disposition. Much like other non-adverse actions, decisions about a Deferred Disposition are left to the discretion of the MPSC.

In considering this comment, the MPSC discussed whether the proposed Bylaws should be changed so that members would be entitled to a discussion with the MPSC about Deferred Disposition decisions. Upon the conclusion of this discussion, the MPSC did not think post-public comment Bylaws changes were necessary. The MPSC was concerned adding a discussion requirement may result in unnecessary delays during the review of urgent and severe risks to patient safety and public health and that members may try to use this process to challenge non-adverse actions. The MPSC also noted that nothing in the proposal would prohibit the member from requesting or the MPSC from offering an informal discussion if discussions about Deferred Disposition warranted an additional conversation. The MPSC can imagine scenarios in which the MPSC may speak to the member about such issues, but did not feel it was necessary to put a requirement to do so in every instance in the proposal.

- **L.12.B. Types of actions** -Within the amended Appendix L, a letter of reprimand has been removed. This is concerning as it creates a fast track to probation or member not in good standing.

L.15.D. MPSC Actions without Board Referral (proposal recommends deleting) -
Letter of reprimand has been removed. See L.12.B. above.

MPSC Response- A focus of the Committee throughout the development of this proposal is to avoid adverse action recommendations, except in dire circumstances and when members fail to adequately address the issues that prompted MPSC review. The Committee never considered an adverse action fast track as rationale for removing Letter of Reprimand as an OPTN action.

During the development of this proposal, the MPSC raised questions about whether there was a distinguishable difference between a Letter of Reprimand and a Letter of Warning. The Committee recognized the main difference is that a Letter of Reprimand entitles the member to an interview. Traditionally, if the MPSC did not believe that the potential noncompliance warranted an adverse action recommendation but it was interested in speaking with the member further, the MPSC would recommend a Letter of Reprimand and offer the member an opportunity for an interview. In consideration of proposed changes that allow the MPSC to offer a member an interview at any time, the MPSC concluded that there would be an insignificant difference between a Letter of Warning and a Letter of Reprimand under the proposed changes to Appendix L. Therefore, the MPSC decided to propose deleting Letter of Reprimand as a formal OPTN action. The MPSC anticipates that removing a Letter of Reprimand is more likely to result in an increase in Letters of Warning than to result in an increase in adverse action recommendations.

- **L.12.D.1.c. Probation Monitoring Requirements-** This section is vague. Programs should have a clear view of what ongoing monitoring actually means. For example, what information will be required by the program and at what time intervals? Does the probation period require site visitation? If so, how many? At what time intervals?

Appendix L: Original Version. L6. Requests for root cause analysis and corrective action plan - This section was very helpful in terms of what the program can expect.

L.15.E.1. Probation (proposal recommends deleting)- Again, at least a broad description of Corrective Action Requirements of Probation can be helpful to the program in question.

MPSC Response- The MPSC acknowledged the need to improve the current Bylaw descriptions regarding adverse action monitoring. The current Bylaws require members be under review for at least 12 months and to notify certain groups or individuals of the adverse action, but does not provide any additional detail or requirements. However, the MPSC recognized that monitoring requirements are dependent upon the issue under review. The MPSC did not want to add requirements that might not be applicable in all situations and would potentially create an unnecessary burden on members and the MPSC. Therefore, the MPSC decided not to add specific requirements regarding Probation; the MPSC will determine appropriate monitoring requirements as needed. The MPSC felt it was appropriate to require that Members Not in Good Standing must provide routine updates to the MPSC and must participate in an on-site visit, and added this information to the corresponding Member Not in Good Standing section of the proposal.

Appreciating that the Probation section referenced does not include significant detail or requirements the MPSC considered removing it entirely during the development of the proposal. The MPSC decided to retain this section to establish that the MPSC conducts the Probation monitoring, not the Board of Directors. Additionally, retaining this section allows the proposed Bylaws for Probation and Member Not in Good Standing to have a similar structure.

Upcoming Meetings

- April 17, 2018, 3:00 – 5:00pm, ET, Conference Call
- June 26, 2018, 3:00 – 5:00pm, ET, Conference Call
- July 17-19, 2018, Chicago
- October 16-18, 2018, Chicago