

## Documenting the Fatal Errors in a Study Issued by the Office of the U.S. Inspector General Attacking Documentation by Podiatrists of Their Nail Care Services

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The study in question was issued by the Office of the Inspector General in June 2002: MEDICARE PAYMENTS FOR NAIL DEBRIDEMENT SERVICES. It is available on the Internet in its entirety at: <http://oig.hhs.gov/oei/reports/oei-04-99-00460.pdf>. This study charges that Medicare paid excessively and improperly to 22.7% of podiatric physicians due to their supposed inadequate charting of nail care procedures for the year 2000.

In order to evaluate the study, it is necessary to do a detailed comparison with standard accepted scientific method and publishing as described by experts. There are a number of ways to conduct scientific studies, but they are generally divided into two specific types: strictly experimental, such as often conducted by physicists, and retrospective, typically conducted by psychologists and sociologists. Both types share in common specific attributes, the most important being the development of data that can be replicated by different researchers who use the same clearly stated criteria. Those who study medical data often use both experimental and retrospective methodology, sometimes in the same study.

The OIG study discussed here fits into the “retrospective” type, but like all such studies it must withstand the burden of peer review. It is within that context that it is evaluated and challenged here. If the study is not accomplished using approved scientific precepts, it becomes a position paper expressing the undocumented opinion of its authors. While there is nothing necessarily wrong with that, this OIG study makes specific recommendations that might involve some severe measures taken against podiatric physicians by Government, solely based upon its findings. It is therefore appropriate to demand that the study and its results are consistent with good science.

This paper is divided into three separate sections:

1. Comparison of the OIG study with accepted scientific method as described by an acknowledged expert.
2. Comparison of OIG study with publication standards as described by acknowledged experts.
3. Errors in deduction, internal conflicts and reliance on inappropriate apriori logic.

In the analysis, I will use two sources to explain the appropriate use of scientific data and reporting. They are:

1. EXPERIMENTAL SCIENCE PROJECTS: An Intermediate Level Guide, available at: <http://www.isd77.k12.mn.us/resources/cf/SciProjInter.html>, written by Associate Professor David Morano of Mankato State University, 27 May 1995, Minnesota State University, Mankato, MN

2. HOW TO PREPARE A SCIENTIFIC PAPER IN APA FORMAT, available at: <http://www.duke.edu/web/psy91/williams/paper.html>, , Kelley A. Lawton and Laura Cousineau, Duke University Libraries and, Van E. Hillard, The University Writing Program, Guide to Library Research, Last Update: Wednesday, 26-Sep-2001 11:56:13 EDT <http://www.lib.duke.edu/libguide/citing.htm>

STATEMENT OF PURPOSE: It is this author's contention that the study entitled Medicare Payments for Nail Debridement Services is inadequate, undocumented and does not follow widely accepted scientific standards of reporting of data, disclosure of data, evaluation of data, citation of source(s), distribution of data into cohorts for appropriate analysis or scientific publishing standards.

EFFECTS OF THE STUDY: The OIG study could have profound effects upon podiatric physicians. It states: "...Even considering the possibility of poor documentation of medical records, the extent of the problem indicates close scrutiny is warranted. At a minimum, the problem suggests medical records are not documented for Medicare payments. More seriously, it suggests that Medicare paid for services not needed and services not provided." #1

This last sentence suggests that Medicare believes a substantial amount of fraud is being practiced by podiatric physicians against Government in order to achieve payment for questionable, unnecessary services. It is likely that this report will receive wide publication among various governmental political and administrative realms, also to the detriment of the podiatric profession.

In other recommendations, the study suggested that: "Medicare carriers (to) closely scrutinize payment for nail debridement services through medical reviews....CMS (Centers for Medicare and Medicaid Services) to collect the overpayment we found in our sample. #2

While the OIG study does not specifically discuss new audits, it does suggest that podiatrists need to be "watched more closely to scrutinize them" for possible Medicare fraud and to collect overpayments:

"CMS requires each contractor to develop a medical review strategy to determine where medical review resources should be deployed in order to maximize their effectiveness. Our contracts are required to perform ongoing data analysis using a variety of sources to identify errors that pose the greatest financial risk to the Medicare program. We will share this report in our next contractor vulnerability report.... The first and immediate action demanded by the study is to "collect overpayments found by the study" and refer the necessary information to do this to the Medicare Intermediaries involved. #3

The OIG study does not present podiatric physicians in a favorable light regarding their services to a needy, rapidly growing percentage of the U.S. population. It is this author's contention that the OIG study is fatally flawed, its contentions undocumented, unproved, and its conclusions inaccurate and improper.

PART I: A Comparison of the OIG study is done to proper scientific method for developing, performing, documenting data and reaching conclusions based upon that data. The expert used in this part of the study is from published material of Associate Professor David Morano of Minnesota State University. #4

## LACK OF APPROPRIATE DOCUMENTATION

### Scientific Standard:

Professor Morano states: “What is common among all sciences, however, is the making of hypothesis to explain observations, the gathering of data, and based on this data, the drawing of conclusions that confirm or deny the original hypothesis. The difference is in what is considered data, and how data is gathered and processed. Data for a physical scientist is numbers. The numbers are often plotted on graphs. Graphs can be used to derive equations that can be used for making predictions. Data, for an anthropologist, could be a recorded interview. Interviews can be compared to other related information. Hence the distinction between the exact sciences (physical sciences that use numbers to measure and calculate results), and other sciences that use descriptions and inferences to arrive at results. If you are not aware of this difference, you could produce a written report for your science project. Your project will then only show what you know about something instead of experimentally answering questions you have about observations you have made.”#4

### Author’s Analyses:

This is an important distinction. Professor Morano states directly that more valuable data could have been obtained by actual direct testing of podiatrists’ charting abilities. This is discussed later in this paper. Cost concerns of such studies should have been irrelevant. After all, this is a Government study; and the infrastructure for conducting them is already in place. Clearly no interviews were conducted to obtain data for the OIG study. Rather, information and data was requested of podiatrists, from which the single podiatrist auditor would develop and process to reach specific conclusions. Those conclusions would then be reported to the OIG and OIG would develop statistics that relied totally upon those data as reported by the single auditor. CMS (Center of Medicare and Medicaid Services) demands that Medicare Intermediaries use a “variety of sources to identify errors that pose the greatest financial risk to the Medicare Program.” #11 This reviewer cannot understand why OIG ignored the very same requirements they demand of Medicare Intermediaries.

Professor Morano continues to make important distinctions between “Natural sciences and those that use inferences to derive results.” It would appear that the OIG study used inferences to achieve their results. The defects of the OIG study are then demonstrated as follows:

1. The weakest link is the single podiatrists hired to perform the actual audit. The actual audit constitutes the heart of the report, upon which all subsequent conclusions are based. There is no indication of any data reported to OIG to prove or document the audit. The material included only shows “what one reviewer” concludes about completely undisclosed data. No chain of documentation can survive a defect at its

genesis. If A plus B equals C, then C cannot be determined accurately if either A or B or both are not correct, supplied or verifiable.

2. It is possible for a single podiatrist reviewer to document the results of his/her review. For example, the OIG study did document requirements for “payment of nail services” #5 However, the single podiatrist auditor does not in any way tabulate, record or demonstrate the data obtained and how it compares to the required documentation. Such data might have reasonably been included in appendices. None is found.
3. The OIG Study specifically listed the data collected under “Data Collection.” #6. This was obtained from podiatrists all over the Country. However, there is no documentation to describe how the data was handled to evaluate individual podiatrists. There is no tabulation of specific defects in charting, where they occurred, how they were defined, contradictions or patterns of inadequacy, etc. Such information is vital to reach logical conclusions. This would have been valuable to the original intent of the study, i.e. (to provide OIG with direction to identify specific inadequacy patterns to help reduce “overpayments “to podiatrists.)
4. The OIG study jumps to conclusions not based upon any published documentation or pre-defined standards.

#### STANDARD SCIENTIFIC MODELS OF STUDIES:

##### Scientific Standard:

According to Professor Morano, the following standards are used to execute scientific studies: #7

“Initial Observation--You notice something, and wonder why it happens. You see something and wonder what causes it. You want to know how or why something works. You ask questions about what you have observed. You want to investigate. The first step is to clearly write down exactly what you have observed.” #7

##### Author’s Analyses:

The published purpose as described in the OIG study is to “Determine the appropriateness of Medicare payments for nail debridement services.” #8  
The OIG study does write down what was reported to them by the single reviewing podiatrist. From the actual study it is impossible to know if any explanatory or demonstration data was disclosed to OIG. It is simply not reported. The closest the OIG study comes to this is in a statement in Appendix B...”OIG will be required to furnish the data necessary (provider numbers, claims information, health insurance claim number, etc.) for the Medicare contractors to initiate and complete recovery action.” #10  
However, all of this data is related to recovery attempts, and has nothing to do with proving reliability of the methodology.

##### Scientific Standard:

“Information Gathering--Find out about what you want to investigate. Read books, magazines or ask professionals who might know in order to learn about the effect or area of study. Keep track of where you got your information from.”#7

Author’s Analyses:

The OIG study does describe that they contracted a single “medical review contractor” to evaluate the data they obtained. They listed that contractor’s qualifications as being a “practicing podiatrist and an active member of the American Podiatric Medical Association.” #8 What is OIG’s definition of a “medical review contractor?” How is their reputed membership in APMA relevant?

Scientific Standard:

“Title the Project--Choose a title that describes the effect or thing you are investigating. The title should be short and summarize what the investigation will deal with. #7”

Author’s Analyses:

The title of the OIG study is clearly and properly stated. #7

Scientific Standard:

“State the Purpose of the Project--What do you want to find out? Write a statement that describes what you want to do. Use your observations and questions to write the statement. #7”

Author’s Analyses:

The purpose of the OIG is properly and clearly identified #8

Scientific Standard:

“Identify Variables--Based on your gathered information, make an educated guess about what types of things affect the system you are working with. Identifying variables is necessary before you can make a hypothesis.” #7

Author’s Analyses:

There are no variables described in the OIG study. For example, there is no discussion on how podiatrists might differ on what constitutes proper and adequate documentation. It is assumed prima facie that the published rules for documentation are sufficient to show what is necessary for payment. Yet there is no discussion on how this information is promulgated to podiatrists. This has serious implications on the study. Unless the study can predict how podiatrists might differ on what constitutes proper coverage, the use of only one contractor to review the collected data is highly suspect.

The OIG assumes that their “medical service contractor” clearly understands and is capable of making the distinctions of what constitutes adequate documentation. However there is no statement in the OIG study that documents this contractor’s skill, experience or qualifications to make those judgments other than his/her irrelevant membership in the APMA or being in “active practice.” This further exposes the “weakened link” hypothesis described above.

Since there is a list of specific requirements for coverage by Medicare in nail procedures, a “point scoring system” could have been constructed and elucidated by the auditor. This has the additional advantage of being transparent and repeatable to peer review. None is found.

How is a “single podiatrist consultant” any more qualified to make a judgment of what constitutes “adequate documentation” compared to the opinion of any other podiatrist sending in his/her own chart notes to OIG to be evaluated? The study does not evaluate or answer that question.

Scientific Standard:

“Make Hypothesis--When you think you know what variables may be involved, think about ways to change one at a time. If you change more than one at a time, you will not know what variable is causing your observation. Sometimes variables are linked and work together to cause something. At first, try to choose variables that you think act independently of each other. At this point, you are ready to translate your questions into hypothesis. A hypothesis is a question which has been reworded into a form that can be tested by an experiment.”#7

Author’s Analyses:

The OIG study is devoid of discussion of variables.

Scientific Standard:

“Make a list of your answers to the questions you have. This can be a list of statements describing how or why you think the observed things work. These questions must be framed in terms of the variables you have identified. There is usually one hypothesis for each question you have. You must do at least one experiment to test each hypothesis. This is a very important step. If possible, ask a scientist to go over your hypothesis with you.” #7

Author’s Analyses:

There OIG study is devoid of hypotheses or the handling of variables related to it.

Scientific Standard:

“Design Experiments to Test Your Hypothesis--Design an experiment to test each hypothesis. Make a step-by-step list of what you will do to answer each question. This

list is called an experimental procedure. For an experiment to give answers you can trust, it must have a "control." A control is an additional experimental trial or run. It is a separate experiment, done exactly like the others. The only difference is that no experimental variables are changed. A control is a neutral "reference point" for comparison that allows you to see what changing a variable does by comparing it to not changing anything.” #7

Author’s Analyses:

There was no discussion about hypothesis, except a general one to “evaluate” payment for nail services. It is reasonable to assume that the authors of the study would not develop a hypothesis first, which might betray a prejudice to confirm their conclusions. That is entirely appropriate. However, there is no scoring or counting of aspects of charting necessary to prove adequate documentation or the triggers that will conclude and prove inadequate charting.

Scientific Standard:

“Dependable controls are sometimes very hard to develop. They can be the hardest part of a project. Without a control you cannot be sure that changing the variable causes your observations. A series of experiments that includes a control is called a "controlled experiment.”#7

Author’s Analyses:

There is no handling of controls or variables in the OIG study. An appropriate control would be to list the specific requirements for payment (which is done) and compare and give examples of inadequate charting, using a numerical scoring system to compare each, along with published triggers of inadequacy.

Scientific Standard:

“Experiments are often done many times to guarantee that what you observe is reproducible, or to obtain an average result. Reproducibility is a crucial requirement. Without it you cannot trust your results. Reproducible experiments reduce the chance that you have made an experimental error, or observed a random effect during one particular experimental run.”#7

Author’s Analyses:

There was no experimentation in this study. However, it would have provided interesting information or data. For example, a group of podiatrists could have been asked to see a group of specific patients with specific nail conditions. A control group could have been established as experts in Quality Assurance as defined by their personal qualifications and having been recommended by APMA. The committee of control specialists could then have examined the codings documented from each of the

respondents. Pictures of the patient's feet, data from their charts, as well as comments by the expert control group could have been used to obtain data to provide useful conclusions. The identities of all of the parties could have been shielded by using anonymous numbers, thus freeing all of the doctors taking part in the study to use their actual, unfettered judgments.

Scientific Standard:

“Some Guidelines for Experimental Procedures-- Select only one thing to change in each experiment. Things that can be changed are called variables. #7

Author's Analyses:

This was not an experimental study.

Scientific Standard:

“Record Your Observations--Observations can be written descriptions of what you noticed during an experiment, or problems encountered. Keep careful notes of everything you do, and everything that happens. Observations are valuable when drawing conclusions, and useful for locating experimental errors.”#7

Author's Analyses:

Observations were recorded. However there were no notes, descriptions, examples of inadequate chart notes, triggers for inadequacy, or any data whatsoever that confirms or proves those conclusions anywhere in the OIG study.

Scientific Standard:

“Perform Calculations--Do any calculations needed from your raw data to obtain the numbers you need to draw your conclusions.”

Author's Analyses: Calculations are included in the study. The entire group of calculations consists of demonstrating that podiatrists have been paid improperly for unnecessary and undocumented services. Estimates are given on the total dollar amount occurring in the year 2000.

Scientific Standard:

“Summarize Results--This can be in the form of a table of processed numerical data, or graphs. It could also be a written statement of what occurred during experiments. It is from calculations using recorded data that tables and graphs are made. Studying tables and graphs, we can see trends that tell us how different variables cause our observations. Based on these trends, we can draw conclusions about the system under study.”

Author's Analyses:

There is no disclosed recorded data upon which calculations have been applied. Variables are not considered. The undisclosed data obtained is from a single podiatric Medical Consultant no more qualified to judge adequacy of charting than those who submitted charts.

Scientific Standard:

“Draw Conclusions--Using the trends in your experimental data and your experimental observations, try to answer your original questions. Is your hypothesis correct? Now is the time to pull together what happened...”

Author's Analyses:

Conclusions have been drawn. But they are not based upon any published or descriptive material. Since the data for evaluation of those conclusions are absent, it is possible that Medicare is paying more than 22.7% for inadequate documentation, less or equal. It is impossible to know if the single “Medical contractor” was either too lenient or too strict with his/her audit. This is a fatal defect to any subsequent conclusions.

## PART II

This section refers to the “Harvard” Method of applying scientific attributes as described by authors, Kelley A. Lawton and Laura Cousineau for publication in the Journal of the American Psychology Association. #9

Scientific Standard:

“Scientists rarely quote other scientists unless something has been said in a very unique fashion. Instead, scientists describe facts, hypotheses, ideas, and theories which other scientists have published, using their own words.” #9

Author's Analyses:

There are no footnotes of documentation in the OIG study. Nor are there any descriptions of facts that demonstrate or prove its conclusions. The appendices of the study, where such material might be typically found do not contain any source attributes.

Scientific Standard:

“Students often ask "when do you need a citation?". The simplest answer is that everything, except common knowledge and ideas which you have come up with on your own, requires a citation. Too few references is more often a problem than too many. #9

Author's Analyses:

Since there are no citations or specific information on data handling, there is no actual proof that the podiatrist quoted actually audited the charts. This could lead to the startling conclusion that the entire audit was a fabrication and never really happened. It is up to OIG to prove that the audit actually occurred, since there is no documentary evidence that it did. We have been assured that data will be "transferred" to intermediaries to collect refunds, (#10), but since this transfer is confidential, we don't really know if it will occur or the nature of the data to be transferred.

### PART III

This section discusses errors in deduction, internal conflicts and reliance on inappropriate logic.

1. An error of deduction occurs on page 1 of the OIG study, when it states that "Medicare Inappropriately paid about 96.8 Million dollars for Nail debridement and related podiatry services." (#12)

Author's Analyses:

There is no proof or documentation to prove this hypothesis.

2. An error occurs on P2 of the OIG study (#12) that states "In about one in every 4 cases, the medical need for nail debridement was not documented in beneficiaries' medical records. Further, more than half of the inappropriate nail debridement payments had other related inappropriate payments."

Author's Analyses:

There is no documentation to prove either claim. This is apriori reasoning not based upon documented evidence.

3. On P 2 of the OIG study it states that "Furthermore, our sample showed more than half 60% of the inappropriate paid nail debridement claims contained related podiatry services. (#12) When a nail debridement payment is determined to be inappropriate, all other podiatry payments for services related to the nail debridement are also inappropriate. The related services would not have been performed in absence of the nail debridement."

Author's Analyses:

The statement that "the other services would not have been performed without first treating the nails" may be valid in some cases, but not in every situation. For example, a podiatrist could have been called upon to treat a patient for a small ulcer. Upon examination the podiatrist realized that it was not really an ulcer, yet the patient

had enlarged nails. So debridement of the nails was accomplished. Hopefully the need for the nail treatment was documented in the chart. Even if imperfectly documented, the argument could be made that other conditions could exist that would have resulted in a treatment visit anyway. There is no data or discussion of specific instances when this might have occurred. This is a nearly perfect example of the dangers of not disclosing evaluation data. It leads to faulty reasoning based upon the OIG study authors' possible prejudices and has no place in a properly documented study.

4<sup>th</sup> and 5<sup>th</sup> Circular reasoning and self contradictory statements:

4. On P 5 of the OIG study under Scope, it states: "We evaluated the medical necessity of nail debridement services in the Calendar Year 2000. We contracted with a podiatrist to review medical records for 110 randomly sampled nail debridement claims. The contractor also reviewed all other podiatry services that were performed on the same date as the nail debridement service to determine if they were related to the nail debridement."#5

5. On P 8, the OIG study states that "Given that the nail debridement service was inappropriately paid, any related podiatry services were also determined to be inappropriately paid." #5

Author's Analyses:

Given that a pre-condition of the study was that any ancillary services would be inappropriate, this author wonders why there was any effort to "determine" if there was a connection between the nail treatment and any other services. Causing additional confusion, the OIG study identifies no criteria of what attributes would constitute a "connection."

Clearly it is possible to document for other services. Just because a podiatrist did not actually treat nails, does not indicate that the other services were not properly documented or unnecessary. Such statements tend to work against OIG, suggesting that there is a possible "political" agenda contained in it. Experts Kelley A. Lawton and Laura Cousineau of Duke University strongly discourage "inappropriate comments" not related to good science. #9 Clearly the OIG authors should "stick" with the facts of their study and not make inappropriate comments possibly demonstrating their personal opinions. This does not reflect well upon the supposed lack of bias involved in their undertaking.

6. On P 9 there is a "Table" identified as Table 2. It is entitled: "Nail Debridement that should never have been paid." #5

Reason for Denying Payments	Claims	Percent
Claims Reviewed	110	110.0%
Medical Records did not support Claim	19	17.3%

No Record that service was provided	3	2.7%
Medical Records not provided to justify claim	3	2.7%
Claims inappropriate paid	25	22.7%

It further states:

“Of the 25 claims inappropriate paid, 19 (17.3%) were not medically justified because they did not contain sufficient documentation to demonstrate that the services were necessary. For example, several claims lacked clinical descriptions of the nail’s condition, while other claims lacked a diagnosis of mycosis.”#5

The recipe for Medicare coverage listed on P5 indicates that “Medicare covers nail debridement for beneficiaries with systemic conditions involving neurological or vascular diseases...Medicare covers nail debridement for ambulatory beneficiaries with clinical evidence of mycosis of the toenail, marked limitation of ambulation, and pain.” #5

Author’s Analyses:

The above coverage rules suggest that the nail condition need not always be specified to be covered. The OIG study has some confusion over this. Apparently this issue is more complex than OIG realizes. In California for example, mycosis is considered irrelevant. That Medicare Intermediary is more concerned about evidence of pain. CMS provides Medicare Intermediaries with instructions and software that has automatic “triggers” that allow coverage in specific situations. Those may or may not agree with the OIG study. OIG’s auditor is probably not aware of this. Often patients with “normally” appearing nails will suffer pain from pressure on it. The cause for this may be a lesion underneath the nail, such as a subungual callus, a distal phalangeal fracture, contusion, reflex sympathetic dystrophy, blood clot or even a tumor, etc. The list of possibilities is actually very long.

So called “rest pain” can occur in patients with very severe vascular disease, which results in exquisite pain on even on “normal” appearing nails. Podiatrists will also see patients with so-called normal appearing nails where such severe flexion contractures exist that it is impossible for anyone but a podiatrist to treat that patient. Such patients will exert an involuntary scream of agony when their toenails or toes are touched and will violently pull away, striking dangerously against the podiatrist attempting to trim the nails.

7. The coverage list also describes that “Medicare covers nail debridement for beneficiaries with systemic conditions involving neurological or vascular diseases.” #5

Author’s Analyses: (Continued on the same subject)

A. That again suggests that a description of the nails is not always necessary to allow payment. Perhaps this is a basic “misunderstanding” between Medicare and providers. The OIG study implies that the condition of the nails must be documented. The Medicare rule suggest otherwise. The single auditor was unaware of these issues or complications arising from English usage. Should practicing podiatrists in the real world “trust” a single OIG auditor without documentation any more than OIG does not “trust” practicing podiatrists without documentation?

B. How does the 2.7% of “Medical Records not provided to justify claim” relate to the “Medical Records did not support Claim (17.3%)”? #5 It suggests a possible comparison that goes unexplained, casting further doubt on this study. What do they actually mean?

#### SUMMARY:

The intention of this article is to expose the unscientific and undocumented nature of the OIG study. I believe this has been accomplished:

1. Since the methodology, criteria and notes of the single auditing podiatrist is kept secret by the authors of the study, it is impossible for a peer to conduct a similar study on the same data. There is no way to speculate that the conclusions obtained by another reviewer would agree with the first auditor. If an academic study cannot be peer reviewed, it is useless.
2. The OIG study does not follow widely recognized scientific method as recommended by academic authorities.
3. The OIG study does not follow normally recognized practice of disclosing citations in their study to explain and detail the information received from various sources. The podiatrist auditor published no work sheets or explanations of criteria. Secrecy is not an issue, since there are well established methods for maintaining auditor and client anonymity. This author believes that there was a deliberate intention to keep such information undisclosed; and that there is enough “opinion” expressed in the OIG study to suggest that those authors have a political agenda to embarrass podiatrists and inflate their own status by encouraging Governmental action against podiatric physicians. We consider such behavior venal, gratuitous and unnecessary.
4. The OIG study is full of illogical, self contradictory and undocumented conclusions that are totally and completely undisclosed and unproved.

#### CONCLUSIONS:

At the very least, this article calls into serious question the veracity of the OIG study. This author has demonstrated clearly that there are fatal flaws which invalidate its conclusions. Authors of scientific studies have carefully drawn parameters in which they must make a real effort to subscribe and follow. A study from the United States Government has no less obligation.

In an inescapable irony, OIG is guilty of the same lack of documentation they charge against 22.7% of podiatrists. Should podiatric physicians attempt to obtain

payment for claims based upon the same lack of documentation, they could be charged with Medicare fraud.

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