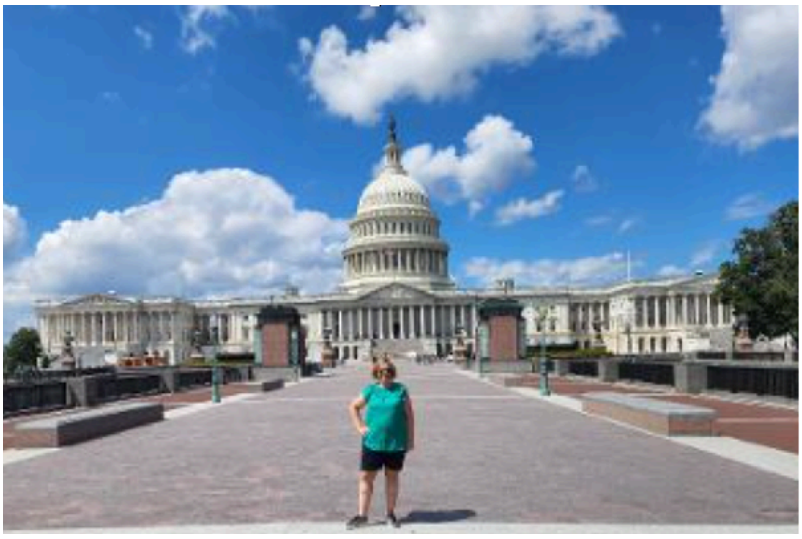
ASCLS The American Society for Clinical Laboratory Science

NEWSLINKS

MARCH/APRIL 2023 AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE - MICHIGAN VOLUME 35, NUMBER 2

President's Message

Meighan Sharp



Happy Spring Everyone!

I truly love what spring represents. Spring has always represented to me, new beginnings, rebirth, and starting fresh. Everything seems to come to life before our eyes. The same can be said about this time of year with ASCLS-Michigan. Spring means coming together as a society to celebrate the profession at the annual Spring Conference. I hope that you all can participate and attend this year's conference in Southfield April 2-4. Coming together to learn, commiserate, and advocate is important for the profession. Join us to learn something new and meet someone new. Let's spring into action and make it a point to attend this year's conference. I also encourage members to attend the annual member meeting during the last day of the conference. There, members will receive valuable information on what the ASCLS-Michigan Board of Directors have been doing to advocate for you and for the profession. I will close with some important dates to consider:

April 2-4, 2023: ASCLS-Michigan Annual Spring Conference, Westin, Southfield, MI

April 4, 2023: ASCLS-Michigan Member Business Meeting, Westin, Southfield, MI

April 23-29, 2023: National Medical Laboratory Professionals Week

June 26-30, 2023: Joint Annual Meeting, Providence, RI

Click here for details and registration.

American Society for Clinical Laboratory Science Michigan

ASCLS-Michigan *Newslinks*

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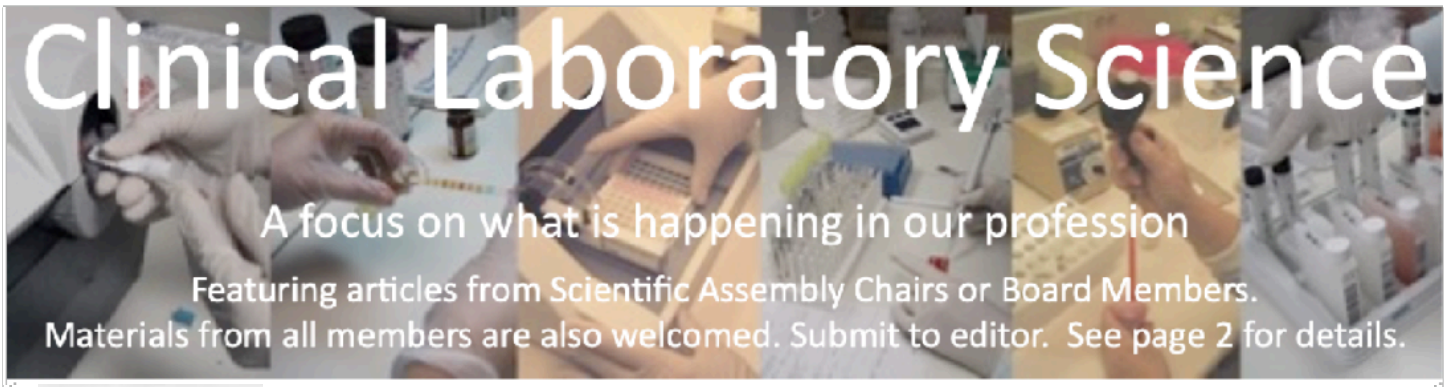


Author in 1963 on a bike of course!

New CLIA Regulations for Proficiency Testing Coming for 2024

Paul F Guthrie, Publications Chair

Last year the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) released a significant update to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Their memorandum[1] gives this summary:

> *Clinical laboratory testing has evolved significantly since 1992 when the CLIA regulations were implemented, and technology is now more accurate and precise than the methods in use at that time. In addition, many tests for analytes not included in the CLIA PT regulations are now in routine clinical use. For example, tests for cardiac markers such as troponins (which are used to diagnose heart attacks) and hemoglobin A1c (a test used to monitor glycemic control in persons with diabetes) were not routinely performed before 1992. Because PT requirements are specified in the regulation, rulemaking is required to update them.*

With the following effective date:

> *The changes to the proficiency testing regulations will be effective on **July 11, 2024**; the delay in implementation will provide proficiency testing providers sufficient time to develop appropriate modules to meet the new requirements. Laboratories are encouraged to enroll in appropriate proficiency testing prior to the implementation date to ensure they are able to receive appropriate challenges in 2024*

The updates can be grouping into the following three categories:

- Adding 29 and removing 6 analytes that proficiency testing (PT) providers must report to CMS.
- Adding or tightening the criteria for acceptable PT performance for 65 non-microbiology analytes
- Making changes to Microbiology PT specifications.

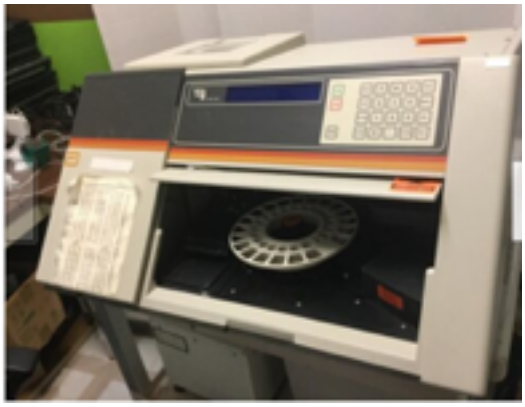
The analytes being added are on the listing below. Of course, most accredited laboratories have always been performing PT for these tests. The difference is the requirement that PT performance will now be reported to CMS.

CLIA Regulation	Analytes
General Immunology CFR 493.927	Anti-HBS
	Anti- HCV
	C-reactive protein (high sensitivity)
Routine Chemistry CFR 493.931	B-natriuretic peptide (BNP)
	ProBNP
	Cancer antigen (CA 125)
	Carbon dioxide
	Carcinoembryonic antigen
	Cholesterol - LDL, direct measurement

CLIA Regulation	Analytes
	Ferritin
	Gamma glutamyl transferase
	Hemoglobin A1c
	Phosphorus
	Prostate specific antigen, total
	Total iron binding capacity (TIBS), direct measurement
	Troponin I
	Troponin T
Endocrinology CFR 493.933	Estradiol
	Folate, serum
	Follicle stimulating hormone
	Luteinizing hormone
	Progesterone
	Prolactin
	Parathyroid hormone
	Testosterone
	Vitamin B12
Toxicology CFR 493.937	Acetaminophen
	Salicylate
	Vancomycin

Several analytes have also been removed from the regulated list:

- LDH isoenzymes
- Ethosuximide
- Quinidine
- Primidone
- Procainamide
- N-acetyl procainamide



Most of those tests are rarely performed these days. For the therapeutic drugs listed here, I recall testing them in the early 1990's on our Abbott TDx (pictured at right). Due to low test volume, we stopped performing those tests many years ago. Some of these drugs are rarely used today because new, less toxic therapies are now available. It was the toxicity that required close monitoring of plasma concentrations on these drugs. A review of the history for one of these drugs is kind of fascinating. Procainamide was developed because the raw source for a cardiac drug with similar effects, Quinidine, was alkaloids from a tropical family of plants (Cinchona) that were not available due to the Japanese Empire control of the Pacific/Indonesia during World War II. [4] On a recent College of American Pathologists Proficiency Testing Survey, only a couple of dozen laboratories were reporting drug levels for Quinidine or Procainamide. For comparison, over 3,100 labs are reporting the drug Digoxin.

Testing menus and laboratory analyzers have changed since CLIA was adopted in 1992. Regulations are being updating to reflect this.

For non-microbiology tests, the listing below has the Acceptance Limit (AL) changes, broken down by discipline. You will note that some of the analytes have an options for a fixed AL. This is because a percentage-based criterion can be unnecessarily stringent at low concentrations – either because of technical feasibility or because medical needs at the low concentration do not require such tight precision. As a result, some analytes have percentage based AL with or without additional fixed AL. The criteria for those AL with both is "whichever is greater".

Routine Chemistry

Analyte	New Criteria * = whichever is greater	Previous Criteria
ALT/SGPT	Target ± 15% or ± 6 U/L	Target ± 20%
Albumin	Target ± 8%	Target ± 10%
Alkaline Phosphatase	Target ± 20%	Target ± 30%
Amylase	Target ± 20%	Target ± 30%
AST	Target ± 15% or ± 6 U/L *	Target ± 20%
Blood gas pO2	Target ± 15 mm Hg or ± 15% *	Target ± 3SD
B-natriuretic peptide (BNP)	Target ± 30%	None
Pro B-natriuetic peptide (proBNP)	Target ± 30%	None
Carbon dioxide	Target ± 20%	None
Cholesterol, high density liprotein	Target ± 20% Target or ± 6 mg/dL *	Target ± 30%
Cholesterol, low density lipoprotein (direct)	Target ± 20%	None
Creatine kinase (CK)	Target ± 20%	Target ± 30%
CK-MB isoenzymes	Target ± 25% Target or ± 3 ng/mL * or presence/absence	MB elevated (presence or absence)
Creatinine	Target ± 0.2 mg/dL or ± 10% *	Target ± 0.3 mg/dL or ± 15% *
Ferritin	Target ± 20%	None
Gamma glutamyl transferase	Target ± 5 U/L or ±15% *	None
Glucose (excluding FDA home use)	Target ± 6 mg/dL or ± 8% *	Target ± 6 mg/dL or ± 10% *
Hemoglobin A1c	Target ± 8%	None
Iron, total	Target ± 15%	Target ± 20%
Lactate dehydrogenase (LDH)	Target ± 15%	Target ± 20%
Magnesium	Target ± 15%	Target ± 25%
Phosphorus	Target ± 0.3 mg/dL or 10% *	None
Potassium	Target ± 0.3 mmol/L	Target ± 0.5 mmol/L
Prostate Specific Antigen, total	Target ± 0.2 ng/dL or 20% *	None
Total Iron Binding Capacity (direct)	Target ± 20%	None
Total Protein	Target ± 8%	Target ± 10%
Triglycerides	Target ± 15%	Target ± 25%
Troponin I	Target ± 0.9 ng/mL or 30% *	None
Troponin T	Target ± 0.2 ng/mL or 30% *	None
Urea Nitrogen	Target ± 2 mg/dL or ± 9% *	Same
Uric Acid	Target ± 10%	Target ± 17%

General Immunology

Discipline: General Immunology		
Analyte	**New Criteria * = whichever is greater**	**Previous Criteria**
Alpha-1 antitrypsin	Target ± 20% or positive or negative	Target ± 3 SD
Alpha-fetoprotein (tumor marker)	Target ± 20% or positive or negative	Target ± 3 SD
Complement C3	Target ± 15%	Target ± 3 SD
Complement C4	Target ± 5 mg/dL or ± 20% *	Target ± 3 S
C-reactive protein (HS)	Target ± 1 mg/dL or ± 30% *	None
IgA	Target ± 20%	Target ± 3SD
IgE	Target ± 20%	Target ± 3SD
IgG	Target ± 20%	Target ± 3SD
IgM	Target ± 20%	Target ± 3SD

Endocrinology

Analyte	New Criteria * = whichever is greater	Previous Criteria
Cancer antigen (CA) 125	Target ± 20%	None
Carcinoembryonic antigen (CEA)	Target ± 15% or ± 1 ng/dL *	None
Cortisol	Target ± 20%	Target ± 25%
Estradiol	Target ± 30%	None
Folate, serum	Target ± 1 ng/mL or ± 30% *	None
Follicle stimulating hormone	Target ± 2 IU/L or ± 18% *	None
Free thyroxine	Target ± 0.3 ng/dL or ± 15% *	Target ± 3SD
Human chorionic gonadotropin	Target ± 18% or ± 3 mIU/mL * or positive or negative	Target ± 3SD or positive or negative
Luteinizing hormone	Target ± 20%	None
Parathyroid hormone	Target ± 30%	None
Progesterone	Target ± 25%	None
Prolactin	Target ± 20%	None
Testosterone	Target ± 20 ng/dL or ±30% *	None
T3 uptake	Target ± 18%	Target ± 3SD
Triiodothyronine	Target ± 30%	Target ± 3SD
Thyroid stimulating hormone	Target ± 20% or ± 2 mIU/L *	Target ± 3SD
Vitamin B12	Target ± 25% or ± 30 pg/mL *	Target ± 30%

Toxicology

Analyte	New Criteria * = whichever is greater	Previous Criteria
Acetaminophen	Target ± 15% or ± 3 mcg/dL *	None
Alcohol, blood	Target ± 20%	Target ± 25%
Blood lead	Target ± 10% or 2mcg/dL *	Target ± 10% or ±4 mcg/dL *
Carbamazepine	Target ± 20% or ± 1.0 mcg/dL *	Target ± 25%
Digoxin	Target ± 15% or ± 0.2 ng/mL *	Target ±20% or ±0.2 ng/mL (greater)
Lithium	Target ± 15% or ± 0.3 mmol/L *	Target ± 0.3 mmol/L or 20% *
Phenobarbital	Target ± 15% or ± 2 mcg/mL *	Target ± 20%
Phenytoin	Target ± 15% or ± 2 mcg/dL *	Target ± 25%
Salicylate	Target ± 15% or ± 2 mcg/dL *	None
Theophylline	Target ± 20%	Target ± 25%
Tobramycin	Target ± 20%	Target ± 25%
Valproic acid	Target ± 20%	Target ± 25%
Vancomycin	Target ± 15% or ± 2 mcg/dL *	None

Hematology

Analyte	New Criteria	Previous Criteria
Erythrocyte Count	Target ± 4%	Target ± 6%
Hematocrit (excluding spun hct)	Target ± 4%	Target ± 6%
Hemoglobin	Target ± 4%	Target ± 7%
Leukocyte count	Target ± 10%	Target ± 15%

Immunohematology

Analyte	New Criteria	Previous Criteria
Unexpected antibody detection	100% Accuracy	80% Accuracy

Microbiology Changes

Microbiology regulations have been modified to remove the types of services listed for each microbiology subspecialty and to add categories of testing (that is, replace the list with broader categories of organisms) for each microbiology subspecialty as described in the bullets below. The goal of the revised microbiology PT regulations is to better reflect current practices in microbiology. The details of the changes to microbiology are extensive. The following is a summary from the lab accreditation service COLA. [2]

CMS will require PT for direct antigen testing in mycology and parasitology; PT is already required for direct antigen testing in both bacteriology and virology. Bacterial toxin detection will now also be part of regular PT challenges for bacteriology. In addition, PT challenges for Gram stains will now require reporting of the bacterial morphology in addition to the Gram reaction.

Any bacteriology PT program must include clinically important species of aerobic and anaerobic bacteria appropriate for the sample sources represented. They must include both Gram-negative and Gram-positive bacilli, and Gram-negative and Gram-positive cocci.

For susceptibility testing, CMS will require at least two PT samples per event, including organisms with a predetermined pattern of susceptibility and resistance to common antimicrobial agents. For bacteriology, PT challenges must include one Gram-negative and one Gram-positive organism.

PT modules for other microbiology subspecialties must also include representatives of medically important organisms. Specific organisms may vary from year to year, but requirements are as follows:

§ 493.913(a)(3): For mycobacteriology, we are proposing that the annual program content must include Mycobacterium tuberculosis complex and Mycobacterium other than tuberculosis (MOTT), if appropriate for the sample sources.

493.915(a)(3): For mycology, we are proposing that annual program content must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: Yeast or yeast-like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.

493.917(a)(3): For parasitology, we are proposing that the annual program content must include intestinal parasites and blood and tissue parasites, if appropriate for the sample sources.

493.919(a)(3): For virology, we are proposing that the annual program content must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample sources.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

In the final rule document, CMS lists this as the hoped outcome of the changes:

> *While we cannot quantify the benefits that implementation of this final rule revising the PT requirements will bring, we believe that the changes will improve the accuracy and reliability of testing and allow for quicker identification of unacceptable practice in laboratories, especially those laboratories that have not previously participated in PT. Remediation after identification of problems should also occur more quickly and clinical test results of marginal or inferior quality are less likely to be used as analytical systems will improve. All of these things will serve to minimize the potential adverse impact to patients and will benefit physicians and healthcare providers while not impacting access to testing.*[3]

And lists the following numbers for impact of the changes:

> *This final rule will impact approximately 35,967 clinical laboratories (total of Certificate of Compliance and Certificate of Accreditation laboratories, as of January 2020) required to participate in PT under the CLIA regulations implemented by the February 28, 1992 final rule, eight current CLIA-approved PT programs, and to a lesser extent, in vitro diagnostics (IVD) manufacturers, healthcare providers, laboratory surveyors, and patients.*[3]

What will all of these changes mean for your lab? With tighter ranges, it is possible the odds of PT failure are likely to increase. **Westgard QC©** is offering a free webinar on March 30th with the topics including "How to optimize the design of your laboratory QC to adjust for new CLIA targets" Click on this hyperlink for registration info: Join us on March 30th, Noon EST to learn

References:

1) Final Rule - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing - Analytes and Acceptable Performance Final Rule (CMS3355-F) QSO-22-21-CLIA (cms.gov)

2) COLA Technical Bulletin 2023-1, Changes to Proficiency Testing Regulations, COLA Inc. https://www.cola.org/contact/

3) Federal Register :: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance accessed March 6, 2023

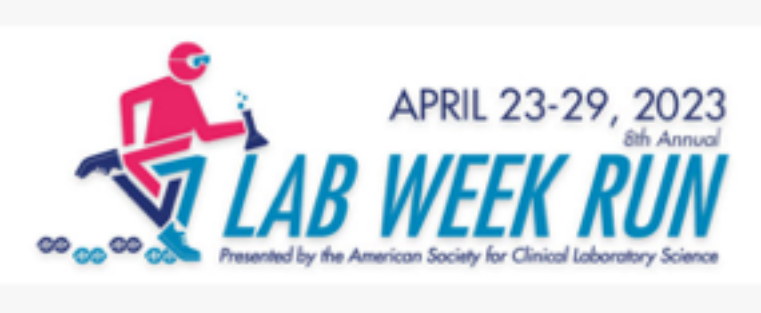
4) Wikepedia, The Free Encyclopedia, Procainamide - Wikipedia accessed March 6, 2023

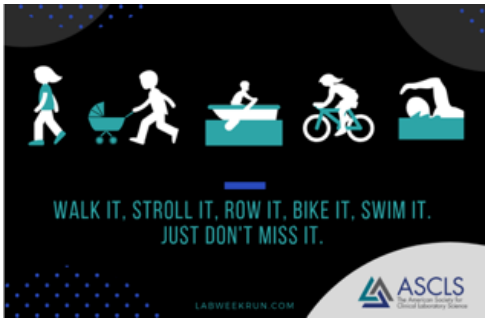
Medical Laboratory Professionals Week April 23-29, 2023

It's time to start planning for 2023 Medical Laboratory Professionals Week (MLPW). This celebration provides the profession with a unique opportunity to increase public understanding of and appreciation for clinical laboratory personnel.

Medical Laboratory Professionals Week originated in 1975 as National Medical Laboratory Week, or NMLW, under the auspices of the American Society for Medical Technology, now called the American Society for Clinical Laboratory Science (ASCLS). In subsequent years, other organizations have served as cosponsors and campaign supporters

Visit the ASCLS Web site for a variety of resources to spread the word: [Medical Laboratory Professionals Week - ASCLS]





Join the Lab Week Run! **Register now at: https://labweekrun.com/**

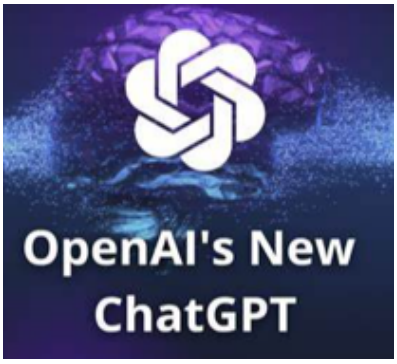
How does a virtual run work?
A virtual race unlike a traditional race can be run at any time during Medical Laboratory Professionals Week (April 23-29, 2023) and can be run anywhere. Participants can walk, use a treadmill, run outside, or even run in another race concurrently. Participants can perform this race at any speed they like. Lab Week Run has had participants run, walk, push baby strollers, walk their dog, hike, and even kayak to complete the 5K distance (or 3.1 miles). Virtual races can be completed all together or over time, whenever and however is most convenient for the participant.

Why should I sign up for this virtual run, how is it different from the others?
Many virtual runs only pledge 5 percent or other small percentages of their profits to stated causes. Our Lab Week Run is entirely not-for-profit. Everything we raise goes to our cause of helping medical laboratory science students and new medical laboratory professionals attend meetings, lobby senators and Congress on behalf of the profession, and become future leaders in this field.

Who makes the finisher medals?
When Lab Week Run was looking for a company to create our finisher medals, we reached out to several and we heard back from one very excited individual, John Breen from Ashworth Awards in Boston, Massachusetts, a company that makes medals for the Iron Man and the Boston Marathon. This individual's mother was a hematologist, so he knows exactly what our profession is. He was inspired to make a unique finisher medal in celebration of our profession and has continued to help us make unique, fun finisher medals every year since. John Breen's mother passed away in 2018, and the ASCLS Education and Research Fund has established a scholarship in Cynthia Breen's honor with a contribution from the Ascending Professionals Forum from Lab Week Run.

Artificial Intelligence is Here: Now What?

Dana Vaughan
Education Scientific Assembly



In a world that is constantly adapting to advancements in technology, the unknown that accompanies change can be scary. Artificial intelligence (AI) is certainly not new; Siri and Alexa are household names, cars are driving themselves, and it's likely that you've used a navigation system at some point to get to your destination. AI is already a staple in education as well. Educators utilize their learning management systems to help with grading, facial recognition software to proctor online exams, and tools like Grammarly to assess writing. While most are comfortable with these common examples, recent advancements in the technology have made it more intimidating.

ChatGPT is a free chat bot tool by creator OpenAI. It answers questions in a conversational manner and can synthesize information based upon prompts from the user. This technology has been a topic of interest and concern because of its ability to write papers and solve complex problems, making it possible for students to complete traditional assignments without significant effort or original thought. This is just the tip of the iceberg regarding its capabilities, which leads to concerns of academic integrity. Another concern is about the validity and ethical sourcing of the information that it generates, as it utilizes countless sources of information that it does not cite. The homepage of ChatGPT warns of its potential to put out biased and/or false information (*Introducing ChatGPT*, n.d.).

While ChatGPT has monopolized the attention, there are several other AI tools that could have an impact on higher education. Presentation slides can easily be produced with the assistance of AI through Beautiful.ai, among other tools. The user provides information for the slides and the tool can adjust formatting and make changes to the text based on user preference. Some options include making the text content shorter, longer, or simpler to understand. You can even ask the tool to change the tone of your writing to be more playful, professional, or assertive (*Beautiful.ai*, n.d.). There are also AI tools related to the generation of art. DALL-E 2 is a tool that can produce an image based on any description that the user provides (*DALL·E 2*, n.d.). All these tools continue to learn and grow as they are used, based on input from users. Not only are these tools improving, but more tools are being developed. For example, Microsoft has released Bing, which has similar capabilities to ChatGPT (*Introducing the New Bing*, n.d.). A simple internet search will provide you with many examples of AI technology that could challenge traditional teaching methods.

While there are many concerns about what technology like this brings, there are clear benefits as well. Students may find tools like ChatGPT helpful to summarize a complex concept or help them understand their notes. There are also AI tools that can aid students in studying by generating flashcards or quizzes based on information they add. AI can also help adapt content for learners with disabilities or learning differences by offering assistive technology such as talk to text (and text to voice), and synthesizing information in new ways. Instructors can also benefit from AI by using it to provide students with the same content in multiple approaches. Certain tools can summarize information into charts, graphs, or bullet points. AI tools can also be used to help make slides to go along with lectures. It may even be used to help save time on grading. If we can find ways to use AI to take over some of the more monotonous tasks of teaching, that may leave more time for the higher impact responsibilities of our job. While I have only given basic examples here, the possibilities are endless and it has the potential to change some of the ways the way we teach in the future. The United States Office of Educational Technology has put out a figure that summarizes examples of how some learning experiences may evolve:

Figure 1: Examples of differences that teachers and students may experience in future technologies.

	Familiar Technology Capabilities	Future Technology Capabilities
Input	• Typing	• Speaking
	• Clicking and dragging	• Drawing
	• Touching and gesturing	• Analyzing images and video
Processing	• Displaying information and tasks	• Assisting students and teachers
	• Sequencing learning activities	• Planning and adapting activities
	• Checking student work	• Revealing patterns in student work
Output	• Text	• Conversations
	• Graphics	• Annotating and highlighting
	• Multimedia	• Suggesting and recommending
	• Dashboards	• Organizing and guiding

(United States Department of Education Office of Educational Technology, 2022)

What impact AI might have on education is a complex question that only time can answer. While there are obvious benefits to the technology, there are also legitimate concerns about its use. As we navigate AI, one thing we can count on is its existence and growth. Learning about its capabilities and considering how it could benefit teaching and learning will serve educators better than ignoring it, and showing students how to use it in ways that benefit them may empower them to use it for that purpose. I imagine teachers faced a similar feeling of uncertainty when calculators became available to students, yet students still effectively learn math today. Education is constantly evolving and reacting to societal changes and technology. While intimidating, AI is just another change we will adapt to and incorporate into our world.

I'll leave you with some advice directly from Chat GPT on how to handle these emerging technologies (2023):

"Overall, teachers should aim to use AI as a tool to enhance their teaching and help students learn more effectively, while also being mindful of the potential risks and ethical concerns associated with AI."

References:

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