The New Brunswick College of Pharmacists' Perspective on the Policy Effects of Point-of-Care Testing Implementation in Pharmacies

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Abstract

Progress in pharmacy allows practitioners to continue giving significant input to both patients and healthcare. Point-of-care testing (POCT) is allowed for pharmacists in seven provinces in Canada. Seeing how POCT can aid in making decisions while on duty, the New Brunswick College of Pharmacists (NBCP) set up policies and regulations to incorporate POCT in New Brunswick. Canadian Provincial Regulatory Authorities depend on policy writing, as it sets the guidelines pharmacists follow. Every province adopts its own scope of practice and methods for making documentation. The paper discusses the NBCP's strategy, methodology and outcomes in making a POCT policy. The team conducted a literature search and looked through the regulations of Canadian provinces and other countries. The findings include information on POCT use, procedures for quality assurance, regulations, learning opportunities and the role of pharmacy technicians in performing POCT in the pharmacy. The paper sets out how NBCP involves professionals and guides its policy decisions. As pharmacies offer more point-of-care services, the NBCP's suggestions can help improve or develop similar practices in other organizations or for other pharmacy professionals.

Keywords: ***Point-of-care testing; scope of practice; pharmacy services; policy.***

1. Introduction

Pharmacists use these tests to work towards ensuring medication and overall health management for their patients. You can now find POCT being used in physician offices, nursing care centers, hospitals and with paramedic units. In practice, POCT is used for tracking drug use, helping manage long-term illnesses and screening for infections. It is necessary for pharmacies to join forces with public health authorities and others to organize the best path for patients who use their infection screening services.

Usually, these tests rely on collecting swabs from a patient's throat, nose or mouth as well as blood from a finger for easier testing. According to the World Health Organization, an effective point of care testing (POCT) stands out as being affordable, sensitive, specific, user-friendly, rapid and robust and does not require large equipment. In addition, it would be desirable for healthcare systems to have real-time links, easier processes for getting samples and care for the environment.

In Canada, what a pharmacist can do at work may vary from province to province. Most provinces refer to Colleges as Provincial Regulatory Authorities (PRAs) which work with the province's government to design and pass health regulations specific to the region(1). In New Brunswick, all pharmacists, pharmacy technicians and pharmacy owners are overseen by the New Brunswick College of Pharmacists (NBCP). The approval last June by the College of new laws governing POCT gave weight to approaches that measure results. They outline how different healthcare professionals must cooperate which referrals are needed and how all medical records should be documented and kept.

According to the New Brunswick Pharmacy Regulations, POCT administration is permitted after the Council (Board) gives its guidance. So, using POCT in the healthcare sector is still untimely until proper guidance is published. Moreover, the College states that pharmacy technicians are controlled under its laws and are named in the regulations as authorized professionals who can assist with test administration under the supervision of pharmacists.

Having clear regulations, the next step would be to set a specific directional policy for POCT which would support existing documents such as the Code of Ethics, Standards of Practice and appropriate laws to ensure clarity and clearer direction. "Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada" from NAPRA has been adopted by most province-wide Colleges, including New Brunswick. These standards require POCT practitioners to fulfill certain expectations along with the policies set by the College(2).

Among their expectations are checking if POCT is appropriate, getting approval from patients, giving tests where

they should be done and reading the findings correctly. It is expected that pharmacy technicians collect the essential information, carry out tests and correctly record all of their findings. In addition, the NAPRA Standards consider how patient confidentiality and privacy should be ensured for services using POCT. Now that practice standards for POCT have been outlined, the NBCP aimed to add further measures to improve safety for patients.

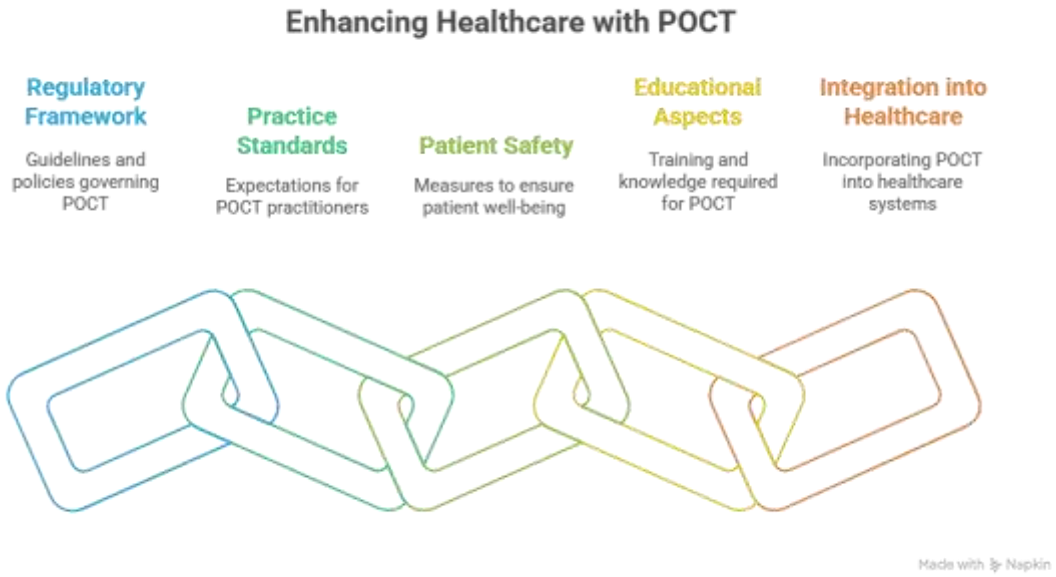

FIGURE 1 Enhancing Healthcare with POCT

Watching how POCTs are used by pharmacy experts in other regions gives meaningful tips on how New Brunswick can employ them and what benefits this will bring to patients. The paper analyzes the NBCP's evaluation of pharmacy-based POCT and compares approaches taken by other jurisdictions to support the development of policies. It will outline policies proposed by the PPC and put them forward for approval of the Council(3).

This process followed by the NBCP ensures each policy considers different sources of information to improve patient safety and support more active roles by pharmacists in healthcare. Exploring existing practices, required standards, regulations and educational aspects in different jurisdictions has allowed the NBCP to put in place POCT processes that match current standards and meet the needs of different provinces.

Because of the information provided, other regulatory bodies and pharmacy specialists can apply or improve their POCT services. The results illustrate that these services should be integrated into pharmacy by ensuring quality, proper training and clear guidelines for all professionals involved. Thanks to their acknowledgment of POCT's benefits, healthcare groups see pharmacy-based POCT as a key improvement to community healthcare, helping to detect problems earlier, provide better care and intervene faster.

2. NBCP Methods

They designed a carefully designed method to ensure all relevant aspects were considered when creating their policy. This section outlines how the Policy Lab gathers important information, reviews regulations in place and interacts with major stakeholders while developing policies.

The Approach to Literature Review

To provide scientific support for lawmakers, NBCP did a thorough review of the available literature using a set of clear guidelines. The review aimed to note how POCT is used in community pharmacy and identify important safety considerations for patients who use POCT in pharmacies.

The researchers searched PubMed with both pharmacy-related (Pharmaci*, Pharmacy) and POCT-related (point of care test, POCT, rapid test) keywords combined using Boolean operators. Just English-language articles from the previous ten years as of May 16, 2022 have been considered. It recorded the most recent developments and offered

some background to understand them(4).

The researchers chose not to include studies unless they were related to pharmacy. Research studies were removed if the tests were not done by pharmacists, if they were not conducted directly in pharmacies or if they focused on COVID-19 testing (because there was already a guideline available on that topic under emergency measures). Researchers looked at the reference sections of relevant papers to identify more suitable articles for review.

Assessment of the Environment's Jurisdictional Factors

To learn about the current regulations, the NBCP conducted a detailed review of POCT rules from different parts of the world. The process included looking closely at the rules and policies in all nine other Canadian provinces and getting additional information from their websites and by reaching out to them directly.

The environmental scan considered strategies in other countries, especially the United States which relies on the Clinical Laboratory Improvement Amendments (CLIA) to waive certain regulations. Looking at Australia and Ireland was thought necessary due to their positive records in the use of pharmacy POCT as described in the literature. Looking at things from a global perspective gave New Brunswick valuable knowledge on different ways laws are enforced and made.

Working With and Consulting With the Experts

Since all parts of the profession had to be on board for implementation, the NBCP engaged stakeholders through a thought-out plan(5). The survey which focused on key issues, was sent out to all pharmacy professionals in the province to understand their opinions.

- The point-of-care tests they were most glad to have in community practice
- Why it is believed beneficial to provide POCT services for patients and healthcare institutions
- Reasons that might hinder the successful execution of the new approach
- Findings that show the employee needs further education or training
- Ability to handle testing parts such as taking the sample, reading the results and checking the accuracy of tests
- The survey gathered data by asking professionals to rate their chances of carrying out POCT services once given the authority. Because of this study, the College could assess how ready each part of the province was for new technology.

Section	Description
Policy Lab Methodology	Comprehensive method ensuring all relevant aspects are considered by gathering information, reviewing regulations, and consulting stakeholders during policy creation.
Literature Review Approach	Systematic PubMed search using pharmacy- and POCT-related keywords; included English-language articles from last 10 years (till May 2022); excluded studies not related to pharmacy or COVID-19.
Jurisdictional Environmental Scan	Detailed review of POCT regulations in Canadian provinces and internationally (US, Australia, Ireland) to learn diverse enforcement and policy frameworks.
Stakeholder Engagement	Survey sent to all provincial pharmacy professionals to assess opinions on POCT tests, benefits, barriers, education needs, and readiness for implementation.
Consultation with Regulators	Ongoing collaboration with New Brunswick health regulators and public health authorities to ensure policy alignment and support for disease reporting requirements.
Committee-Based Policy Development	Policies developed through Professional Practice Committee meetings to analyze evidence and draft policy, followed by approval from the College Council for regulatory compliance.
Evidence Synthesis & Thematic Analysis	Organized findings by themes: POCT uses, quality assurance, regulations, education, roles, implementation challenges, and success factors to inform

Section	Description
	recommendations.
Policy Outcome	Framework combining scientific evidence, regulatory review, and practitioner experience to create actionable, research-supported policies tailored for New Brunswick practice settings.

TABLE 1 key points of the policy development approach

While developing, the NBCP held continuous discussions with other health regulators in New Brunswick to guarantee that their policies matched those currently in place. Recognition was given to the need to engage government public health authorities because their support would be necessary for tests that must report diseases and for establishing where cases should be sent if detected.

Policies are developed using a committee-based approach

- Following a set procedure, the NBCP transferred research results into beneficial policies. At two key stages in the process, the Professional Practice Committee, consisting of pharmacists and regulators, was assembled.
- They gathered together and considered all the evidence from the review studies, environmental scan and survey to set the main policy objectives and priorities.
- After developing the policy's main ideas, the committee again examined the draft to ensure its answers to urgent needs were also actionable(6).
- Upon receiving PPC approval, the policy went on to be considered and discussed by the College Council (its governing Board). The process included insights from multiple experts and ensured that the policy upheld required regulations and standards.

Evidence Synthesis and Analysis Scheme

Information was organized systematically to gather findings from various sources. Various topics were recognized that relate to:

- Community pharmacists often use POCT for these purposes.
- Requirements for quality assurance and what should be followed
- Laws and regulations vary from one place to another.
- Obtaining education and updating knowledge
- The tasks that each should perform have been detailed.
- Obstacles to implementing certain things and elements that lead to positive outcomes

Using the analysis of key themes, experts were able to create recommendations that support patient safety and also aim to provide more accessible healthcare. The College worked to keep up-to-date research and statistics in mind as it adapted to the many types of practice found in different areas of New Brunswick.

The use of this planning framework allowed the NBCP to base its policies on both science, history and the everyday experience of clinicians. Following this pattern made certain that the created policy would be supported by research and could actually be put into place in New Brunswick.

3. The use of POCT in local pharmacies

In a pharmacy, applying point-of-care testing provides fast access to important clinical details that benefits patients. This section explores the research behind various POCT uses in community pharmacy for managing chronic diseases and screening infectious diseases.

Application for the management of chronic diseases

Testing Someone's Blood Sugar with HbA1C

Because Health Canada allows it, several handheld devices can give an HbA1C reading in five minutes using just a small blood sample, making them suitable for pharmacies. After studying a wide range of sources, we found that results for pharmacy-based HbA1C testing were uncertain but hopeful. A number of observational studies did not see any difference in HbA1C levels before and after treatment, while others proved that the treatment achieved

significant results.

Research conducted in Alberta showed that pharmacist-directed insulin treatment for type 2 diabetes using POCT was effective. Following 26 weeks where pharmacists intervened, patients managed to reduce their HbA1C values by 1.8% (95% CI 1.4–2%) which is equal to the results seen with physician involvement. As a result, managing diabetes in a pharmacy along with point-of-care testing can lead to important improvements in sugar control.

A lipid profile is used to measure your cholesterol and other lipids(7).

Most health Canada-authorized machines for lipid testing provide results for total cholesterol, HDL, LDL and triglycerides. While some research did not find any difference in total cholesterol after six months compared to the beginning or if managed by a doctor, a few studies indicated certain lipid measures had improved. According to the two observation studies, after two years of using pharmacist intervention, triglycerides decreased by a non-significant amount of 21.68 mg/dL (95% CI 34.74 to 8.61 mg/dL).

A study in both Alberta and Saskatchewan pharmacies showed more solid evidence of the effect. People who got additional advice from a pharmacist along with education, POCT, physician referral and regular follow-up had a 57% chance of having a physician test their cholesterol or modify their medications, more than those in the general education group (31% chance OR 3.0). These findings indicate that POCT provided by pharmacists can improve how cholesterol risk is handled and managed.

Testing the Function of the Kidneys

Pharmacists rely on kidney function tests to help decide on the correct dosage for patients with kidney disease. In an Ontario pilot study, 11.24% of adults at risk for chronic kidney disease (n=10) showed an eGFR below 60 mL/min/1.73 m^2 and thus had to be referred further.

Results of a Netherlands research showed that including POCT with clinical decision support systems can enhance medicine safety. Seven antibiotics were flagged by the system as unsafe when eGFR data was missing for patients who were 70 and above. Although only a few alerts required POCT, the evidence gathered from the tests allowed doctors to make changes to 15 drug prescriptions. Since community pharmacists can spot and manage kidney function issues, they can always adapt drugs if allowed or advise when a different specialist is required.

Management of Blood Clotting (INR Testing)

For patients on warfarin, doctors monitor their INR every now and then to determine if the dose needs to be adjusted. There are four observational studies that focused on pharmacists supporting INR testing, either collaborating with others or acting independently in warfarin therapy(8). Overall, it was found that patients in pharmacist-managed care had slightly higher TTR (7.99%) and results favored pharmacist care, but these findings were not statistically significant (95% CI −0.74–16.71%).

A study in New Zealand found that atrial fibrillation patients monitored by pharmacists in an anticoagulation clinic had an average TTR of 78.6% (range 49.3 to 100%). TTR outcomes were significantly better when pharmacies tested for TTR than when they were tested by doctors, by 16.7% ($p<0.001$). Apart from the results, POCT in pharmacies saves patients' time by allowing them to avoid waiting for requisitions, traveling to labs and receiving their results.

Infectious Disease Screening Applications

There is alcohol test for group A streptococci available.

Performing rapid streptococcal tests verifies the need for antibiotics and helps promote wise antibiotic use. After studying over 7,050 symptomatic patients from pharmacies in British Columbia, Alberta and Nova Scotia, the research team found that about 25.4% of those patients tested positive. Of all positive cases, 1,234 patients were given same-day prescriptions, expressing how efficiently the healthcare was provided. Ninety-one percent of survey takers saw the location as convenient and 79% considered the service to be valuable.

Notable factors to consider are how sensitive the test is and how it affects children differently. Due to the more serious complications in children and the possibility that about 7.5% of people in the general population are not aware they have tuberculosis, reliable tools and methods are needed for testing purposes. Most times, implementation is successful when the team uses advice from the advisory board, runs formal training and maintains contact with primary care physicians in the area.

Influenza Testing

Most Influenza POCTs use a swab from the nose or the back of the nose to identify both A and B strains of influenza. An analysis of patients at U.S. pharmacies confirmed the virus in 22.9% of the cases (out of 19) and indicated that 15 of those positive cases were treated with oseltamivir. Among the 73 patients tested at two independent pharmacies, thirteen positive cases were found; all but one of those positive patients were given antiviral prescriptions(9).

It has been found that by carefully selecting screening criteria, tests can be used more appropriately. In one study, emergency department records showed that according to new proposals, a third of patients would meet the criteria for pharmacy testing and not those for high-risk cases. According to researchers, using the right protocols ensures that tests are neither used too little nor too much.

Screening is available for both HIV and Hepatitis C infections

Testing for HIV and hepatitis C based on antibodies can be done in various community locations. Antibody-based tests are more useful to check people considered high-risk, not those who have already been exposed, because it takes the body 90 days to produce and detect antibodies (the CDC recommendation). Because a significant number of transmissions come from people who do not realize they are infected, easier access to screening can result in early treatment for those who test positive.

A pharmacy dedicated to Washington's homeless community tested ten persons who had walked in and found eight with hepatitis C. Pharmacists in Alberta and Newfoundland and Labrador were trained thoroughly before they began to use HIV POCT in the APPROACH study. During the pilot, one positive case was found and all patients agreed they felt very comfortable at the pharmacy for this kind of testing. When a Walgreens trial with over 3,600 participants took place in the United States, HIV positivity was 0.8% before four people who reacted were never traced.

Since HIV and HCV are required to be reported nationally, pharmacists must cooperate with public health officials to introduce these screening programs. By coordinating efforts, we make sure, report back, confirm the results and connect a person to the relevant care providers in the broader healthcare system.

4. Different countries have their own regulations for POCT

Across different regions, the introduction of point-of-care testing depends on regulations, the link to primary healthcare and what professionals are allowed to do. This section outlines the ways in which various regions and countries manage POCT in pharmacies, giving useful information for developing a policy in New Brunswick.

Laws and Rules for Different Canadian Provinces

Since Canada lacks national guidelines for implementing POCT, each province comes up with its own ways to regulate their use. Even though the Canadian Standards Association adopted ISO22870 advice for POCT, this relates to hospitals, clinics and ambulatory care settings but not to community pharmacies.

Beliefs from the Western Culture

In British Columbia, there is no clear regulation saying whether a pharmacist can practice POCT. Members of the pharmacy team may conduct certain tests in the absence of patients, yet they must obtain approval through a managing program of the College of Physicians and Surgeons of British Columbia. The Ministry of Health in each province offers general guidance for anyone running POCT services for the community.

In Canada, Alberta is the leader in using pharmacy POCT and it has solid regulatory rules that provide all necessary standards, guidelines and resources. Alberta uses research-based checklists along with permission for new ideas, a model that other provinces have used as inspiration(10).

In Saskatchewan, only the Medical Laboratory Licensing Act sets the rules for POCT. They can only do POCT if a license from a medical laboratory has been approved for them or because of the emergency situation of COVID-19 testing. Point-of-care tests cannot be conducted by Saskatchewan pharmacists at this time as they lack general authority.

The laws and rules that govern transportation in Canada are referred to as Central Canadian Regulation.

Pharmacists in Manitoba are capable of performing COVID-19 tests, but they can only explain or help patients have results of other types of tests. As a result, pharmacists can give advice on medications but leave the collection of specimens to others.

In July 2022, Ontario permitted POCT for tests other than COVID-19, but only for glucose, HbA1C, lipids and INR. This situation highlights the authorities' decision to adopt prevention measures only in areas supported by scientific data.

Pharmacists in Quebec may perform POCT for any case, thanks to the government's open access policy which promotes their autonomy and still maintains regular practice standards.

Atlantic Canadian Guidelines

In Nova Scotia, POCT is stated within the testing standards of practice, so pharmacists and their team members are able to perform different tests on patients.

There are similarities with Ontario as Prince Edward Island limits acceptable tests to glucose, HbA1C and INR, but lipid tests are not among their approved tests.

While providing clinical staff with detailed POCT guidelines in Newfoundland and Labrador, the system also allows for different types of tests.

In both provinces with well-designed policies and those that are only beginning to create them, there are similarities in the main points covered. This means that professionals are required to check a device's accuracy, decide which tests are required, avoid performing duplicate tests, set common laboratory ways of working, maintain quality documentation and create laboratories that respect patient rights and stay safe.

Overseas Rules and Standards

Participation in the United States CLIA Waiver System

The US has developed its own system using the Clinical Laboratory Improvement Amendments (CLIA) waiver. The federal Food and Drug Administration states that CLIA-waiver approved tests can be conducted by health workers since these are considered easy to perform, even though errors are still possible and may create serious issues.

Categories in the CLIA system are endocrinology, urinalysis, hematology, virology, bacteriology, immunology, toxicology and general chemistry and each has more than one test. Yet, depending on the state, pharmacists may not all have the same access to these tests. CLIA waivers are granted to 60% of Alaska's pharmacies, yet none of Nevada's are allowed them.

In most states, collaborative practice agreements allow pharmacists to prescribe based on the results of tests. Idaho is one state that has made it possible for pharmacists to prescribe immunizations after receiving results from POCT tests for influenza and streptococci. With the COVID-19 pandemic, federal emergency actions were able to temporarily override what pharmacists could do in each state regarding CLIA waivers.

Australian Quality Framework

The National Pathology Accreditation Advisory Council provides the framework that regulates the work of Australian pharmacists. Their standards for POCT refer to International Organization for Standardization standards (ISO-22870), requiring medical staff to stick to the makers' instructions, warn about using devices in unapproved ways, assign responsibility to certain practitioners, write guidelines for the organization and manage risks.

The Australian system is based on training, caring for the environment, standardized testing methods and safety in the workplace. It helps maintain the quality of testing by ensuring that it is accessible and also meets strict standards.

How Regulation is Handled in Europe

Ireland is an example of how European laws allow pharmacists to use POCTs for both screening and monitoring activities. The Pharmaceutical Society of Ireland helps promote best practices around employees, tools and assuring quality. Moreover, they have to abide by the Health Products Regulatory Authority guidelines for community POCT.

- Just as Health Canada is required in New Brunswick, Ireland groups devices into the same performance categories decided by the Irish Medicines Board for quality assurance during testing.
- There are both 'paper trails' of similarity and differences in regulations.
- In many different locations and systems, several shared regulations can be seen.
- Before using testing equipment in their systems, most frameworks want it to be approved by regulatory bodies.
- Special rules may change, but all places insist on quality measures corresponding to each exam type.

- Documentation: Keeping a complete history of all tasks related to testing and quality is expected everywhere in the industry.
- Professional Competency: All frameworks believe it is essential for people conducting tests to have proper training and prove their competency.

Key places where liberals and conservatives differ are:

- Test limits can be as open as no discrimination for an exam to including only tests picked from a particular list.
- In some places, there is a direct link between authorized POCT testing and prescribing medicine, while others do not allow this.
- Having technicians hands-on can be approved differently in different regions.
- Not all countries require external accreditation or certification.
- Because regulators in New Brunswick use different rules, the NBCP could consider several options for pharmacy-based POCT and design their strategy according to the province's needs and practices.

5.Conclusion and Future work

This analysis looked at the use of point-of-care testing services in pharmacies to gather information for developing health policies in New Brunswick. Using a literature review, an environmental scan and engaging with stakeholders, the New Brunswick College of Pharmacists confirmed a policy base that ensures patient safety and offers additional services.

Through a careful review, some important factors that should be part of POCT policies were pinpointed. Some of these standards are quality assurance guidelines, competency standards, suitable tests in various scenarios, clear recording of all activities and connection with healthcare-related systems. The fact that these factors are present in various regulations emphasizes their role in securing the success of POCT.

According to the NBCP, policies should be as strong as they need to be, depending on how potentially dangerous a treatment can be to patients. This method ensures that the required protection is neither excessive nor insufficient. Those in pharmacy who use standard POCT approaches in their organization can use the same strategies to create meaningful protocols for their own practice.

Any progress in pharmacy practice should prompt regulatory bodies to systematically look at existing policies and ensure that they are current. This demonstrates that excellent evaluation, talking with various stakeholders and examining previous solutions aid in developing wise government policies. As a result, pharmacists and pharmacy technicians in New Brunswick will be able to offer more services to patients while upholding high standards.

The knowledge gathered supports other jurisdictions by offering them useful advice on how to integrate or improve their POCT practices. By providing this analysis, the NBCP aids the continuous growth of pharmacy practice everywhere and helps the profession remain an essential part of main healthcare deliveries. Don't forget to check your answers again.

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Conflicts of interest

The authors have no conflicts of interest to declare

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