Legislative Assembly of Ontario

Assemblée législative de l'Ontario

Legislative Research
Information and Technology Services Division
Room 2520, Whitney Block
Queen's Park
Toronto, Ontario M7A 1A9
Telephone: (416) 325-3675
Facsimile: (416) 325-3696

Recherche législative
Division des services de l'information et de la technologie
Bureau 2520, Edifice Whitney
Queen's Park
Toronto (Ontario) M7A 1A9
Téléphone: (416) 325-3675
Télécopieur: (416) 325-3696

200454

BLOOD MANAGEMENT AND SAFETY (*2020 ANNUAL REPORT* OF THE AUDITOR GENERAL OF ONTARIO)

BACKGROUND MATERIAL FOR HEARINGS*

Prepared for:

Standing Committee on Public Accounts

Prepared by:

Laura Anthony
Research Officer
Legislative Research

March 11, 2021

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CONTENTS

PREAMBLE 1

OVERVIEW 1

FINANCIAL INFORMATION 2

AUDIT OBJECTIVE AND SCOPE 2

MAIN POINTS OF AUDIT 2

AUDITOR GENERAL'S RECOMMENDATIONS AND POSSIBLE COMMITTEE QUESTIONS 3

- Risk of Transmitting Disease through Transfusion is Low 3
- Blood Data Stored in Multiple Systems Limiting Real-time Data 4
- Immunoglobulins Used for Conditions Not Included in the Provincial Guidelines 6
- Ontario Hospitals Not Required to Report Transfusion Errors and Injuries 7
- Blood Supply Meeting Demand in Most Cases, but Short-Term Shortages Occur 8
- Best Practice Guideline Helps Reduce Ontario Usage of Blood Components and Products 9
- Ministry Does Not Monitor Cost-Effectiveness of Blood Utilization Programs 10
- COVID-19's Impact on Blood System 13

APPENDICES 14

PREAMBLE

This research package has been prepared by Legislative Research with input from the Office of the Auditor General (the Auditor). It provides a brief summary and relevant documents for the Committee's hearings on "Blood Management and Safety" in the Auditor General's *2020 Annual Report.* It is recommended that Members refer to the chapter (see Appendix item 1) when quoting the Auditor.

OVERVIEW

Canadian Blood Services is responsible for providing a safe, secure and affordable supply of blood, blood products and their alternatives to the provinces and territories.

Blood Components and Products

Donated blood is either:

- broken down into its **component parts** (plasma, red blood cells, and platelets) for direct transfusion; or
- separated, or fractionated, into **blood products**, which are purified concentrations of a certain combination of proteins derived from plasma and also include recombinant products, which are not derived from plasma; blood products are used to treat specific conditions such as neurological and immune disorders.

Hospitals in Ontario obtain their blood components and products from Canadian Blood Services. Blood components used in hospitals are obtained from Canadian donors who voluntarily provided blood without compensation to Canadian Blood Services. In contrast, Canadian Blood Services purchases most processed blood products it supplies to Ontario hospitals from foreign countries, primarily through the United States and others in Europe.

Immunoglobulins (Ig) are a type of blood product, used for a range of conditions, such as immune disorders, neurological conditions and other medical problems. Ontario pays more for immunoglobulins than all other blood products combined.

Federal-Provincial Relationship

The federal and provincial/territorial governments (except Quebec) signed a Memorandum of Understanding (MOU) in 1998 to establish Canadian Blood Services as Canada's national blood operator.

Two federal organizations are involved in blood management and oversight: Health Canada and the Public Health Agency of Canada.

- Health Canada regulates blood according to federal regulations, which involves inspecting hospitals and blood donor clinics for such

activities as blood storage and processing, and collecting and reviewing data about investigations of adverse transfusion reactions related to the safety of the blood. Ontario relies on Health Canada to inspect Ontario hospital blood banks and Canadian Blood Services donor sites for adherence to the federal Blood Regulations, which are regulations under the federal *Food and Drug Act* that specifically relate to protecting the blood supply in Canada.

- The Public Health Agency of Canada conducts public health surveillance of errors and adverse events related to blood transfusion.

Financial Information

Ontario's Ministry of Health (Ministry) and all Canadian provinces and territories except Quebec (which has its own blood service) provide funding to Canadian Blood Services.

In 2019/20, the Ministry of Health contributed $562 million to Canadian Blood Services—representing about 50% of total funding from all provinces and territories—to provide blood components and products to Ontario hospitals at no cost to them. About 40% of this funding went toward blood components; the other 60% went toward blood products.

Audit Objective and Scope

The audit's objective was to assess whether the Ministry of Health (Ministry), in conjunction with Canadian Blood Services, had effective systems and procedures in place to provide Ontarians access to a safe and sufficient supply of blood components and products that meets their health-care needs in a cost-effective manner and complies with contractual agreements and relevant policies and procedures.

The audit criteria were established based on a review of applicable legislation, policies and procedures, internal and external studies, and best practices.

Main Points of Audit

The audit found that while the supply of blood components and products as of August 2020 was safe and has been reasonably reliable, the COVID-19 pandemic has magnified existing weaknesses in the reliability of the supply of the immunoglobulin (Ig) blood product. Canadian Blood Services fell short of its own goal of obtaining 50% of blood plasma needed for this product in Canada (it obtained 13.7% in 2019/20). The audit noted that the effect of the pandemic on Ig has not yet been realized because of the significant lead time to fractionate plasma and produce Ig.

Further, the audit found that neither the Ministry nor Canadian Blood Services had systems to assess how hospitals are using blood to treat patients or whether they are using it appropriately since they rely on the clinical expertise in each hospital for appropriate blood use. The Ministry has indicated that it is responsible for promoting the appropriate use of blood and achieving better value for money.

Other audit findings include:

- Ontario relies heavily on suppliers in the United States for essential and high-demand blood products including immunoglobulins (Ig), which is fractionated from plasma collected by these suppliers. This reliance on US-based suppliers presents a risk to the health of people in Ontario who need these products, should the supply chain be disrupted.
- Hospitals' use and waste of blood is not well reported and tracked. Although Canadian Blood Services encourages hospitals to report their use through the Blood Component and Product Disposition Database, some hospitals either do not report or report inconsistently.
- The Ministry-sponsored Ontario Regional Blood Coordinating Network (Network) cannot require hospital staff to change practices in blood use; the Network is funded to identify and address issues in blood use in Ontario hospitals.
- The Ministry has not conducted regular assessments of the Nurse Transfusion Coordinators program (Program). The Program funded 28 nurses in 23 hospitals to counsel patients toward actions that reduce the need for blood transfusions in upcoming surgeries and improve patient outcomes.
- The Ministry pays Canadian Blood Services over $500 million annually for blood without confirming that it only pays for blood components and products hospitals received.

AUDITOR GENERAL'S RECOMMENDATIONS AND POSSIBLE COMMITTEE QUESTIONS

Risk of Transmitting Disease through Transfusion is Low

The audit found that Canadian Blood Services has put additional measures in place since the Krever Inquiry that have improved the safety of supply.[1] Canadian Blood Services publicly reports on all of its safety measures and publishes annual statistics on its surveillance of transmissible blood-borne infections. According to Canadian Blood Services, there have been no confirmed cases of blood-borne infections of HIV, Hepatitis B or Hepatitis C resulting from a blood transfusion

[1] The Krever Inquiry investigated systemic weaknesses in the blood supply system that resulted in about 2,000 people in Canada becoming infected with HIV and another 30,000 with hepatitis C through contaminated blood or blood products.

since the early 2000s. Canadian Blood Services reports the results of its investigations to Health Canada.

The audit found that Health Canada did not identify significant blood safety risks in its inspections of blood banks. A blood bank is a unit within a hospital laboratory that stores and distributes blood components and products for use within the hospital. From 2015 until July 2020, Health Canada had inspected all 14 registered blood banks that perform higher-risk activities and one out of 144 non-registered blood banks in Ontario. The audit did, however, note that the Health Canada inspections identified deficiencies, for example, risks associated with identifying and investigating adverse transfusion events. The Auditor noted that the Ministry was not aware that most unregistered blood banks were not inspected by Health Canada and the Ministry did not obtain and review the data from Health Canada's inspections of blood banks and donor sites.

Auditor's Recommendation 1

To better monitor compliance with federal regulations for the risk of unsafe blood storage and handling practices in Ontario hospitals and further reduce the potential risk of a negative health impact on patients, we recommend that the Ministry of Health:

- establish a mechanism to discuss and receive information from Health Canada on which Ontario hospital blood banks and Canadian Blood Services blood donor centres in Ontario will be inspected by Health Canada, and to obtain and share the results of the hospital inspections with Ontario Health; and
- regularly review Health Canada inspection reports to identify common risk areas and target these problem areas in future education initiatives for hospitals.

Possible Committee Questions

1. Has the Ministry established a process to understand which Ontario hospital blood banks and Canadian Blood Services blood donor centres were and are to be inspected by Health Canada? Further, has the Ministry obtained the inspection results and shared them with Ontario Health?

2. Does the Ministry have plans to regularly review Health Canada inspection reports on Ontario hospital blood banks and Canadian Blood Services blood donor centres in Ontario and share lessons learned and best practices with hospitals?

Blood Data Stored in Multiple Systems Limiting Real-time Data

Blood inventory, usage and clinical data on patients are stored in different information systems across all Ontario hospitals. The audit noted that this patchwork of systems may have contributed to the use of immunoglobulins for conditions beyond the primary uses outlined in provincial guidelines. Further, the

patchwork of systems reduces the effectiveness of provincial measures to reduce blood waste.

The audit also found:

- hospitals still order blood by fax machine;
- 43% of hospitals did not report their use of blood by blood type in 2019/20;
- hospitals are not required to report their use and inventories of blood to Canadian Blood Services, resulting in a lack of information about how blood is used and how much is available for ongoing use;
- clinical information on patients who receive blood transfusions in Canadian hospitals, which is collected by the Canadian Institute for Health Information, does not always indicate the blood component or product transfused, or the number of units transfused;
- Canadian Blood Services does not have access to real-time information to assist it in locating and retrieving blood expediently from hospitals if it becomes concerned about the quality of blood in hospitals;
- Canadian Blood Services does not collect data on prescribed dosages, intended frequencies of use, duration of treatments, and patient outcomes;
- over 5,000 units of red blood cells and over 5,000 units of platelets were still wasted annually in each of the last three years (2017, 2018 and 2019); and
- the Ministry has rejected two proposals with proposed solutions to blood-management data systems based on immediate costs, but did not factor in longer-term savings.

Auditor's Recommendation 2

To support data-driven decision-making in managing the supply of blood components and products, including redistributing them to patients who need them most, and to inform forecasting of demand, we recommend that the Ministry of Health, in conjunction with Ontario Health:

- as an interim solution in the absence of an integrated technology solution, request all hospitals report weekly to Canadian Blood Services their full inventory details for those blood components and products that are under a shortage advisory, and monitor hospitals' compliance;
- actively monitor Canadian Blood Services' exploration of an online ordering system for hospitals in British Columbia;

- assess and develop an appropriate information technology solution—leveraging existing initiatives such as the blood database at McMaster University—to extract relevant data, including the amount of blood used and conditions for which it was used to treat, from multiple hospital systems; and
- work with Canadian Blood Services by providing Ontario data to further develop its forecasting approaches, including factors such as patient demographics.

Possible Committee Questions

3. What steps have been taken to modernize the process of how hospitals order blood?

4. What progress has the Ministry made in developing an information technology solution to extract relevant data on blood use from multiple hospital systems to help with forecasting and understanding utilization patterns?

Immunoglobulins Used for Conditions Not Included in the Provincial Guidelines

The audit found that neither Canadian Blood Services nor the Ministry collects information on how immunoglobulins are used in Ontario hospitals. The Local Health Integration Networks (LHINs) that fund hospitals also do not collect this information. The audit stated without information on the conditions that Ig is used to treat, the Ministry cannot assure that it is used appropriately in accordance with the preferred conditions listed in the provincial utilization guidelines. The Ministry developed Ontario-specific utilization guidelines in 2009 to inform hospitals on Ig's common and clinically appropriate uses, dosages, and frequency of administration.

Canadian Blood Services is funded directly by the Ministry of Health to provide blood components and products to Ontario hospitals. The audit noted that as a result, hospitals have less of an incentive to actively monitor the amount of blood they use or waste.

Auditor's Recommendation 3

To better manage the demand and supply of immunoglobulins so that they are available for Ontarians who need them most and to avoid the costs of wasted product, we recommend that the Ministry of Health, in consultation with Ontario Health:

- collect more complete data from hospitals on how immunoglobulins are being used and identify emerging conditions that may warrant inclusion in provincial utilization guidelines;

- eliminate the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines (Guidelines) state that the product is not recommended for use;
- educate physicians and monitor Ontario hospitals' adoption of the Guidelines; and
- assess potential tools, including updating the Guidelines as needed to prohibit uses where there is no credible evidence that they improve health outcomes, to achieve more appropriate use of blood products—particularly immunoglobulins—according to patient need.

Auditor's Recommendation 4

To better manage the demand and supply of immunoglobulins so that they are available for Ontarians who need them most and to avoid the costs of wasted product, we recommend that the Ministry of Health, in conjunction with Canadian Blood Services, monitor the international situation regarding the supply and demand of immunoglobulins given the impact of COVID-19 on supply.

Possible Committee Questions

5. Has the Ministry considered changing the funding model to try to improve how hospitals monitor blood use?

6. What steps has the Ministry made to educate hospitals and physicians to promote better adherence to the Ontario Immune Globulin Utilization Guidelines in order to reduce the unnecessary use of immunoglobulins?

7. What have the Ministry and Canadian Blood Services done to monitor the international supply and demand of immunoglobulins since the start of the COVID-19 pandemic?

Ontario Hospitals Not Required to Report Transfusion Errors and Injuries

The Public Health Agency of Canada co-ordinates two blood transfusion surveillance systems that collect transfusion adverse event and error data: the Transfusion Transmitted Injuries Surveillance System (Injury Surveillance System) and the Transfusion Error Surveillance System (Error Surveillance System). This data is used to inform decision-making to improve patient safety, by providing a national platform, however reporting is largely voluntary.

The audit found that in 2019, all 158 hospital sites in Ontario reported some—but not all—transfusion injury data to the Injury Surveillance System, and only three formally reported transfusion errors to the Error Surveillance System. The audit report noted that more complete tracking of adverse transfusion events and errors by all Ontario hospitals could help improve transfusion practices.

Auditor's Recommendation 5

To improve the tracking of transfusion errors and injuries, we recommend that the Ministry of Health (Ministry), in consultation with Ontario Health

- establish a plan to raise awareness and require all hospitals to report serious transfusion-related incident data to the Ministry; and
- monitor compliance with the plan on an annual basis.

Possible Committee Question

8. What steps has the Ministry taken to encourage more hospitals to track and more fully report transfusion injuries and errors?

Blood Supply Meeting Demand in Most Cases, but Short-Term Shortages Occur

The audit report noted that blood shortages are not common but do occur. Canadian Blood Services experienced actual shortages of blood components and products on two occasions in the five-year period between August 2015 and July 2020. The longest shortage lasted for almost three months mid-2019 for a form of immunoglobulins that patients can inject themselves.

Canadian Blood Services set a goal to achieve 50% self-sufficiency in plasma to produce immunoglobulins by 2023/24. However, the audit found that since 2013/14, the portion of plasma collected domestically for the purposes of Ig production has been declining steadily, from 22.7% to 13.7% in 2019/20.

Canadian Blood Services told the Auditor that there is a greater need to collect plasma above and beyond pre-pandemic levels since it estimates less plasma will be available from the United States.

Auditor's Recommendation 6

To protect the supply of blood products needed to meet the needs of patients who rely on them, in light of continuing lessons and experiences from the COVID-19 pandemic and its impact on plasma sufficiency in Canada, we recommend that the Ministry of Health request that Canadian Blood Services expediently update the plan to achieve the 50% national self-sufficiency goal, specifying actions and timelines to reach this goal, with monitoring and reporting back on the plan.

Possible Committee Questions

9. Has the Ministry obtained an updated plan from Canadian Blood Services that specifies actions and timelines to achieve 50% national self-sufficiency in plasma by 2023/24?

10. What actions has Canadian Blood Services taken since the COVID-19 pandemic began to ensure sufficient plasma supply?

Best Practice Guideline Helps Reduce Ontario Usage of Blood Components and Products

The Ministry provides funding to the Ontario Regional Blood Coordinating Network (Network), led by two hospitals and one university, to promote appropriate use of blood and improve patient safety. The Network receives funding from the Ministry to educate and improve hospital practices around blood transfusion, including Ig guidelines.

The audit found that not all hospitals adopt the best practices the Network promotes, and not all hospitals participate in its studies, limiting the Network's and Ministry's effectiveness and ability to fully understand how all hospitals in Ontario use blood and whether they are adhering to best practice guidelines. Further, the audit found none of the contractual agreements between Canadian Blood Services and its funding provinces and territories clearly assign the responsibility for researching and promoting blood alternatives or define the different types of alternatives that are available. The Ministry told the Auditor that provinces and territories are responsible for making blood alternatives available to reduce the need for transfusion, but this responsibility has not been formalized in any documents.

Auditor's Recommendation 7

To increase hospitals' adoption of, and compliance with, Ontario Regional Blood Coordinating Network (Network) guidelines on transfusion medicine best practices and better achieve value for the funds paid to the Network, we recommend that the Ministry of Health:

- consult with the Ontario Hospital Association to develop a plan to increase hospitals' participation in Network activities and adoption of its best practices and to make required information available to the Network; and
- monitor hospitals' participation in Network activities to ensure the adoption of best practices improve over time.

Possible Committee Question

11. What steps has the Ministry taken to ensure hospitals follow transfusion medicine best practices?

Auditor's Recommendation 8

To encourage more effective, evidence-based use of blood components, blood products and alternatives to blood at hospitals, we recommend that the Ministry of Health:

- work with both the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to periodically assess cost-effective alternatives to blood; and
- use data on the uses of immunoglobulins, obtained under Recommendation 3, to inform areas of focus for the Ministry's decision-making on alternatives.

Possible Committee Question

12. Has the Ministry communicated with the Canadian Agency for Drugs and Technologies in Health to inquire about its work or to start a project to study blood alternatives?

Ministry Does Not Monitor Cost-Effectiveness of Blood Utilization Programs

The Ontario Nurse Transfusion Coordinators program funds the placement of specialized nurses in hospitals to provide care and counselling to patients before surgery aimed at reducing their need for blood transfusions during surgery. The audit found that the Ministry does not have information to compare the transfusion rates of hospitals that have this Program with those of hospitals that do not as a way to measure the effectiveness of the Program. The audit's findings include:

- nurses do not all follow Program guidelines on what constitutes a counselling session;
- program administrators have not assessed which nurse's recommended actions are followed more frequently; and
- in 2019/20 the vast majority of nurse co-ordinators had been instrumental in helping patients avoid transfusions, but the work of three nurse co-ordinators did not result in enough savings to justify the salaries paid.

Auditor's Recommendation 9

To evaluate the effectiveness of the Ontario Nurse Transfusion Coordinators in improving patient outcomes and reducing the cost of surgical procedures, we recommend that the Ministry of Health:

- collect and assess data on a representative selection of transfusion activities associated with specific surgical procedures, including data

on the number of units of blood transfused, the estimated cost to transfuse and the number of patients transfused, in hospitals with program nurse co-ordinators compared to hospitals without program nurse coordinators; and

- request the Program administrators develop more comprehensive performance indicators and outcome measures that demonstrate the success of this program, establish targets, collect data from program nurses to measure against targets, and report this information annually to the Ministry.

Possible Committee Questions

13. Has the Ministry put a process in place to collect and assess data on a selection of transfusion activities associated with surgical procedures to compare data between hospitals that have transfusion nurse co-ordinators and hospitals that do not?

14. Has the Ministry requested that the Ontario Nurse Transfusion Coordinators program administrators improve program performance indicators and outcome measures?

Payments for Blood

The audit also noted that the Ministry does not have processes to confirm that its payments for blood components and products are reasonable since it does not perform any reconciliations between what hospitals receive and what the Ministry pays for.

Auditor's Recommendation 10

To confirm its payments to Canadian Blood Services are reasonable and commensurate with blood shipped to Ontario hospitals, we recommend that the Ministry of Health put a process in place to verify that payments to Canadian Blood Services are for products shipped and received by Ontario hospitals, with underlying unit costs that are based on audited financial statements of Canadian Blood Services.

Possible Committee Question

15. Has the Ministry established a process to verify that payments to Canadian Blood Services are reasonable?

Data on Transfusion Injuries and Errors to Monitor Patient Outcomes

The audit found that the Ministry does not use transfusion injuries and errors reported to the two national transfusion surveillance systems to monitor whether Ontario hospitals on the whole have fewer incidents year over year. Further, Ontario's Injury Surveillance System program administrators still did not have

any evidence that the Injury Surveillance System in Ontario had helped improve patient safety.

Auditor's Recommendation 11

To reduce the risk to Ontario patients from transfusion errors and injuries in Ontario hospitals, we recommend that the Ministry of Health, in consultation with Ontario Health:

- clarify where responsibility should reside for monitoring transfusion surveillance data reported by hospitals;
- monitor trends of serious transfusion incidents in Ontario; and
- establish a plan with Ontario hospitals for them to share the investigation reports of serious transfusion incidents on a timely basis, which includes communicating any lessons learned to other hospitals.

Possible Committee Questions

16. What steps has the Ministry taken to clarify responsibility for monitoring transfusion surveillance data reported by hospitals?

17. Has the Ministry established a plan with hospitals for them to share investigation reports on transfusion incidents?

Public and Internal Reporting Does Not Provide Meaningful Information on Ontario Activities

The audit found that Canadian Blood Services does not break down performance (such as product demand, productivity, quality and safety) by province. The Auditor noted that the Ministry had not requested provincial performance reporting in the five years prior to the audit (and there was nothing to prevent provinces from requesting provincial data).

Auditor's Recommendation 12

To strengthen the Ministry of Health's ability to evaluate Canadian Blood Services' performance in providing safe blood to Ontario hospitals cost effectively, we recommend that the Ministry of Health:

- request Canadian Blood Services break out Ontario results for national measures that can reflect Canadian Blood Services' performance relevant to Ontario;
- regularly review and assess the effectiveness of national performance measures and revise accordingly with Canadian Blood Services through mechanisms available; and
- request Canadian Blood Services provide at least annual feedback on trends of Ontario results.

Possible Committee Question

18. Has the Ministry requested that Canadian Blood Services provide Ontario-specific performance data?

COVID-19's Impact on Blood System

The audit report noted that blood therapies for COVID-19 are currently under development (which use a recovered COVID-19 patient's antibodies to help treat current COVID-19 patients). Twenty-seven Ontario hospital sites are participating in a North American study to test the safety and effectiveness of this treatment.

The audit report repeatedly highlighted concerns of disruption to the immunoglobulin supply in Ontario given supply chain issues due to the pandemic, particularly global plasma production. The audit report stated that the full effect of the pandemic on the supply of blood products has not yet been realized. However, the audit noted shortages are expected to affect the supply to the fall of 2021 due to the fact that:

- shifting donor behaviours are reducing the amount of plasma being collected in the United States;
- prices for Ig are expected to increase; and
- Canada's reliance on US Ig may be affected by presidential orders to ban the export of medical supplies and drugs (as occurred in April 2020).

Auditor's Recommendation 13

To prepare for the event of limited supply of immunoglobulins and protect Ontarians who rely on these products to live, we recommend that the Ministry of Health:

- introduce any needed further measures across Ontario hospitals to ensure that immunoglobulins are provided to patients according to provincial utilization guidelines or guidelines within the National Immune Globulin Shortage Plan (Shortage Plan), and that alternatives are researched, identified and used to treat conditions that would otherwise be treated with immunoglobulins;
- work with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in a national response as recommended with the Shortage Plan; and
- clarify how Canadian Blood Services and all provincial and territorial governments will ensure equitable distribution of immunoglobulins to patients in most critical need in the event of a sudden shortage so that the treatment needs of Ontario patients are appropriately addressed.

Possible Committee Questions

19. Has the Ministry explored if additional measures are needed in hospitals to ensure immunoglobulins are administered according to provincial utilization guidelines?

20. Has the Ministry asked Canadian Blood Services how it will ensure equitable distribution of immunoglobulins in the event of a shortage?

APPENDICES

1. Auditor General, "Blood Management and Safety" in *2020 Annual Report*.

2. Auditor's News Release Summary of Report.