

### Summary

- ✓ **Clinical decision support systems provide real-time guidance to physicians on the appropriateness of diagnostic imaging tests for a given patient during the ordering process. Access through computerized order entry systems or via electronic health records allows decision support to be used as part of normal workflow. Clinical decision support systems can range from simple tools for a select number of imaging studies and indications to broad systems encompassing several indications and imaging procedures. Recommendations are based on a wide variety of guidelines that may be modified to reflect local practice patterns and the availability of certain diagnostic imaging modalities.**

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- ✓ **The Canadian Association of Radiologists (CAR) has developed diagnostic imaging referral guidelines to help inform the ordering of the most appropriate imaging test for the clinical presentation. An estimated 10% to 20% of requests for diagnostic imaging from referring clinicians are inappropriate, based on CAR guidelines, leading to unnecessary exposure to radiation, increased wait times, and ineffective use of health care resources. The CAR diagnostic imaging referral guidelines are based on the limited amount of evidence that is available and on the consensus opinion of experts.**

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- ✓ **Three studies reported decreases in the outpatient utilization of magnetic resonance imaging (MRI) and computer tomography (CT) after embedding decision support into computerized order entry systems or the electronic health record. One of these studies also reported an increase in the appropriateness of the tests ordered after the implementation of decision support. One study showed that the use of a computerized physician order entry decision support system was associated with an increase in the diagnostic yield of CT angiography for pulmonary embolism in an emergency department. These findings are limited by study designs that did not control for variables that may account for temporal changes unrelated to the intervention and data from a single institution in the United States, which may limit generalization to Canadian settings.**

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- ✓ **Clinical decision support systems have not been extensively employed in Canada; however, several provinces have shown interest in this technology. Two demonstration studies conducted by CAR in Manitoba indicated that decision support did not affect ordering patterns. The reasons reported for the low acceptance of decision support were a lack of integration with existing patient information systems, software limitations, insufficient guideline coverage of actual practice, the timing of advice, lack of belief in the usefulness of decision support, reliance on colleagues for advice, and a perceived disruption of workflow. A third study is evaluating how to improve physician uptake of clinical decision support recommendations.**

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- ✓ **Further investigation is needed to determine the impact of clinical decision support on diagnostic imaging outcomes and practices. There are limited data linking the implementation of decision support with the appropriateness of the tests ordered. There are no published studies that demonstrate an effect of clinical decision support systems on patient outcomes. There is a need for comparative effectiveness research and objective clinical evidence of health outcomes to guide the development of diagnostic imaging referral guidelines.**

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## Background

The use of diagnostic imaging procedures, including high-tech modalities such as magnetic resonance imaging (MRI), computer tomography (CT), and positron emission tomography (PET), has significantly risen in the last decade.<sup>1</sup> The Canadian Association of Radiologists (CAR) estimates that 10% to 20% of requests for diagnostic imaging from referring clinicians are inappropriate, based on CAR guidelines, leading to unnecessary exposure to radiation, increased wait times, and ineffective use of health care resources.<sup>2</sup>

The operational costs for diagnostic imaging in Canada are an estimated C\$2.2 billion.<sup>2</sup> In the United States, radiology benefits management (RBM) firms have emerged in an effort to help health plans control costs by approving or denying reimbursement for imaging exams, based on a set of predetermined guidelines for medical necessity and appropriateness.<sup>3</sup> Physicians are required to call an RBM firm to verify plan coverage before ordering the exam. However, the process of prior notification or pre-authorization can cause delays in diagnosis and treatment and creates administrative burdens for health care providers.<sup>1</sup> Clinical decision support systems have been proposed as an alternative strategy to increase the appropriateness of diagnostic testing.<sup>1</sup>

## The Technology

Clinical decision support systems provide real-time guidance to physicians on the appropriateness of diagnostic imaging tests for a given patient during the ordering process.<sup>4</sup> Although some clinical decision support tools are available as stand-alone web portals, access through computerized order entry systems or the electronic health record allows decision support to be used as part of normal workflow. Clinical decision support systems can range from simple tools for a select number of imaging studies and indications to broad systems encompassing several indications and imaging procedures. Recommendations are based on a wide variety of guidelines that may be modified to reflect local practice patterns and the availability of certain diagnostic imaging modalities.

Once the physician enters the patient-specific information, the decision support system provides a utility score (clinical appropriateness) for the

chosen test and, when necessary, offers an alternative procedure that better suits the patient's indication, based on the evidence. The physician can select the recommended procedure or override the system's suggestion to proceed with the originally requested test. Immediate feedback from decision support at the point-of-order eliminates wait times for diagnostic imaging scheduling. Commercial clinical decision support systems include RadPort (Nuance Healthcare, Nuance Communications, Burlington, Massachusetts),<sup>5</sup> DSCloud (Medicalis Corporation, San Francisco, California),<sup>6</sup> and OrderRight (MedCurrent, Toronto, Ontario)<sup>7</sup>.

## Regulatory Status

As the purpose of clinical decision support systems is to recommend the most appropriate diagnostic imaging test rather than to replace a treatment decision made by the health care professional, clinical decision support systems are not regulated as medical devices in Canada.<sup>8,9</sup>

## Patient Group

High-tech diagnostic imaging scans (including MRI, CT, and PET) are used for a wide variety of patient groups and clinical indications requiring the diagnosis or staging of disease. Between 2000 and 2005, the federal government invested C\$3 billion to improve access to CT and MRI diagnostic imaging scans.<sup>10</sup> As a result of this significant financial investment, the number of scanners and exams performed in Canada has grown. Between 2009 and 2010, 1.4 million MRI exams and 4.2 million CT exams were performed in Canada.<sup>11</sup> These figures are almost double the number of exams performed between 2003 and 2004 for each imaging modality.

## Current Practice

A referral for diagnostic imaging is usually made by a family physician or a specialist, depending on the policies of each health region, the geographic location of the ordering physician, the availability of technologists and diagnostic imaging modality equipment, and the medical reason for requesting the scan.<sup>10</sup> In some jurisdictions, medical students, residents, chiropractors, and nurse practitioners are permitted to order diagnostic imaging within certain limitations. Radiologists supervise the performance

of the requested imaging procedure and interpret the results.

CAR released diagnostic imaging referral guidelines in 2005 to help inform the ordering of the most appropriate imaging test for the clinical presentation.<sup>12</sup> The guidelines were prepared by an expert advisory committee and based on a systematic review of the clinical and economic literature,<sup>13</sup> The Royal College of Radiologists guidelines,<sup>14</sup> and expert opinion. The level of scientific evidence for each recommendation is included, to enable the physician to assess the robustness of the advice offered. Updated guidelines will be released in early 2012.

## The Evidence

Four studies<sup>4,15-17</sup> have assessed the impact of the integration of clinical decision support systems into computerized order entry or the electronic health record on imaging utilization rates and diagnostic yield. All of these studies were conducted in the United States.

A retrospective cohort study conducted at the Virginia Mason Medical Center (Seattle, Washington) analyzed the staged implementation of evidence-based clinical decision support built into ordering systems for selected high-cost, high-frequency imaging procedures (lumbar MRI, brain MRI, and sinus CT).<sup>4</sup> Outpatient imaging utilization rates (defined as the number of patients receiving imaging tests as a proportion of patients with selected clinical conditions), as well as overall imaging utilization before and after the intervention, were determined. The intervention consisted of a decision support system based on a set of locally derived imaging guidelines developed by Virginia Mason providers, following the review of national and international evidence-based guidelines and the primary literature. Failure to document compliance with the approved indications prevented the order from being activated. Decision support was not implemented for brain CT, which was used as a control. Results showed that utilization rates for the head CT control group did not change before and after the implementation of imaging decision support (risk ratio [RR] 0.97; 95% confidence interval [CI] 0.78 to 1.21;  $P = 0.37$ ). There were statistically significant reductions in the utilization rates for the targeted procedures after the intervention. Rates of imaging after the

implementation of decision support were 23.4% lower for lumbar MRI for low back pain (RR 0.77; 95% CI 0.67 to 0.87;  $P < 0.001$ ), 24% lower for head MRI for headache (RR 0.76; 95% CI 0.64 to 0.91;  $P = 0.001$ ), and 27% lower for sinus CT for sinusitis (RR 0.73; 95% CI 0.65 to 0.82;  $P < 0.001$ ). Decision support was also associated with decreases in the overall imaging volumes of lumbar MRI, head MRI, and sinus CT, regardless of the diagnosis.

A retrospective study at the Massachusetts General Hospital (Boston, Massachusetts) assessed the effect of the introduction of computerized order entry and a decision support system on the growth rate of outpatient MRI and CT imaging over seven years.<sup>15</sup> RadPort software was purchased to provide decision support when ordering high-cost imaging studies. The sets of indications for specific examinations and the appropriateness scores were based on the American College of Radiology (ACR) Appropriateness Criteria,<sup>18</sup> supplemented with guidelines that were locally developed by consensus panels of radiologists, primary care physicians, and other clinicians in relevant clinical specialties. The decision support system provided feedback to physicians at the time of ordering, but even orders with low appropriateness scores were allowed to proceed to imaging. Results showed a sizable reduction in the annual growth rate of outpatient CT (from 12% down to 1%) after decision support implementation, despite an increase in the number of patient visits during the same period. The utilization of MRI also decreased, but less so (from 12% down to 7%). This finding may be partly the result of a general tendency for some providers to substitute MRI for CT due to the risk of radiation associated with CT scanning.

The Institute for Clinical Systems Improvement (ICSI) — a non-profit, quality improvement organization serving hospital and medical groups in Minnesota — conducted a one-year pilot study to assess whether medical groups could use standardized appropriateness criteria to order diagnostic imaging scans.<sup>1</sup> A locally derived decision support system based on the ACR Appropriateness Criteria<sup>18</sup> was integrated into the electronic health record ordering system. More than 2,300 physicians from five medical groups, representatives from four health plans, and members of the Minnesota Department of Human Services participated in the pilot. A retrospective audit of 299 charts (151 cases seen within the six months before the decision support system was implemented, and 148 cases seen

after implementation) was performed on a random sample of adult patients from one of the medical groups (HealthPartners Medical Group, Minneapolis, Minnesota).<sup>16</sup> The effect of decision support on the utilization and appropriateness of three frequently ordered diagnostic imaging procedures (head CT, head MRI, and lumbar spine MRI) was assessed. Decision support was associated with reductions of 36.5% and 20% in the volumes of head CT and lumbar spine MRI orders, respectively. Head MRI order volume increased by 3.3%. This finding may reflect the substitution of MRI for CT scans to avoid the risk of exposure to radiation. Combined results for the three procedures showed that a statistically significantly larger proportion of studies ordered after implementation of decision support fit appropriateness criteria, compared with calling an RBM firm (89.2% versus 79.5%, respectively;  $P = 0.02$ ).

A prospective interventional study conducted at a Veterans Affairs Medical Center (White River Junction, Vermont) measured the change associated with the introduction of a computerized decision support system on the proportion of cases with a positive CT angiography result for pulmonary embolism in the emergency department.<sup>17</sup> A validated prediction algorithm<sup>19</sup> was embedded in a computerized physician order entry system, which resulted in a risk score and a recommendation to either first obtain a D-dimer test for low-risk scores or proceed directly to CT angiography for high-risk scores. It was not mandatory for physicians to follow the recommendations provided by decision support. Retrospective comparison data were obtained from 205 patients before implementation of decision support. A total of 393 patients with suspected pulmonary embolism, 229 (58%) of which underwent CT angiography, were evaluated during a four-month period after the implementation of decision support. Physician non-adherence to the computerized decision support system occurred in 105 (26.7%) cases. The implementation of the computerized decision support was associated with an overall increase of 4.4% (95% CI 1.4% to 10.1%) in the proportion of CT angiography results positive for pulmonary embolism. The increase in the proportion of positive cases was nearly twofold higher (8.4%; 95% CI 1.7% to 15.4%) when cases in which emergency physicians did not adhere to the computerized decision recommendations were excluded, suggesting that poor compliance limited

the potential effect on overall yield. Fifteen patients underwent CT angiography despite a low risk score or negative D-dimer test, none of whom had a positive result for pulmonary embolism. Emergency physicians did not order CT angiography for 44 patients despite a high-risk score or positive D-dimer test. Two of these patients returned to the emergency department with negative outcomes (one presented with a pulmonary embolism and the other was diagnosed with deep vein thrombosis). The decision support system was poorly accepted by emergency physicians due to lack of belief in its clinical utility, impatience with the time required, and a preference for intuitive judgment, leading to its removal from the computer order entry system.

Limitations of these studies include designs that did not control for variables that may account for temporal changes occurring regionally and nationally, unrelated to the intervention; unknown contribution of the Hawthorne effect (whereby providers alter their behaviour by virtue of knowing that they are being observed); and data from a single institution in the United States, which may limit generalization to Canadian settings. In addition, by introducing barriers to the ordering of diagnostic imaging, there is the potential that providers will “game” the system, developing ways to modify or supplement information to continue to order inappropriate studies.

## Adverse Effects

One study evaluated the potential for adverse patient outcomes after a computerized decision support system was used to determine whether to perform CT angiography in patients presenting to an emergency department with possible pulmonary embolism.<sup>17</sup> Emergency department records were screened for six months to determine whether patients returned for evaluation of pulmonary embolism after an initial negative result. Eight patients returned to the emergency department and were re-evaluated for pulmonary embolism with CT angiography. None of these patients had a pulmonary embolism on repeated CT angiography after an initial negative evaluation result. However, confirmation of a negative pulmonary embolism diagnosis through direct patient follow-up was not conducted.

## Administration and Cost

The cost of the purchase and integration of commercial decision support software into the computerized order entry or the electronic health record in Canadian health care settings is not known. According to Nuance Healthcare, pricing for this technology is very involved and based on many factors, which makes quoting a specific value complicated to ascertain. In general, pricing is based on a number of methodologies to acquire and/or use the RadPort decision support tool. These pricing methods can include fees based per click, overall volume and usage (per high-tech transaction), and per member per month (for insurance coverage). In addition, there are a number of target groups that would typically invest in this technology, including providers and provider groups, insurance companies, and government agencies. One source estimated a cost between US\$600,000 and US\$700,000 for the development and implementation of RadPort decision support software at the Massachusetts General Hospital in Boston.<sup>20</sup>

## Concurrent Developments

In addition to the use of clinical decision support systems embedded into computerized order entry, or the electronic health record on desktop or laptop computers, other modes of access to decision support are being investigated. A cluster randomized trial conducted in 20 emergency departments in France investigated whether using a hand-held decision support system specifically developed for PalmOS (Palm Inc., Sunnyvale, California) could improve the appropriateness of the sequence of diagnostic imaging tests used to confirm or exclude a diagnosis of pulmonary embolism.<sup>21</sup> The hand-held decision support system consisted of locally derived recommendations based on a validated prediction tool.<sup>22</sup> Results demonstrated a greater increase in the proportion of patients who received appropriate diagnostic workups in the hand-held decision support group compared with the paper-based guidelines group (adjusted mean difference 19.3%; 95% CI 2.9% to 35.6%;  $P = 0.023$ ).

ACR has developed the Anytime, Anywhere application to provide point-of-care access to the ACR Appropriateness Criteria, for hand-held mobile devices such as the iPhone, Blackberry, and

Palm.<sup>23</sup> ACR members can purchase the application from the ACR website for US\$15. Diagnostic Imaging Pathways, a clinical decision support tool developed at the Royal Perth Hospital in Australia, can be accessed as an iPad application.<sup>24</sup> This application can be purchased for C\$3.99 from the Apple iTunes App Store.<sup>25</sup>

## Rate of Technology Diffusion

Clinical decision support systems have not been extensively employed in Canada; however, several provinces have shown interest in this technology. Commercial manufacturers have targeted insurance companies and large health care institutions in the United States that are motivated to reduce the expenditures associated with inappropriate imaging.<sup>26</sup>

In July 2010, the Centers for Medicare & Medicaid Services announced that it would conduct a demonstration project to determine if electronic decision support can improve quality of care and reduce unnecessary radiation exposure by promoting appropriate ordering of high-tech imaging services.<sup>27</sup> Participants — including the National Imaging Associates and four hospital systems across a range of geographic areas, physician specialties, and practice settings — will use a decision support system provided through Medicalis Corporation (San Francisco, California) and GE Healthcare (London, United Kingdom).<sup>28</sup> The decision support provided to physicians will consist of guidelines created by several professional medical societies, including ACR and the American College of Physicians. The two-year demonstration project will assess the impact of decision support systems used by physicians on the appropriateness and utilization of advanced high-cost medical imaging modalities (MRI, CT, and nuclear medicine) ordered for fee-for-service Medicare beneficiaries.<sup>29</sup>

In November 2010, ICSI announced plans to launch a statewide initiative to offer a decision support system to all medical groups and hospital-based clinics in Minnesota, based on positive results from the year-long pilot.<sup>1</sup> The approach allows providers to order high-tech diagnostic imaging tests — including MRI, CT, PET, and nuclear cardiology — for elective outpatient imaging procedures without calling an RBM firm for prior health plan notification. The ICSI steering committee licensed RadPort software (Nuance Communications, Burlington, Massachusetts) to provide a common set of

appropriateness criteria.<sup>30</sup> The appropriateness criteria can be accessed through the electronic health record or via a stand-alone web portal, enabling medical groups and hospital-based clinics of varying sizes and capabilities to adopt clinical decision support.<sup>30</sup> ICSI will also be using Nuance's RadCube data warehouse tool<sup>31</sup> to collect data on how specific imaging studies affect patient outcomes across different health care systems. These data will be used to expand or revise the appropriateness criteria. ICSI estimates an annual savings of US\$28 million for the Minnesota health care community from decreases in the rate of inappropriate imaging, increased clinic efficiencies, and reduced administrative costs, with the use of clinical decision support.<sup>1</sup>

## Implementation Issues

The implementation process of clinical decision support systems involves providing physicians with information to explain the reasons for the change in ordering practice and training resources on the technical aspects of decision support.<sup>32</sup> Information technology resources are required for integration of clinical decision support into computerized order entry or the electronic health record, resolving technical problems, and the ongoing maintenance of decision support systems.

Two demonstration studies conducted in Manitoba by CAR have highlighted challenges in the implementation of clinical decision support systems into ordering practices in Canada.<sup>32,33</sup> Using Medicalis decision support software, CAR's diagnostic imaging referral guidelines<sup>12</sup> were incorporated into a computerized physician order entry system. The first study was conducted at 14 different locations (including the emergency department, in-patient units, outpatient clinics, and individual clinicians' offices) at the Children's Hospital in Winnipeg.<sup>32</sup> All orders placed through decision support software (Percipio, Medicalis Corporation, Waterloo, Ontario) over the course of a year were analyzed. Results showed that 10.9% of diagnostic imaging requests were inappropriate according to the guidelines. Pediatricians followed decision support recommendations in 2% of imaging requests that were considered inappropriate, and cancelled 11% of tests identified as duplicates. A host of reasons for the low acceptance rate of decision support were reported, including:

- a lack of integration with existing patient information systems
- software limitations, including the inability to process requests for multiple imaging studies for the same patient in a single order or to assess the appropriateness of orders that did not include differential diagnoses
- insufficient guideline coverage of actual practice
- the timing of advice: the physician had already committed to the imaging decision before ordering it
- physician perspectives on the usefulness of decision support (some stating it was too generic or not relevant to the complex or high-risk patients being treated)
- reliance on colleagues for advice when unsure of what test to order.

The second study assessed the acceptance of decision support over 36 weeks in a group of family and general practitioners at a rural family medicine clinic in Steinbach.<sup>33</sup> Two Medicalis software systems were used (SmartReq and Decision Support Server). A project server was housed on-site at the clinic to enable decision support to interact with the clinic's electronic medical record. The decision support system identified 24% of the orders as inappropriate and supplied a best practice prompt. Physicians followed suggestions from decision support on 25% of initially inappropriate orders. Perceived disruption of workflow was identified as the largest barrier to the acceptance of decision support.

The findings from these two studies indicate that improving the acceptance of decision support will involve a continuous process that requires regular review with users and the willingness and capability to modify software to suit user groups. A third study at the Children's Hospital in Winnipeg is evaluating how to improve compliance with the diagnostic imaging referral guidelines.<sup>34</sup> The anticipated completion date is June 2012. Interventions being investigated include receiving feedback on individualized performance, working with department heads or medical directors for individualized feedback, and targeted group teaching. It is hoped that the results from this study will increase knowledge on which techniques might best support changing physician behaviour, diagnostic imaging practices, and physician uptake of the recommendations in clinical decision support systems.

To date, CAR has worked with Medicalis decision support software, but has had discussions with other clinical decision support vendors to gauge opportunities to incorporate CAR's referral guidelines into other software products. CAR's goal is to have imaging guidelines widely available to physicians in the near future. Canada Health Infoway is working with the provinces and territories to accelerate the development and adoption of other digital tools, such as electronic health information systems and picture archiving and communications systems, which should ultimately align with decision support implementation.<sup>10,35</sup>

Further investigation is needed to determine the impact of clinical decision support on diagnostic imaging outcomes and practices. Although there is evidence that clinical decision support systems may reduce the outpatient utilization of diagnostic imaging procedures, there are limited data linking the implementation of decision support with the appropriateness of the tests ordered. There are no published studies to date that demonstrate an effect on patient outcomes. Furthermore, because very few outcome-based or cost-effectiveness data on radiology studies are available, the accuracy and relevance of utility scores regarding patient benefit are unknown.<sup>36</sup> The CAR diagnostic imaging referral guidelines are based on the limited amount of evidence that is available and on the consensus opinion of experts.<sup>36,37</sup> There is a need for comparative effectiveness research and objective clinical evidence of health outcomes to guide the development of diagnostic imaging referral guidelines. Further research into the use and acceptance of guidelines by ordering physicians, as well as the value of initiatives to improve physician ordering behaviour, will determine whether clinical decision support systems will be widely adopted in Canada.

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