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August 19, 2022

To whom it may concern,

We are pleased to submit a response to Health Canada's RFI regarding the Canadian Dental Care Plan.

As a global medical device company whose innovations are transforming the way dental health professionals deliver orthodontic, restorative, and preventative treatments to millions of people around the world, Align Technology is gratified by the introduction of a new Canadian Dental Care Plan and stands ready to support the development and implementation of that plan to improve the overall oral health of Canadians.

Please reach out to us if you have any additional questions on our response.

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Request for Information on the
Canadian Dental Care Plan for Health Canada

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RFI #: Posting ID 13656103 (Doc3591046546)

Introduction:

As a global medical device company whose innovations are transforming the way dental health professionals deliver orthodontic, restorative, and preventative treatments to millions of people around the world, Align Technology is gratified by the introduction of a new Canadian Dental Care Plan and stands ready to support the development and implementation of that plan to improve the overall oral health of Canadians.

In Canada, there are a number of underserved populations who struggle to access dental services. These include people with low incomes, children in low-income families, people without dental insurance, older adults residing in institutions or with low incomes, indigenous peoples (e.g., First Nations, Inuit, Métis), refugees and newcomers, people with disabilities, and people living in rural regions. People living with human immunodeficiency virus (HIV) or AIDS in particular have a stigmatizing, chronic condition that may lead to disability; hence, they are also identified as being vulnerable.[1]

All of these populations continue to face multiple barriers to accessing dental care such as cost, fear and dental phobia, denial of care, stigma, and discrimination that contribute to disproportionately higher rates of untreated dental caries, periodontal diseases, missing teeth, and oral pain, as well as greater dental care needs. Health Canada has identified key target populations to be addressed with the CDCP – starting first with children under 12 in 2022 and then expanding to young people under 18, seniors and persons living with a disability in 2023[2]. All are populations with specific needs that can benefit from better oral health care.

Children and young people under 18:
Oral heath literacy, dental hygiene training, non-invasive interventions (fluoridation and sealants) and dental care are particularly important for children and teens as they help patients build and maintain healthy natural dentition for life. Untreated cavities can cause pain and infections that may lead to problems with eating, speaking, playing, and learning. Children who have poor oral health often miss more school and receive lower grades than children who don't[3]. Moreover, there are reports on the direct link between timely oral health care and improved self-esteem, better dietary intake, and increased overall mental health and school performance.[4]

Children should also be screened for dental development problems such as impacted or missing teeth, or misalignment of the teeth and jaws that can cause lasting oral health consequences into adolescence and adulthood (including loss of permanent teeth). The Canadian orthodontic society recommends that all children be evaluated by age 7 when early, potentially minimal treatment can address these problems. And today, added to traditional dental exams and X-rays, digital intraoral scans allow a child's dental development to be evaluated and tracked over time while minimizing radiation exposure.

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9203663/
[2] Message from the Minister of Health regarding Request for Information from Industry on Proposed National Dental Care Program - Canada.ca
[3] https://www.cdc.gov/oralhealth/basics/childrens-oral-health/index.html
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9059447/

Clear aligner orthodontic therapy can be a valuable care option in this population to reduce some of the discomfort and increased risk of cavities associated with traditional brackets and wire treatment. Advanced clear aligner products are available for children as young as 6 who need Phase I or "interceptive" orthodontic treatments to address problems or alignment issues that could damage permanent dentition and provide a foundation for permanent teeth.

Designed to accommodate the shorter clinical crowns and erupting teeth of children, these clear aligners can provide predictable dental arch expansion)[5] and concurrently adjust the bite relationship, straighten teeth, and address a broad range of challenges young patients face without the need for additional appliances. And for children and teens with Class II malocclusion, or "overjet" who need bite correction, an advanced, integrated clear aligner system is available[6] that allows doctors to simultaneously move the patient's jaw forward and align their teeth – also without the need of additional appliances.

Seniors:
Seniors are living longer than ever before. Advances in oral health care prevention and disease treatment mean that many seniors will have some or all of their natural teeth. As we age, teeth undergo changes. Sometimes these changes are affected by the use of medications and chronic diseases. Public health experts increasingly recognize the connection between oral health and overall health and programs to enhance oral health (particularly addressing periodontal disease) often have the added benefit of lowering the incidence of non-communicable diseases such as diabetes, heart disease and stroke. Additionally, treatments to address disease (treat cavities) and restore functional dentition (bridges, crowns and implants) are important contributors to basic nutrition and wellness and all aspects of health. And digital tools such as intraoral scanners offer this group diagnostic options that limit radiation exposure and can also increase efficiency in the processes of restorative dental care.

Persons living with a disability:
Individuals with special needs including those with physical or developmental disabilities frequently experience barriers to dental care. The ability to pay for care remains a primary obstacle to obtain oral health care services for this population. Additional barriers to dental care include language barriers, sensory impairments, physical impairments, psychosocial issues (e.g., low oral health literacy, dental anxiety, past negative experiences), limited transportation, cultural barriers, and dental professionals with limited training to treat patients with special needs.[7]

People with intellectual disabilities have poorer oral hygiene and higher prevalence and greater severity of periodontal disease, untreated caries, dentofacial deformities and tooth loss. For specific example, patients with Down syndrome have smaller than average teeth and missing teeth. It's also common for their teeth to have roots that are shorter than average. People with Down syndrome have a small upper jaw that may cause crowding of the teeth which could result in the permanent teeth being impacted because there is no room in the mouth for them to come in.

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[5] Invisalign First
[6] Invisalign with Mandibular Advancement
[7] https://www.aegisdentalnetwork.com/cced/2021/09/the-largest-minority-population-with-unmet-oral-health-needs-individuals-with-disabilities

General

Question 5: As we develop the CDCP, what are the biggest risks that Canada should be aware of so that appropriate mitigation strategies can be put in place? What opportunities should be explored?

1. Opportunity: Leverage digital technologies and telehealth to improve patient care and support prevention

Align strongly believes that digital technologies – those underpinning dental practice and patient care and those supporting doctor-patient communication, or teledentistry -- can facilitate increased and better access to oral health services, increase dental practice and provider efficiencies and help Health Canada implement the CDCP in a cost-effective manner. Conversely, if technologies like digital intraoral scanners, platforms that connect practitioners with specialists and dental labs, and telehealth (or teleconsultation) capabilities are not included in Health Canada's approach it would be a missed opportunity in providing care.

1a. Improve patient outcomes and increase efficiency in restorative dentistry.

Digital scans can substantially improve the care process of restorative dentistry (crowns, bridges, veneers, and implants), enhance patient outcomes and lower the burden on the health care system.

- Portable and powerful, **digital intraoral scanners** enable dentists to **create a 3D digital image of a patient's mouth *without harmful radiation*** – an important consideration for potentially vulnerable or fragile populations such as children and pregnant women. Fast and precise, and more comfortable for patients than traditional alginate impressions, digital scanning captures every tooth surface and mouth structure in hundreds of thousands of digital data points, providing a level of detail that cannot be achieved with impressions and X-rays alone.
- Though some larger practices do their own lab work or fabricate appliances on site, many rely on external labs to fabricate restorative appliances. When this is the case, treatment workflows are transformed by transmitting the patient's digital scans from the dental office directly to the labs where restorative appliances are made, rather than sending physical impressions which are then digitized to fabricate the appliances. This eliminates steps and cuts turn-around time.
- Digital files improve the fabrication accuracy of appliances or restorations. The initial fit is improved, and the need for 'remakes' can be substantially reduced or eliminated.
- Eliminating remakes in turn reduces waste and potentially lower the number of appointments needed to complete a restoration, reduce patient (or parent/caregiver) time out of work or school, cut travel and lower costs.
- Digital scans can be appended to a patient's permanent digital record for easy portability and are also a highly efficient way to provide supporting data for prior authorization processes and benefit adjudication.

1b. Improve preventive care and patient self-care.

Digital intraoral scanners support early identification of problems and prompt intervention. By providing a sequential visual record[8] of a patient's oral condition over time, they also help practitioners identify and track ongoing oral health issues such as gum recession, educate their patients on the need for self-care, and help them understand the need for necessary treatment.

Attempting to diagnose cavities -- especially those between teeth -- is complicated by variations in the shape and alignment of teeth and limitations of X-rays such as differences in exposure level or bad angles or overlapping contacts in the captured image. Advanced scanners equipped with multiple imaging modalities including Near Infrared Imaging (NIRI) **can actually scan the internal structures of a tooth** (i.e., enamel and dentin) in real-time, and when combined with the 3D data and intra-oral colour photos, can help practitioners to detect and monitor the development of caries lesions (cavities) between teeth or above the gumline without using harmful radiation[9]. Identifying cavities in the **earliest stages[10] when they can be more easily addressed helps a*void the need for more extensive (and costly) restorations.***

Using these tools will also allow Health Canada to track the impact of oral health treatment and practice efficiency initiatives over time and provide strong evidence of the effectiveness of these efforts – supporting extension of the CDCP to the entire Canadian population over time.

2. Opportunity: Leverage digital technologies and telehealth to a.) increase the scope and impact of every accredited provider and extend access to underserved especially vulnerable populations; and b.) lower incidence rates and impact of non-communicable diseases.

2a.) Use technologies and the efficiencies gained in the practice and during the course of treatment to expand the capacity of accredited providers to serve more patients and extend care to underserved and/or remote populations.

Improving oral and overall health in expanding populations and remote locations will increasingly be challenged by the declines in the number of accredited dental health providers seen in some countries, or, as in Canada an urban-rural discrepancy in the access to care. In May, in testimony before the House of Commons Standing Committee on Human Resources, Skills and Social Development and the Status of Persons with Disabilities, Dr. Robert Sutherland, CDA president, and Dr. Euan Swan, CDA manager of dental programs provided context on the situation in Canada. "There is not a shortage of dentists in Canada," explained Dr. Sutherland. However, statistics from the Canadian Institute for Health Information show that 21% of Canadians live in rural areas, while only 11% of dentists practice in these areas.

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[8] iTeroTimeLapse technology

[9] Data on file at Align Technologies, December 4, 2018

[10] In a recent clinical study, the iTero NIRI technology of the iTero Element 5D imaging system was found to be 66% more sensitive than bitewing X-rays in detecting early enamel lesions. Journal of Dentistry (10/24/2021) "Reflected near-infrared light versus bite-wing radiography for the detection of proximal caries: a multi-center prospective clinical study conducted in private practices."

Accordingly, it is more vital than ever to maximise the reach and impact of every accredited provider.

Digital tools and technologies can streamline processes involved in care, potentially reduce the number appointments involved in complex multi-step treatments (implants, complex restorations, orthodontic therapy) and enable some treatment monitoring visits to be 'virtual.' This shift in the way care is delivered makes access to expert providers and state-of-the-art care more realistic for remote populations (see discussion of digital scanning technologies, 1a.). And these changes also increase practitioner flexibility and free 'chair time' to allow accredited professionals to treat more patients.

Triage and oral health treatment planning and care for remote communities.
The same non-invasive, no radiation scanning technology could also be used to support oral health screening of children or adults in remote underserved populations through primary care providers or possibly mobile clinics[11] staffed by dental hygienists or nurses. Comprehensive digital patient records containing 3-D digital scans, NIRI images and colour photographs can then be electronically sent to a distant accredited dentist to triage patients, reach or confirm a preliminary diagnosis, recommend treatment, and direct the course of care. That care may be a simple oral hygiene program undertaken by the patient; dental cleaning, fluoride and sealant application and oral hygiene instruction by a local dental hygienist or nurse supervised by the dentist; or treatments that will require dental office visits such as treatment of caries, periodontal disease, or functional dental issues (broken, cracked or missing teeth or damaged old restorations).

Create a foundation for lifetime oral heath in children.
Children should be screened for dental development problems such as impacted or missing teeth, or misalignment of the teeth and jaws that can cause lasting oral health consequences into adolescence and adulthood (including loss of permanent teeth). The Canadian orthodontic society recommends that all children be evaluated by age 7 when early, potentially minimal treatment can address these problems. And today, added to traditional dental exams and X-rays, digital intraoral scans allow a child's dental development to be evaluated and tracked over time while minimizing radiation exposure.

Clear aligner therapy may be a valuable treatment options for these early orthodontic interventions in children who live in remote areas. Clear aligners are Class II medical devices and like traditional 'brackets and wire" braces, advanced clear aligners can be used, sometimes in combination with other orthopaedic appliances or surgery to address all classes of orthodontic malocclusions. But clear aligner orthodontic therapy has advantages not found with traditional brackets and wire treatments.

The treatment is made possible by digitally driven virtual modelling and treatment planning; state-of-the-art manufacturing, and mass customization; and materials that are simultaneously stiff enough to move teeth, yet still flexible enough for a patient to comfortably and easily insert or

[11] The Alberta Dental Association and College supports mobile home dental clinics which travel to rural Alberta to provide care where it otherwise is not available.

remove the aligner from their mouth as needed. Once a physical exam has been completed, treatment planned and initiated, and the first set of aligners checked for fit, clear aligner therapy eliminates the potential for emergency practice visits to repair broken brackets or wires and monitoring treatment progress can be done with a mix of virtual and in person consultations.

Every one or two weeks, as directed by their doctor, patients simply exchange their current set of custom-made clear aligners for the next set. Over the course of treatment, clear aligners gently and gradually move their teeth through the bone of the jaw. And importantly, unlike conventional 'brackets and wire' braces, clear aligners are easily removable for brushing and flossing, making it easy to maintain good dental hygiene during treatment.

Specialized, advanced clear aligner products for children and adolescents can integrate effective skeletal, functional, or developmental corrections with teeth straightening and potentially eliminate the need for additional appliances such as orthodontic "headgear". A clear aligner product is available for children as young as 6 who need Phase I or "interceptive" orthodontic treatments (including dental arch expansion) to address problems or alignment issues that could damage permanent dentition and provide a foundation for permanent teeth. Designed to accommodate the shorter clinical crowns and erupting teeth of children, this line of clear aligners[3] can provide predictable dental arch expansion and concurrently adjust the bite relationship, straighten teeth, and address a broad range of challenges young patients face without the need for additional appliances. And for children and teens with Class II malocclusion, or "overjet" who need bite correction, an integrated clear aligner system[6] is available that allows doctors to simultaneously move the patient's jaw forward and align their teeth – also without the need of additional appliances.

Address the needs of particularly vulnerable populations and enhance health and quality of life.

As noted earlier, Individuals with special needs including those with physical or developmental disabilities may be among those that need dental care the most but frequently experience barriers to care. Patients with conditions such as cleft lip and palate suffer from an increased burden of care across the first two to three decades of life. Needed orthodontic care utilizing clear aligners can help mitigate the increased risk for decalcification of the teeth that may accompany treatment with brackets and wires. The use of digital scanners and enhanced practice workflows also has particular positive impact for these patients – potentially reducing the number of visits needed for treatment, increasing the practitioner's ability to conduct some treatment monitoring remotely, and by allowing for better planning for future restoration or replacement of congenitally missing teeth.

Many people with intellectual disabilities have poorer oral hygiene and higher prevalence and greater severity of periodontal disease, untreated caries, and tooth loss. And some conditions are linked to oral anomalies. For example, patients with Down syndrome have smaller than average teeth and missing teeth. It's also common for their teeth to have roots that are shorter than average. People with Down syndrome have a small upper jaw that may cause crowding of the teeth which could result in the permanent teeth being impacted because there is no room in the mouth for them to come in.

These individuals could greatly benefit from early interceptive orthodontic treatment as children to correct misalignments of the jaw and create space for permanent teeth to come in. Clear aligners may be a good option for these patients as well – correcting these problems without the use of additional orthodontic appliances (like headgear), supporting effective oral hygiene since aligners can be removed to brush and floss teeth, and eliminating the potential stress of emergency dental visits to repair broken brackets and wires.

2b. Lower the incidence of non-communicable diseases (NCDs) in the Canadian population by improving oral health.

Poor oral health and untreated periodontal diseases have been linked to other conditions (NCDs) such as diabetes[12], heart disease, aspiration pneumonia and inflammatory conditions like strokes, osteoporosis, and cancer.

These links are detailed in scientific literature and national health systems increasingly recognize that by improving oral health you make a positive impact on these conditions and lower the toll of NCDs on citizens and the health care system. On June 29, 2022, the UK's National Institute for Health and Care Excellence (NICE) updated its guidance on Type 2 Diabetes management with new specific recommendations related to periodontitis. In the updated evidence review from NICE the committee authors state, "Overall, it was agreed that the benefits [of periodontal treatment in patients with Type 2 diabetes] outweigh the minor side effects and the treatment of periodontitis using conventional non-surgical techniques should be recommended to improve diabetic control.[13]"

In addressing the allocation of resources and impact of treatment the committee said: "The committee recognised that periodontal treatment is cost-effective for people with type 1 and type 2 diabetes in the base case analysis, and the results remain robust across most scenarios in the sensitivity test. Although the treatment appears not cost-effective under some scenarios (e.g., shorter time horizon, lower compliance/response rate, reduced treatment benefit over time), the committee felt that these were extreme cases and unlikely to reflect the real-world practice. In addition, the committee discussed about the potential resource impact and agreed that the new recommendations will increase health professionals' awareness of periodontitis among people with diabetes. This might lead to a short-term increase in the number of dental appointments, but the associated cost increase is likely to be overweighed by the long-term benefits in the improvement of dental and diabetic outcomes.[13]"

Here too there is an opportunity to address the potential shortage of trained staff by maximizing every interaction between a patient and health care provider to enhance both oral and overall health. **Oral health professionals and primary care medical staff should have a shared understanding of the risk factors and oral manifestations of non-communicable diseases, and the likely impact of non-communicable diseases on oral health and periodontal disease.** Where dental and non-dental care staff alike understand the connections between oral

[12] https://diabetes.ca/about-diabetes/stories/diabetes-and-your-teeth
[13] NICE guideline NG17 and NG28. Evidence review D for periodontal treatment to improve diabetic control in adults with type 1 or type 2 diabetes NG17 and NG28: Evidence review D periodontitis (nice.org.uk)

and overall health and can act as an effective multidisciplinary team, patients have the potential to benefit from early diagnosis, intervention, and well-coordinated care.

Some individuals may see their dentists more frequently than they do their doctors especially those who visit the office at regular intervals for teeth cleaning and other routine preventative care and are otherwise feeling well. As such, these **dental check-ups may be one of the few times that these people interact with the health care system – meaning that dentists may have a unique place in educating patients on the risk factors of NCDs --** detecting the oral manifestations of otherwise asymptomatic health conditions and referring their patients for further medical assessment. Similarly, nurses and general practitioners who suspect periodontal disease in their patients should feel comfortable providing advice on oral hygiene and providing referrals to dentists where necessary.

Align is encouraged by the heightened focus on the oral health needs of the Canadian population and believe that resources committed to oral health will also contribute to early identification of people at risk for NCDs and support prompt intervention.

3. Mitigate Risk by Updating Statutes and Regulations to Keep Dentists at the Centre of Care

Align understands risks as well as the opportunities that come with digital solutions in oral health. As we've discussed, technological innovation can improve patient care, enhance treatment outcomes, and expand access to care, **but new tools and methods must continue to prioritize and support doctor-directed care. Laws, regulations and practice standards must evolve to incorporate these new digital tools while continuing to ensure that licensed dentists direct and manage patient care.**

Teledentistry can be highly effective way for doctors and potential new patients to become acquainted before the first office visit. And once an in-office exam has taken place the doctor-patient relationship is established teledentistry can further build and enhance established doctor-patient relationships by adding a convenient way for doctors and patients to communicate in case of questions or emergencies or enhance treatment monitoring between office visits. A mix of virtual and in person appointments can create practice efficiencies (and allow accredited dental health professionals to provide care to more patients) and increase convenience for patients or the parents or caregivers to patients. Fewer in person appointments in the course of care means less time out of school or work and contributes to lowering the carbon footprint of patients traveling for treatment.

Plan Rules and Coverage

Question 13: What basket of services is common to basic dental plans that could serve as a starting point for coverage under this new program?

1. **Recognize properly aligned teeth and jaws as a fundamental foundation of oral health and include orthodontic care in coverage in certain patients and for certain conditions.**

Although orthodontic care is sometimes seen as a cosmetic intervention or discretionary care, in reality, it is the foundation of an interdisciplinary approach to oral care that prioritizes helping patients achieve, protect, and preserve functional, natural dentition for life. Early orthodontic intervention can set children and young people on a path to good oral health, by moving teeth into a position that makes them easier to clean and care for. But more importantly, early orthodontic evaluation and intervention can help address dental development problems such as impacted or missing teeth or misalignment of the teeth and jaw that can cause lasting oral health consequences into adolescence and adulthood (including loss of permanent teeth.) The Canadian orthodontic society recommends that all children be screened for these problems by age 7 when early, potentially minimal treatment can address these problems.

Clear aligners are Class II medical devices and like traditional 'brackets and wire" braces, advanced clear aligners can be used, sometimes in combination with other orthopaedic appliances or surgery to address all classes of orthodontic malocclusions. But clear aligner orthodontic therapy has advantages not found with traditional brackets and wire treatments.

The treatment is made possible by digitally driven virtual modelling and treatment planning; state-of-the-art manufacturing, and mass customization; and materials that are simultaneously stiff enough to move teeth, yet still flexible enough for a patient to comfortably and easily insert or remove the aligner from their mouth as needed. Once a physical exam has been completed, treatment planned and initiated, and the first set of aligners checked for fit, clear aligner therapy eliminates the potential for emergency practice visits to repair broken brackets or wires and monitoring treatment progress can be done with a mix of virtual and in person consultations.

Every one or two weeks, as directed by their doctor, patients simply exchange their current set of custom-made clear aligners for the next set. Over the course of treatment, clear aligners gently and gradually move their teeth through the bone of the jaw. And importantly, unlike conventional 'brackets and wire' braces, clear aligners are easily removable for brushing and flossing, making it easy to maintain good dental hygiene during treatment.

Specialized, fully integrated clear aligner products that combine effective skeletal, functional, or developmental corrections with teeth straightening are available for children and adolescents. Advanced clear aligner products[3] are available for children as young as 6 who need Phase I or "interceptive" orthodontic treatments (including arch expansion) to address problems or alignment issues that could become worse as they grow and provide a foundation for permanent teeth. Designed to accommodate the shorter clinical crowns and erupting teeth of children, this line of clear aligners can provide predictable dental arch expansion and concurrently adjust the bite relationship, straighten teeth, and address a broad range of challenges young patients face without the need for additional appliances. And for children and teens with Class II malocclusion,

or "overjet" who need bite correction, an advanced,[6] integrated clear aligner system that allows doctors to simultaneously move the patient's jaw forward and align their teeth – also without the need of additional appliances.

2. Support adoption and use of advanced digital scanners to increase efficiency throughout the dental practice ecosystem, improve and extend care and reduce the burden on the health care system.

- Portable and powerful, **digital intraoral scanners** enable dentists to **create a 3D digital image of a patient's mouth *without harmful radiation*** – an important consideration for potentially vulnerable or fragile populations such as children and pregnant women. Fast and precise, and more comfortable for patients than traditional alginate impressions, digital scanning captures every tooth surface and mouth structure in hundreds of thousands of digital data points, providing a level of detail that cannot be achieved with impressions and X-rays alone.
- Extend care to remote communities and underserved populations.
    - Conduct oral scans of children or adults in remote primary care or clinic settings. Transmit comprehensive digital patient records containing 3-D digital scans, NIRI images and colour photographs to remote dentists who can use this rich data to triage patients, reach or confirm a preliminary diagnosis, recommend treatment, and direct the course of care. Care may be:
        - a simple oral hygiene program undertaken by the patient;
        - dental cleaning, fluoride and sealant application and oral hygiene instruction by a local dental hygienist or nurse supervised by the dentist; or
        - treatments that will require dental office visits such as treatment of caries, periodontal disease or functional dental issues (broken, cracked or missing teeth or damaged old restorations).
- Transform workflows for restorative treatment (crowns, bridges, veneers and implants) are transformed for practices who rely on external labs to fabricate restorative appliances.
    - Steps are eliminated and turn-around time is reduced when the patient's digital scans are transmitted electronically from the dental office directly to the labs where restorative appliances are made, rather than sending physical impressions which are then digitized to fabricate the appliances.
    - Fabrication accuracy on appliances or restorations is improved by going directly from the digital file to fabrication. The initial fit is improved, and the need for 'remakes' can be substantially reduced or eliminated.
    - Elimination of remakes can reduce waste and shorten the overall time-span of treatment and potentially lower the number of appointments needed to complete a restoration. This can reduce patient (or parent/caregiver) time out of work or school, cut travel and lower costs.
- Transform orthodontic workflows.
    - Steps are eliminated and turn-around time is reduced when the patient's digital scans are transmitted electronically from the dental office directly to the treatment planning facility where CAD/CAM designers draft digital treatment plans for orthodontist or dentist review and approval. Eliminating physical impressions saves time, shipment costs and packaging waste.

  - Fabrication accuracy on clear aligners is improved and the need for 'remakes' can be substantially reduced or eliminated. This in turn reduces waste.
  - Clear aligner orthodontic therapy has advantages not found with traditional brackets and wire treatments. Once a physical exam has been completed, treatment planned and initiated, and the first set of aligners checked for fit, clear aligner therapy eliminates the potential for emergency practice visits to repair broken brackets or wires and monitoring treatment progress can be done with a mix of virtual and in person consultations.
  - Fewer in person appointments can reduce patient (or parent/caregiver) time out of work or school, cut travel and lower costs.
- Support and increase efficiency in treatment prior authorization and coverage benefit adjudication.
  - Digital scans appended to a patient's permanent digital record are portable, easily transmissible and provide excellent data to support prior authorization processes and coverage adjudication.
- Enhance diagnosis of caries.
  - Attempting to diagnose cavities -- especially those between teeth -- is complicated by variations in the shape and alignment of teeth and limitations of X-rays such as differences in exposure level or bad angles or overlapping contacts in the captured image. Advanced scanners equipped with multiple imaging modalities including Near Infrared Imaging (NIRI) can actually scan the internal structures of a tooth (i.e., enamel and dentin) in real-time, and when combined with the 3D data and intra-oral color photos, can aid practitioners to detect and monitor the development of caries lesions (cavities) between teeth or above the gumline without using harmful radiation Identifying cavities in the earliest stages when they can be more easily addressed helps avoid the need for more extensive (and costly) restorations.
- Help practitioners identify and track ongoing oral health issues, educate their patients on the need for self-care, and help them understand the need for necessary treatment.
  - Digital intraoral scanners also allow dentists to compare patient records over time. This helps patients visualize tooth wear or the gum recession that can signal periodontal disease.

Dental Care Providers

Question 30: With the implementation of this program, what do you foresee the impact being on the capacity of the dental care providers to provide services to Canadians? How could that capacity be increased?

Improving oral and overall health in expanding populations and remote locations will increasingly be challenged by declines in the number of accredited oral health providers including dentists seen in some countries, or, as in Canada, an urban-rural discrepancy in the access to care. In May, in testimony before the House of Commons Standing Committee on Human Resources, Skills and Social Development and the Status of Persons with Disabilities, Dr. Robert Sutherland, CDA president, and Dr. Euan Swan, CDA manager of dental programs provided context on the situation in Canada.

"There is not a shortage of dentists in Canada," explained Dr. Sutherland. However, statistics from the Canadian Institute for Health Information show that 21% of Canadians live in rural areas, while only 11% of dentists practice in these areas.

Accordingly, it is more vital than ever to maximise the reach and impact of every accredited provider.

If investment is made and digital tools and technologies are broadly adopted, they can streamline processes involved in care, potentially reduce the number appointments involved in complex multi-step treatments (implants, complex restorations, orthodontic therapy) and enable some treatment monitoring visits to be 'virtual.' This shift in the way care is delivered makes access to expert providers and state-of-the-art care more realistic for remote populations (see discussion of digital scanning technologies below), and these changes also increase practitioner flexibility and free 'chair time' to give accredited professionals the ability to treat more patients through their practice.

1. Triage and oral health treatment planning and care for remote communities.

The same non-invasive, no radiation scanning technology could also be used to support oral health screening of children or adults in remote underserved populations through primary care providers or possibly mobile clinics[11] staffed by dental hygienists or nurses. Comprehensive digital patient records containing 3-D digital scans, NIRI images and colour photographs can then be electronically sent to a distant accredited dentist to triage patients, reach or confirm a preliminary diagnosis, recommend treatment, and direct the course of care. That care may be a simple oral hygiene program undertaken by the patient; dental cleaning, fluoride and sealant application and oral hygiene instruction by a local dental hygienist or nurse supervised by the dentist; or treatments that will require dental office visits such as treatment of caries, periodontal disease or functional dental issues (broken, cracked or missing teeth or damaged old restorations).

2. Broad adoption and use of digital intraoral scanners and changes in practice workflows underpin the potential expansion of provider capacity.

Digital scanners can substantially improve the care process of restorative dentistry (crowns, bridges, veneers, and implants), enhance patient outcomes and lower burden on the health care system. The same workflow efficiencies can be realized in orthodontic care.

- Portable and powerful, **digital intraoral scanners** enable dentists to **create a 3D digital image of a patient's mouth *without harmful radiation*** – an important consideration for potentially vulnerable or fragile populations such as children and pregnant women. Fast and precise, and more comfortable for patients than traditional alginate impressions, digital scanning captures every tooth surface and mouth structure in hundreds of thousands of digital data points, providing a level of detail that cannot be achieved with impressions and X-rays alone.
- Though some larger practices do their own lab work or fabricate appliances on site, many rely on external labs to fabricate restorative appliances. When this is the case, treatment workflows are transformed by transmitting the patient's digital scans from the dental office directly to the labs where restorative appliances are made, rather than sending physical impressions which are then digitized to fabricate the appliances. This eliminates steps and cuts turn-around time.
- Digital files improve the fabrication accuracy of appliances or restorations. The initial fit is improved, and the need for 'remakes' can be substantially reduced or eliminated.
- Eliminating remakes in turn reduces waste and can potentially lower the number of appointments needed to complete a restoration, reduce patient (or parent/caregiver) time out of work or school, cut travel and lower costs.
- Digital scans can be appended to a patient's permanent digital record for easy portability and are also a highly efficient way to provide supporting data for prior authorization processes and benefit adjudication.

Digital intraoral scanners can **improve preventive care, support early intervention and motivate patient self-care.** By providing a sequential visual record[8] of a patient's oral condition over time, they also help practitioners identify and track ongoing oral health issues (such as gingivitis or gum recession) educate their patients on the need for self-care and help them understand the need for necessary treatment.

Attempting to diagnose cavities -- especially those between teeth -- is complicated by variations in the shape and alignment of teeth and limitations of X-rays such as differences in exposure level or bad angles or overlapping contacts in the captured image. Advanced scanners equipped with multiple imaging modalities including Near Infrared Imaging (NIRI) **can actually scan the internal structures of a tooth** (i.e., enamel and dentin) in real-time, and when combined with the 3D data and intra-oral colour photos, can help practitioners to detect and monitor the development of caries lesions (cavities) between teeth or above the gumline without using harmful

radiation[14]. Identifying cavities in the **earliest stages[15] when they can be more easily addressed helps a*void the need for more extensive (and costly) restorations.***

Using these tools will also allow Health Canada to track the impact of oral health treatment and practice initiatives over time and provide strong evidence of the effectiveness of these efforts – supporting extension of the CDCP to the entire Canadian population over time.

[14] Data on file at Align Technologies, December 4, 2018

[15] In a recent clinical study, the iTero NIRI technology of the iTero Element 5D imaging system was found to be 66% more sensitive than bitewing X-rays in detecting early enamel lesions. Journal of Dentistry (10/24/2021) "Reflected near-infrared light versus bite-wing radiography for the detection of proximal caries: a multi-center prospective clinical study conducted in private practices."