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Connected Devices to Support Remote Examination and Diagnosis in Primary Care and Specialty Care



Image courtesy of TytoCare Ltd.

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Methods

This report presents an overview of an emerging health technology, a description of some of the published clinical studies, and a summary of some important considerations related to the potential implementation of technology. This report was not prepared using systematic review methods and did not involve critical appraisal or analysis of relevant study findings. This report is not intended to provide recommendations for or against the use of a particular technology.

Literature Search Strategy

A limited literature search was conducted by an information specialist on key resources including MEDLINE via Ovid, Scopus, PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were TytoHome and remote monitoring devices. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2018 and August 20, 2020.

Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was TytoHome (or related devices manufactured by TytoCare Ltd.). Conference abstracts and grey literature were included when they provided additional information to that available in the published studies.

Peer Review

Manufacturers were given the opportunity to comment on an earlier draft; manufacturer input was received and addressed in this report.

Summary

- The COVID-19 pandemic rapidly moved health care from an in-person environment to a virtual environment: a shift that patients and clinicians in Canada had been indicating a readiness and willingness for in recent years.
- The number of appointments that can be provided as a virtual visit is limited by the ability to assess a person’s physical signs and symptoms such as heart and lung sounds.
- TytoHome is a set of connected devices intended to support the remote examination of physical signs and symptoms as part of a virtual visit between patients and clinicians.
- Limited published evidence of the feasibility, validity, and reliability of TytoHome suggests it may be useful to support remote examinations during virtual visits.
- Issues such as cost, technical requirements, physician remuneration, and licensing may all impact the ability to implement technologies like TytoHome in Canada.

Background

The physical (or clinical) exam is an evaluative tool that has been used for centuries by clinicians for patients presenting with a variety of health concerns.¹ Despite advances in diagnostic technologies, such as portable ultrasound, recent studies have reaffirmed the value of the physical examination as a tool to support diagnosis and treatment, and for its importance in building good relationships between clinicians and their patients.^{2,3} The idea and practice of delivering care to patients outside of traditional health care settings is not new and patients, clinicians, and policy-makers in Canada have shown an increased readiness and willingness to receive and deliver care virtually, including using virtual visits as an alternative to in-person appointments.^{4,6} Despite this readiness, the scope of care considered suitable for virtual visits may exclude many components of the physical exam.^{7,8} The rapid shift from in-person care to virtual care during the COVID-19 pandemic has also led to an emergent need for technologies that can safely and effectively support patient care at a distance.^{5,7} One technology that may support remote examination during a virtual visit is TytoHome.⁹

The Technology

TytoHome (TytoCare Inc., Israel⁹) is a set of connected devices (i.e., “physical objects that can connect to each other and other systems via the internet”¹⁰) intended to support the remote examination of patients by clinicians during virtual visits.¹¹ The system includes:⁹

- the Tyto Device (described further on)
- a digital otoscope, digital stethoscope, and tongue depressor adaptors
- the TytoApp (a smartphone app compatible with Android and iOS devices).

By integrating peripheral devices like a digital stethoscope, TytoHome may help facilitate some virtual visits that would normally require an in-person appointment to assess the patient.

Prerequisites for using TytoHome include access to:¹²

- a high-speed wireless internet connection (a smartphone or other portable wireless internet hotspot may also be used)
- a smartphone or tablet device compatible with the TytoApp.

Clinicians integrating TytoHome into their practices must also set up TytoVisit – a proprietary telehealth platform intended to support virtual visits, scheduling, and more, and capable of integrating with electronic medical records and other existing telehealth platforms.¹³ According to the manufacturer, patients using TytoHome can also share the examination data collected by the device with their own health care provider even if their clinician is not a Tyto user (Menahem Shikhman, TytoCare Ltd., New York, NY: personal communication, Nov 16, 2020).

Prior to using TytoHome, a patient must also sign up for an account, register their system, and pair the TytoApp to the Tyto Device.¹² Multiple patients can be registered using the same account. Clinicians choosing to use TytoHome to support their practices can issue registration details to their patients.

Once set-up has been completed, patients and caregivers can review the built-in self-guided training videos.¹¹ Following training, patients and caregivers can use the app to start a video visit with a clinician in real time, collect and send examination data for review by a clinician at a later time (called “Exam and Forward” in the TytoApp), or view messages from a clinician (such as visit notes or examination files) sent to the app’s inbox.¹²

When selecting a real-time video visit, TytoApp allows patients and caregivers to choose between an immediate appointment with a national or regional provider group using the TytoCare platform or an appointment with their own clinician (provided their clinician is a Tyto user).¹² Before the visit begins, patients are asked to provide a list of symptoms and to complete a short questionnaire describing the reason for their visit. When the clinician is available, the patient is prompted to join the video visit and the appointment begins. Video and audio are provided throughout the visit using the smartphone’s built-in camera and microphone.

Video visits with a clinician and “Exam and Forward” are supported using the hand-held Tyto Device.¹² Along with a touchscreen on the front, the Tyto Device includes an integrated camera, integrated infrared thermometer, and attachment ring for the included adaptors on the back. Using the touchscreen, patients or caregivers can collect data and images to support the:

- ear exam (using the digital otoscope adaptor)
- heart and lung sounds exam (digital stethoscope)
- heart rate exam (digital stethoscope)
- skin exam (integrated camera)
- temperature taking (integrated thermometer)
- throat exam (tongue depressor).

Health care organizations in the US have also indicated that TytoHome can be used to evaluate digestive issues (i.e., listening to bowel sounds using the digital stethoscope) and to support comprehensive physical examinations.^{14,15}

If needed to support a real-time video visit, the Tyto Device is controlled remotely by the clinician, who guides the patient or caregiver in its placement and use throughout the examination.¹² Examination data (e.g., images, sounds) are available to the clinician in real time.

Patients and caregivers may also send examination data to their clinician at a time outside of a video visit. When using the Exam and Forward feature of TytoHome, patients or caregivers are guided in the placement and use of the Tyto Device using instructions displayed on the device’s touchscreen and in the

TytoApp. Once collected, the examination data are sent to the requesting clinician for review through the TytoApp.

Availability

TytoHome was licensed as a Class 2 medical device by Health Canada in 2018.¹⁶ In Canada, TytoHome is available for purchase by patients of the Cleveland Clinic Canada¹⁷ alone or as part of its Express Care Online service.¹⁸ According to the manufacturer, the system is also available from three other Canadian telehealth vendors (Menahem Shikhman: personal communication, Nov 16, 2020). In the US, TytoHome is available for purchase from BestBuy¹⁹ and is a care option for patients in some health care organizations.^{14,15,20-23}

Cost

The Cleveland Clinic Canada lists the price of TytoHome as CA\$599. In the US, the retail price of TytoHome is US\$299.^{19,24} Appointments with a TytoHome clinician are reported to cost up to US\$59 per visit.²⁴ In Canada, TytoHome can be purchased alongside access to the Cleveland Clinic Canada’ Express Care Online service. A one-year subscription to Express Care Online plus a TytoHome system costs:²⁵

- CA\$898 (individual access)
- CA\$1,048 (individual and partner)
- CA\$1,098 (individual and family).

The cost of continued access to the Express Care Online service for one year is CA\$299 (individual), CA\$449 (individual and partner), or CA\$499 (individual and family).²⁶

Additional patient and caregiver costs include those associated with high-speed wireless internet and smartphone or tablet ownership.

The costs associated with acquiring, accessing, and implementing TytoHome for health care providers or health care organizations were not identified.

Who Might Benefit?

Because they are intended to support remote examinations, devices like TytoHome could help facilitate virtual visits not currently recommended due to safety, feasibility, and liability concerns.^{7,8} While the largest proportion of health care visits in Canada (prior to the COVID-19 pandemic) occur in-person – regardless of geographic location, age, sex, or care need – patients have repeatedly been found to be ready and willing

to receive care through a virtual visit.^{5,6} Findings from surveys commissioned by the Canadian Medical Association in 2018 and 2020 provide some understanding of which patients may benefit most from enhanced virtual visits using devices such as TytoHome. These include:

- people who have already had a virtual visit, younger people, and people who were already frequent users of the health care system (who were all found to be more likely to say they would use virtual visits for more than one-half of their visits than other respondents)⁶
- people without a family doctor were found to be more likely to access care through a virtual visit compared with people with a family doctor.⁵

Additionally, one US health care organization suggests that TytoHome may be most beneficial to families with children wishing to avoid trips to a physician's office or an emergency department for a diagnosis.¹⁵

The shift away from in-person visits during the COVID-19 pandemic provided the opportunity to ask patients in Canada about their preferences for receiving care following the pandemic and also offers insight into which patients could benefit from devices like TytoHome.⁵ For example, nearly 40% of respondents indicated that virtual visits are ideal for first-contact appointments for their complex needs (40%), routine needs (36%), or basic needs (39%).⁵

Current Practice

While virtual visits are not a new concept in Canada's health care system, the COVID-19 pandemic led groups across the country to quickly develop new guidance to support and encourage their use.^{7,27} Much of this guidance aligns with guidance provided to clinicians in the 2020 *Virtual Care Playbook* produced jointly by the Canadian Medical Association, the College of Family Physicians of Canada, and the Royal College of Physicians and Surgeons of Canada.⁸ In general, according to the guidance, care suitable for virtual visits excludes assessments of ear pain, cough, or where it is necessary to listen to heart and lung sounds to evaluate the patient.⁸ The Canadian Medical Protective Association's COVID-19 guidance also explicitly states that virtual visits are "not a substitute for in-person assessments and clinical examinations."⁷

Summary of the Evidence

One study of the TytoHome system²⁸ and one study of an unspecified Tyto system (described only as the "Tyto Device") were identified in the literature.²⁹ Both studies received funding from the manufacturer.

In a randomized, non-blinded study, Notario et al. assessed the feasibility and usability of the TytoHome system for a home-based remote examination by caregivers of 24 children with medical complexity previously enrolled in a US pediatric complex care program.²⁸ The primary outcomes measured were the ability of clinicians to connect with patients using the system (feasibility), the ease of use of the TytoHome system, and the acceptability of video, image, and sound quality (usability).²⁸ Secondary outcomes of the study assessed the impact of TytoHome on health system resource utilization (e.g., hospitalizations, emergency room visits) and clinician and family satisfaction compared to a control group.²⁸

In a diagnostic cohort study, McDaniel et al. assessed the clinical validity and reliability of the Tyto Device in 50 children receiving care at a US pediatric cardiology clinic.²⁹ The primary outcome (diagnostic equivalence) compared the quality of heart sounds, lung sounds, and images of the tympanic membrane captured by the Tyto Device with those captured by other, stand-alone, digital examination devices already in use in the clinic's telemedicine program.²⁹ The study's secondary outcome compared the clinical findings (i.e., no clinical finding, significant clinical finding, and presence/absence of significant clinical finding could not be determined) of the Tyto Device to those from the other devices to assess which device best provided accurate clinical information.²⁹

Overall, both studies concluded the system would be a useful tool for supporting remote physical examinations in children with complex medical conditions.

Results

Interpretation of the results of both identified studies are limited by their small size.^{28,29} The primary outcomes examined (feasibility, utility, diagnostic equivalence) may also be of limited use in understanding the place of TytoHome in clinical practice.

Health System Resource Utilization

In their secondary outcomes, Notario et al. found mixed results regarding the use of health system resources between patients assigned to receive care using TytoHome and those assigned to the control group.²⁸ The authors reported that patients in the TytoHome group had a greater rate of emergency department visits and acute office visits compared with the control group. Conversely, the TytoHome group had a lower rate of hospital admissions and a lower rate of intensive care unit (ICU) admission than the control group. Regarding the avoided use of health system resources, the authors reported seven telehealth visits in the TytoHome group that prevented an in-person visit. This included the prevention of three emergency department visits, three outpatient visits, and one ICU admission.

Feasibility

Notario et al. reported that clinicians successfully connected with patients using the TytoHome system in 46 of 50 (92%) encounters. In nine of the 46 successful connections (19.6%), clinicians reported the connection as problematic.²⁸

Usability

Overall, Notario et al. reported that caregivers and clinicians found the usability of the system to be acceptable, with the exception of the otoscope, where ear wax build-up or caregiver discomfort in using the device were reported to affect the usability of this attachment.²⁸

Diagnostic Equivalence and Utility of Information

McDaniel et al. reported the heart sounds, lung sounds, and tympanic membrane images captured by the Tyto Device to be of higher quality compared with the other stand-alone digital examination devices (i.e., digital stethoscope and digital otoscope) already in use in the study clinic's telemedicine program.²⁹

McDaniel et al. also reported that the Tyto Device was more likely to capture clinical information (i.e., images and sounds) to support a clinical finding than the stand-alone digital examination devices already in use in the study clinic's telemedicine program.²⁹

Other Research

The manufacturer's website reports three additional studies of the Tyto Device:³⁰

- a pilot project that deployed the professional version of TytoHome (TytoPro, described later) to schools in North Carolina³¹
- a prospective study of the Tyto Device to assess children presenting to the emergency department of a pediatric children's hospital in Israel³²
- a case study about the implementation of the TytoClinic in a large US health system's home-based palliative care program.³³

According to the manufacturer, TytoHome has also been evaluated with:

- employees of a major US retail company
- patients of a health care organization in Israel, where the system was deployed following the results of an evaluation³² and subsequent pilot study

- members of a private Swiss health insurance provider
- patients of a private US pediatric health care organization
- patients of a US telehealth provider (Menahem Shikhman: personal communication, Nov 16, 2020).

Safety

No studies evaluating the safety of using TytoHome to support remote examinations were identified. Neither of the identified studies examined or reported safety outcomes. The US FDA considers the safety of the stethoscope adaptor and the built-in thermometer to be similar to other equivalent digital devices.³⁴⁻³⁶

Cost-Effectiveness

No studies evaluating the cost-effectiveness of TytoHome were identified. The secondary outcomes in one study of children with complex medical conditions reported a US\$9,425 per patient savings driven by fewer hospitalizations and not including patient costs such as travel and lost wages.²⁸ Potential cost savings of implementing TytoHome have also been reported in unpublished case studies (Menahem Shikhman: personal communication, Nov 16, 2020).

Patients' Perspectives

In their study of children with medical complexity, Notario et al. surveyed caregivers (n = 13) about their satisfaction using TytoHome.²⁸ The authors reported that respondents reported being satisfied and comfortable using the system and that they found TytoHome easy to use. Additionally, the authors reported that, although survey scores did not change, comments provided by caregivers suggested that they became more comfortable using the system over the course of the study. One caregiver also commented that the ability to access care through telehealth (TytoHome) reduced their worries of staying at home.

Concurrent Developments

In addition to TytoHome, TytoCare Ltd. produces two other systems built around the Tyto Device:¹³

- TytoPro (licensed by Health Canada as a Class II medical device³⁷) – intended for virtual visits facilitated by health care professionals and designed with more robust hardware for everyday office use
- TytoClinic – a portable telehealth clinic intended for use in locations such as schools and long-term care facilities that, in addition to the TytoPro system, includes a pulse oximeter, blood pressure cuff, and an iPad with stand.

One additional study of the Tyto Device was identified in a clinical trial registry.³⁸ The study (status unknown) is intended to evaluate the use of the Tyto Device's thermometer to assess body temperature compared with another infrared thermometer and a standard of care thermometer.³⁸ Published results of this study were not identified.

Similar connected devices to TytoHome that could support remote examination of patients include:

- DUO ECG + Digital Stethoscope (Eko Devices, Inc., Oakland, California), a combination digital stethoscope and electrocardiogram prescribed to patients by clinicians for use with a companion smartphone app³⁹
- StethoMe (StethoMe sp. z o.o., Poznań, Poland), a hand-held digital stethoscope and companion smartphone app that uses artificial intelligence to allow patients to assess heart and lung sounds remotely.⁴⁰

Operational Considerations

Many of the potential issues related to the implementation and uptake of TytoHome in the Canadian health care system can be expected to be like those associated with the uptake and implementation of virtual visits more generally. A 2020 CADTH Policy Insights report identified three key areas for enabling virtual visits in Canada:⁴¹

- legislative and regulatory modernization (i.e., physician remuneration, physician licensing, and information privacy and security)
- technology adoption (i.e., interoperability and standardization, patient capacity to use technology)
- improved patient and clinician experience (i.e., continuity of care, acceptance of virtual visits, broadband internet access).

In addition to these issues, the 2020 *Virtual Care Playbook* identifies a number of other issues clinicians must consider prior to implementing virtual visits.⁸ These include:

- appropriate hardware (e.g., large monitors, a high-resolution camera, high-quality headphones and microphone) and software (e.g., secure and privacy legislation compliant) for the clinician
- establishing a schedule that can accommodate virtual visits.

When considering TytoHome (or similar devices) specifically, several additional issues — many of which related to equitable access to the device — may emerge, including:

- the costs of the device, smartphone, wireless high-speed internet, and appointments borne by patients if not covered by private or public insurance programs
- access to reliable wireless high-speed internet to transmit examination data (an issue that required correction in one study of TytoHome²⁸) that cannot be addressed by using another medium for the visit, such as the telephone
- a need for familiarity with the device in order to successfully complete remote examinations (an issue that emerged in one study of TytoHome, but for which the authors noted an improvement over the course of the study that may not be feasible for all patients)²⁸
- the ability of patients living alone to complete some remote examinations (e.g., lung sounds) that require positioning the device behind the back or in other awkward or difficult-to-reach positions.

Final Remarks

Public funding and the implementation of technologies such as TytoHome in Canada may require additional research and planning to ensure equitable access, as well as an understanding of which patients, with what health concerns and in which settings, would benefit most from its use. For example, while the available evidence suggests TytoHome could benefit patients with complex or specialized care needs, the system is marketed to a population of patients and their families without complex or specialized care needs who have not been participants in the published, peer-reviewed studies. The rapid shift by patients, clinicians, and the health care system during the COVID-19 pandemic from in-person care to virtual care (including virtual appointments) may help facilitate answers to these questions, as could shifting patients' preferences and expectations for receiving comprehensive care from the location of their choosing.

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