

O₂ Connectors: US clinician experience and preferences, implications for adoption of universal design

Michael Pedro, MD, Medical Director and Vice President,
Vyairé Medical

Company Statement

This white paper is shared with our healthcare colleagues to increase knowledge about the experience of health care professionals with O₂ adapters and connectors, including single-use or reusable Christmas-Tree adapters and universal connectors. Vyairé Medical is not seeking to promote, endorse or advise the use of its products for O₂ delivery settings. The use of any O₂ delivery system must first be reviewed and evaluated by each facility's medical and administrative staff before implementation.

Introduction

The use of oxygen (O₂) during medical procedures is ubiquitous and benefits patients. O₂ delivery systems have distinct physical connection designs that create the need for different sized O₂ tubing unless an adapter for the connection or hose is used. The most common O₂ adapter is a single-use nipple and nut design, also known as a Christmas-Tree adaptor (CTA). However, without adequate training on proper use of CTAs, their incorrect reuse with connectors is common, particularly a failure to replace after each patient use. Also problematic are reusable CTAs that require disinfection after each patient, a process that requires time, resources and adherence to standards to effectively avoid healthcare-associated infections (HAIs). A convenient alternative to such adapters is the universal O₂ connector affixed to O₂ tubing that enables connection directly to a flowmeters with or without a CTA. This universal design offers time savings, and potential to reduce HAIs and equipment costs. Moreover, a recent survey of respiratory therapists revealed preference for universal O₂ connectors compared to standard connectors employing CTAs. Overall, respondents rated universal O₂ connectors as easier to use compared to standard O₂ connectors with a CTA ($p = 0.013$). Also, more therapists rated universal O₂ connectors as equally easy (45 percent), or much easier (19 percent) relative to standard O₂ connectors ($p < 0.0001$).

Background

The use of oxygen (O₂) during medical procedures is ubiquitous and benefits patients in settings that include the operating theater, recovery room, inpatient hospital room,

or transport. Essential for anesthesia breathing circuits, O₂ also reduces the incidence of hypoxemia and wound infection in non-

anesthesia settings, as well as plays a role in decreasing nausea and vomiting.^{1,2,3,4,5}

However, O₂ delivery systems have distinct physical connection designs that create the need for different sized O₂ tubing unless an adapter for the connection or hose is used.

Use of adapters is common in acute care settings. However, without easy adaptation, the diversity in equipment specifications can create a burden on staff time, equipment and costs, which can lead to incorrect reuse of adaptors or hinder the use of supplemental O₂ in other settings, such as transport to recovery.⁶

The most common O₂ adapter is a green conical, tiered nipple and nut design, also known as a Christmas-Tree adaptor (CTA) (Figure 1). This adapter keeps tubing in place and limits leaks during O₂ delivery to the patient.

The CTA features tiered “branches” to secure tubing while the bottom houses a nut to screw the adapter onto the oxygen outlet’s concentrator nipple.



Figure 1: Christmas-Tree Adaptor. Source: Vyaire Medical, Inc.

O₂ ADAPTOR REUSE AND INFECTION CONTROL

A limitation of most CTAs is that they are a vulnerability for infection control when not used correctly. Most CTAs are single-patient use devices, but many CTA manufacturers do not explicitly label their adaptors as such, and health care professionals may assume the device can be reused, which makes the adapter a possible source of a healthcare-associated infection (HAI).

About 1 in 31 U.S. patients daily develops at least one infection in association with hospital care, including ventilator-associated events.⁷ HAIs not only add illnesses but also deaths, with associated expenses that cost billions of dollars to the U.S. healthcare system.⁸

To aid in infection prevention and control, reusable devices for patient care delivery must be reprocessed only with appropriate cleaning, disinfection, and/or sterilization as described in the manufacturers’ instructions for use (IFUs).

The U.S. Food and Drug Administration (FDA) requires reusable devices to have IFUs, which also must indicate the number of times a device can be reprocessed.⁹ The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) helps safeguard reprocessing by requiring the use of IFU standards unless the hospital has a validated procedure for any deviation.¹⁰

In contrast, the FDA specifies that single-use devices are disposable and

“...intended for use on one patient during a single procedure. It is not intended to be reprocessed (i.e., cleaned and disinfected or sterilized) and used on another patient. If a device does not have reprocessing instructions, regardless of labeling, it should be considered single-use and disposed of appropriately (i.e., according to federal, state, and local regulations) after one use.”¹¹

2017 SURVEY POINTS TO LACK OF O₂ ADAPTOR EDUCATION

Despite these guidelines and regulations, misuse of single-patient use CTAs via reuse appears to be common in the absence of targeted education. For example, a 2017 survey and education project conducted by staff at Loma Linda University Health of 48 healthcare professionals in one hospital acute care setting characterized the misuse of CTAs and the role of education in re-establishing correct CTA use.¹²

The study found via a baseline survey that 65 percent of nurses, patient care assistants and other hospital staff did not follow manufacturer IFU guidelines for single-patient use CTAs and reusable adaptor regarding reuse. Of those surveyed, only 35 percent reported switching single-patient use CTAs after each patient, 39 percent switched after every shift, 23 percent only switched after the single-patient use CTAs appeared soiled and 3 percent reported never switching the single-patient use CTAs .

The study's intervention was an educational project on appropriate use of single-patient use CTAs to staff, including discussion in staff huddles at shift starts, postings on the adaptor situation, background, assessment, recommendation (SBAR) in common staff areas, emails and auditing to the discharge checklist. After education, compliance to single-patient use CTA manufacturing IFU increased 150 percent, with 93 percent of staff reporting switching single-patient use CTAs after each patient.

Reusable adapters for O₂ connectors, which typically are disinfected after each patient use, also are problematic because the cleaning and sterilization process requires time, resources and adherence to IFUs or validated standards to effectively avoid HAIs.

Alternatively, universal O₂ connectors offers time savings, and the potential to reduce HAIs and equipment costs, particularly for acute care settings. These connectors attach O₂ tubing directly to flowmeters without the need for a CTA, although they may also be used with a CTA. The universal connectors use tube-ends cuffs that lock to 7/8" (22mm) connections (Figure 2)



Figure 2: Disposable Vinyl-tipped Oxygen Tubing with a U/Connect-It Connector. (Source: Vyair Medical)

New Survey Reports O₂ Adaptor Experience and Preferences

A recent survey of respiratory therapists reported in this paper reveals preference for universal O₂ connectors compared to standard connectors using single-patient use CTA or reusable O₂ adapters.

DESIGN

To evaluate respiratory therapists in U.S. healthcare facilities use, training, and preferences about O₂ adapters and connectors, Vyair Medical, Inc. fielded an online survey using SurveyMonkey Inc., from March 15 to 26, 2021. Candidate respondents received a survey link via email from Vyair's sales force staff.

The survey employed 20 questions that included an answer mix of yes/no, multiple choice, or Likert scale ratings as well as a single question using an open text field in which respondents could explain the rationale for their answers (Appendix).

The survey design used logic to automatically skip questions not relevant to the respondent based on previous answers. For example, participants that indicated only use of reusable adapters at their facility were not asked how often they switched out single-patient use CTAs.

The Likert scale questions asked respondents to rate their response to a statement based on a five-level scale: for example, very difficult, difficult, neutral, easy, and very easy. Other questions had Likert scales that ranged from strongly disagree to strongly agree or much more difficult to much easier.

ANALYSES

Of the 48 respondents completing the survey, the majority of respondents answered all relevant survey questions, with a median of two respondents skipping a given question. Data from incomplete survey responses were included in the analyses.

Visualization of the distribution of responses to the questions used diverging stacked bar plots. Investigators then compared the proportion of respondents stating a neutral or agree responses to the proportion of disagree answers using the one-sample z-test for proportions.

As an additional analysis, the researchers applied a linear scale from -2 (e.g., very difficult) to 2 (e.g., very easy), calculated the mean response and performed one-sample t-tests to compare the mean response to neutral (i.e., score = 0).

Investigators powered the survey sample size based on the following question: "How do you rate using universal O₂ connectors vs. using standard O₂ connectors with O₂ nipple (Christmas tree) adapters?" Specifically, at least 35 participants were required to show whether the majority of respondents rated universal connectors at least as easy to use as standard O₂ connectors with a CTA. The researchers assumed the true population that rate universal O₂ connectors positively was 70 percent, 5 percent Type I error rate, and 80 percent power.

RESULTS

All the respondents to the survey (48/48, 100 percent) were members of their hospital's respiratory therapy staff. The majority of respondents (34/48, 71 percent) used single-patient use CTAs, with half exclusively using single-patient use (24/48, 50 percent) while some worked at facilities using a mix of single-patient use and reusable adapters (10/48, 21 percent).

The results of the survey suggest many facilities do not offer adequate training on the proper use of single-patient use CTAs. Less than half of the respondents (22/46, 48 percent) correctly identified the JCAHO guideline that reuse of CTAs must following the manufacturer's IFU.

Furthermore, just one-third (15/46, 33 percent) reported the availability of formal training on

the use of CTAs to them and these trainings usually occurred only once (9/15, 60 percent) or a few times annually (5/15, 33 percent).

Perhaps because of inadequate training, reported incorrect use of O₂ adapters by respondents was common. For facilities using single-patient use CTAs, nearly one-third (10/33, 30 percent) reported not properly switching the adapter after each patient. Proper use was more common for reusable adapters, with most therapists (25/29, 86 percent) responding that they disinfected the devices after each patient.

Universal O₂ connectors can be connected directly to a flowmeter or to a flowmeter with a CTA. Overall, respondents reported that both connecting and disconnecting a universal O₂ connector directly to a flowmeter or a CTA to be relatively easy. Most therapists (between 26 and 36 out of 43, 60 to 84 percent) reported it was easy or very easy to connect and disconnect a universal O₂ connector with or without a CTA.

The remaining survey questions explored the respondents' experience and preferences of

standard and universal O₂ connectors. Nearly all therapists (45/48, 94 percent) reported familiarity with universal O₂ connectors. More therapists were neutral (13/43, 30 percent), agreed (15/43, 35 percent), or strongly agreed (10/43, 23 percent) that using universal O₂ connectors saved them time during their shifts [Figure 3 (top), 38/43, 88 percent, z-test, p < 0.0001]. The therapists' average rating for universal O₂ connectors was positive (0.67, t-test, p < 0.0001).

Overall, respondents rated universal O₂ connectors as easier to use compared to standard O₂ connectors with a CTA (mean score: 0.36, t-test, p = 0.013). More therapists rated universal O₂ connectors as equally easy (19/42, 45 percent), easier (7/42, 17 percent), or much easier (8/42, 19 percent) relative to standard O₂ connectors [Figure 3 (bottom), 34/42, 81 percent, z-test, p < 0.0001].

In the open text answer explaining the rationale for their rating, the therapists' responses reiterated the findings from the survey: that universal O₂ connectors are time-effective, cost-effective, reduce infections, and are preferred in an emergency.

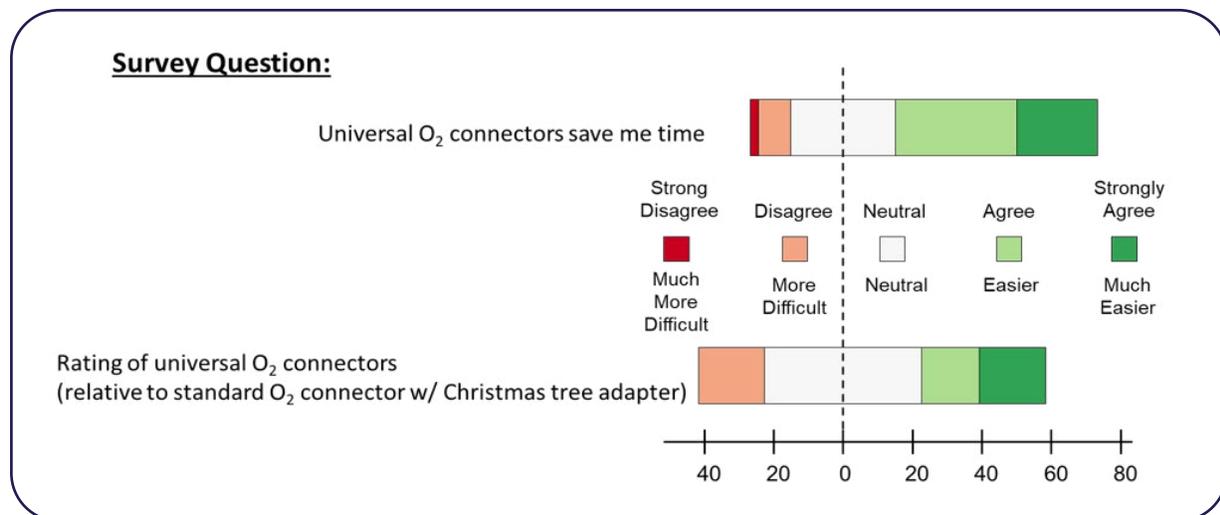


Figure 3: Distribution of Responses to Questions Rating Universal O₂ Connectors.

The stacked bar graphs visualize the Likert scale responses. Rating for the top question ranged from Strongly Disagree (dark red) to Strongly Agree (dark green), while ratings for the bottom question ranged from Much More Difficult (dark red) to Much Easier (bottom) (dark green). The width of bar segments is proportional to the percentage of respondents providing that answer. The bars representing the neutral responses (white) are centered on the y-axis. Note that both stacked bars are biased to the right because more respondents answered positively to the questions.

Discussion

Infection prevention and control to protect the health of patients receiving O₂ therapy could improve with proper adherence to JCAHO guidelines on use of disposable CTAs and reprocessing of reusable equipment for connecting O₂ sources with tubing.

Currently, respiratory therapists do not receive adequate training on the proper use of single-patient use CTAs, which can lead to their lack of replacement and incorrect reuse, according to the current study. Failure to follow JCAHO guidelines also brings the risk of levying fines on the facility. When JCAHO guidelines are followed, staff time must be spent on disposal and replacement of the single-patient use CTAs.

The use of reusable O₂ adapters requires disinfection after each patient, a process that also consumes time and resources, particularly to adhere to validated cleaning protocols to effectively avoid HAIs as defined by the adapters' IFUs.

In contrast, universal O₂ connectors offer an easier to use connection that saves staff time while following infection control standards. Most therapists surveyed stated a preference for universal O₂ connectors compared to standard O₂ connectors with an O₂ adapter.

Of note, in addition to their convenience, time savings, and reduction in HAIs, universal O₂ connectors have potential to save healthcare facilities money compared to using standard O₂ connectors with single-patient use CTAs.

For example, the \$0.81 per unit cost of Vyair's U/Connect-It™ universal O₂ connector is less than the combined cost of a standard O₂ connector and single-patient use CTA, \$0.88. With an average savings is \$0.07 per item, the total savings for a given facility could rapidly increase when the volume of units is considered. As illustrated in Table 1, the predicted average annual savings could exceed \$24,000 for a hospital consuming a high volume of connectors after switching to universal adapters. The savings estimates were based on individual hospitals' actual pricing with Vyair and assumed facilities replace single-patient use adapters after each patient.

Table 1. Predicted Annual Savings of Switching to U/Connect-It Universal O₂ Adapters From Standard O₂ Adapters with CTAs

| Hospital Rank (Volume of Annual Total Standard O ₂ Adapters Purchased) | Average Annual Standard O ₂ Connector Units Purchased | Average Annual Savings |
|---|--|------------------------|
| Top 10 | 151,573 | \$24,781 |
| Top 11 – 25 | 69,931 | \$8,764 |
| Top 26 – 100 | 44,383 | \$5,908 |
| Top 101 – 250 | 24,725 | \$3,325 |
| Top 251 – 1,000 | 10,223 | \$1,059 |

Average annual savings estimates are based on actual pricings for the top 1,000 out of a total of 13,072 individual hospitals. Average savings assume facilities replace single-patient use adapters after each patient. Data Source: Historical Vyair sales data.

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26125 North Riverwoods Blvd, Mettawa, IL 60045, USA

vyaire.com

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Appendix

Survey Questions and Answers



1. Please select your current role

- Respiratory Therapy Staff
 - Nursing RN
 - Other (specify below)
-

2. Which type of O₂ nipple (Christmas tree) adapter does your facility use?

- Disposable (Single-Patient Use)
- Reusable
- Mix of both disposable and reusable
- Don't use O₂ nipple (Christmas tree) adapters
- Don't know

3. When using disposable or single-patient use O₂ nipple (Christmas tree) adapters, how often are they switched out?

- After every shift
- Only when soiled
- After each patient
- Rarely, but they are wiped down/disinfected periodically
- Don't know
- Not applicable

4. When using reusable O₂ nipple (Christmas tree) adapters, how often are they wiped down/disinfected?

- After every shift
- Only when soiled
- After each patient
- Rarely, but they are wiped down/disinfected periodically
- Don't know
- Not applicable

5. Which statement best describes the Joint Commission's (JCAHO) guidelines regarding the reuse of O₂ nipple (Christmas tree) adapters?

- None of the above
- The manufacturer's instructions for use (IFU) must be followed, unless validated hospital protocol exists to deviate
- All O₂ nipple (Christmas tree) adapters may be reused if they are properly disinfected
- All O₂ nipple (Christmas tree) adapters must be disposed of after each patient

6. Are you aware of any formal training or education given by your facility on the proper use of O₂ nipple (Christmas tree) adapters?

Yes

No

7. Have you participated in any formal training or education given by your facility on the proper use of O₂ nipple (Christmas tree) adapters?

Yes

No

8. How often does your facility educate its staff about the proper use of O₂ nipple (Christmas tree) adapters?

After every shift

Once a week

Once a month

Few times a year

Once

9. During my shift, it is inconvenient to search for an O₂ nipple (Christmas tree) adapter if one is needed.

Strongly agree

Agree

Neither agree or disagree

Disagree

Strongly disagree

10. Have you used or are you familiar with universal O₂ connectors (pictured left)?

Yes

No

11. Universal O₂ connectors save me time during my shift.

Strongly agree

Agree

Neither agree or disagree

Disagree

Strongly disagree

12. How would you rate connecting a universal O₂ connector directly to a flowmeter?

Very easy

Easy

Neither easy nor difficult

Difficult

Very difficult

13. How would you rate connecting a universal O₂ connector directly to an O₂ nipple (Christmas tree) adapter?

Very easy

Easy

Neither easy nor difficult

Difficult

Very difficult

14. Connecting a universal O₂ connector directly from a flowmeter is easy.

Strongly agree

Agree

Neither agree or disagree

Disagree

Strongly disagree

15. Disconnecting a universal O₂ connector directly from an O₂ nipple (Christmas tree) adapter is easy.

Strongly agree

Agree

Neither agree or disagree

Disagree

Strongly disagree

16. Have you used a universal O₂ connector with a nebulizer when giving a neb treatment?

Yes

No

17. When giving a neb treatment, was the universal O₂ connector used with an O₂ nipple (Christmas tree) adapter or attached directly to the flowmeter?

Used with an O₂ nipple (Christmas tree) adapter

Attached directly to the flowmeter

I've given neb treatments both ways

18. When giving a neb treatment using a universal O₂ connector used with an O₂ nipple (Christmas tree) adapter did the universal O₂ connector ever become disconnected from the Christmas tree?

Yes

No

19. At what flow rate did the universal connector become disconnected?

0 – 5 lpm

6 –10 lpm

11 – 15 lpm

>15 lpm

I don't know

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20. How do you rate using universal O₂ connectors vs using standard O₂ connectors with O₂ nipple (Christmas tree) adapters? Universal O₂ connectors are:

Much easier

Easier

Same

More difficult

Much more difficult

21. Explain why you chose your answer in the previous question.