

Surgical Outcomes Auditing Systems in Humanitarian Organizations

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Abstract

Background Operation Smile is a humanitarian volunteer-based organization that provides cleft care around the world. Successful primary surgery is the key to improving the quality of life of patients with oral clefts. A cleft surgery outcomes database and evaluation system has been developed and implemented.

Methods During Operation Smile's "World Journey of Smiles" in November 2007, a total of 4100 patients were operated on during a 10-day period at 40 simultaneous missions in 25 countries. Photographs taken before surgery, right after surgery, and at the follow-up consultations were entered in a database and used as media to evaluate surgical outcomes objectively by independent unbiased evaluators. Data about complications collected during the postoperative consultations were also entered.

Results A postoperative consultation, 6 months to 1 year after surgery was conducted at 24 sites, 19 of which sent back postoperative images; and most returned postoperative examination forms. At those 19 sites, 703 of 1917 patients returned for a 6- to 9-month postoperative visit, for a 36.67% return rate. After matching before and after pictures, 562 patients were able to be entered into the database, allowing 580 procedures to be evaluated. Feedback reports have been sent to 134 volunteer surgeons around the world. Results were compared among sites and locations; and the places where future actions were needed to improve the quality of surgery were identified.

Conclusions The current outcomes evaluation system has proven beneficial in tracking patient outcomes, auditing surgical performance, and providing feedback to surgeons and other team members. Challenges are discussed.

Introduction

Orofacial clefting is the second most common birth defect and the most frequent of all birth defects affecting the craniofacial region. Cleft lip, with or without cleft palate, is among the most common of all major birth defects, occurring with an incidence of 1:500 to 1:2500 in various populations; the incidence varies with geographic location, ethnic group, and socioeconomic conditions [1]. Approximately 270,000 babies will be born with oral clefts in 2009. This number illustrates how big the problem is and shows the need to address such deformities at a truly global level. Specialized corrective surgery is needed to improve the patient's appearance and function. Subsequent impairment of nasolabial appearance, maxillofacial and dental development, speech, and hearing are common and produce significant functional disabilities. These are also accompanied by psychosocial maladjustment. Interdisciplinary cleft care—including surgery, speech, nursing, ear/nose/throat (ENT), orthodontics, social work, and psychology, among others—is highly recommended to maximize a child's potential.

There are limited global health resources, especially when dealing with non-life-threatening conditions such as oral clefts. In developing countries, there is a huge backlog of untreated cleft patients due to limited health resources coupled with the reality that most patients need an average of three staged surgical procedures and highly specialized multidisciplinary treatment, which may not be even a remote possibility in their home setting.

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The humanitarian volunteer-based model has been highly successful at not just providing surgical and comprehensive care but with mobilizing goodwill and encouraging volunteer work as an expression of a concerned and caring society. Volunteers (local and international) should maintain the highest standards of care and work in conjunction with local health care providers, transferring skills and exchanging knowledge with them [2].

Operation Smile operated on 134,520 cleft patients during its first 25 years. The organization has evolved according to each country's characteristics and needs, from

- a purely international mission model (care provided by international health care providers)
- to a mixed model with international and local missions (care provided mainly by local teams with input from international volunteers)
- to local missions (care provided by purely local teams)
- to Cleft Care Centers (where interdisciplinary cleft care is provided by local health providers in a daily base) [3]

All of these scenarios are conducted with a constant global standard of care, demanding infrastructure that would allow international excellence. This growth and evolution has improved access to surgery but has made it more difficult to monitor the standards of care accurately for the wide range of outcomes that need to be measured, including hearing, speech, facial growth and appearance, oral health, and malocclusion [4, 5].

As with any other health organization, there is concern about complications and bad outcomes that may compromise a patient's future and add to the burden of cleft care. Volunteers must be audited for their performance, and outcomes improvement systems should be designed. Successful primary operations can minimize the need for multiple secondary revisions and allow more primary cases to be treated. Successful primary repairs are likely to reduce the duration and complexity of treatment, reducing the need of ancillary procedures, such as speech therapy, orthodontics, and maxillary osteotomies.

Evidence-based knowledge about the ideal care for children with cleft lip and palate is rare; there are few well conducted intercenter or prospective studies with large samples of patients. Prospective randomized clinical trials are extremely difficult to conduct owing to small sample sizes and obvious ethical issues. A wide range of cleft management protocols exist throughout the world, yet the diversity of practice is startling. The Eurocleft study was based on a registry of 201 centers among which there were 194 different cleft treatment protocols [6]. The current evidence shows that simple treatment protocols that minimize the burden on the child can produce equivalent or better results than complex ones [7, 8], but no evidence exists to prove the opposite. Few

studies have examined large patient sets that put forward best practices for optimal outcomes in cleft repairs. Additionally, one of the big pieces missing in the medical literature is the use of unbiased evaluations, where series of outcomes are evaluated by external evaluators who have no interest in proving or denying any researcher's hypothesis.

The ultimate goal of cleft care is to provide the patient a "normal" life, without handicap or disability. However, the measurement of overall normalcy is a highly complex proposition. The measurement system must reflect the degree of handicap that persists despite (or as a result of) treatment, such as shortcomings in nasolabial appearance, palate integrity (fistulas), velopharyngeal function (speech), hearing, dentoskeletal development, and finally psychosocial adjustment.

Within the field of craniofacial surgery, there is a tendency to try to assess outcomes as soon as possible [9]. However, it has been widely accepted that obtaining final outcomes takes an extended period of time; and for accuracy reasons, outcomes should not be evaluated too early. Although this may be true for speech and craniofacial growth, it may not retain its validity for some important facial characteristics, such as lip or nose symmetry. Our studies have shown that adequate assessment of nasolabial appearance is possible within as little as 1 year after surgery. Speech, hearing, and the impact on skeletal growth take longer to assess. Although waiting to assess certain outcomes is vital for obtaining accurate data, it is important to detect surgeons with bad outcomes and harmful or unnecessary procedures as soon as possible. Atack et al. [10, 11] proved that harmful or unnecessary treatment modalities could be detected within 5 years of implementation by demonstrating statistically significant intercenter differences in craniofacial growth by the age of 5 years.

Methods

A pilot cleft outcomes program was implemented during Operation Smile's "World Journey of Smiles" (WJOS) in November 2007. During a 10-day period, 1900 volunteers—700 from the United States and 1200 from 43 other participating countries—provided surgery for 4100 patients at 40 simultaneous mission sites in 25 countries. Preoperative and immediate postoperative photographs were taken of each patient. Local foundations were encouraged to organize 6-month to 1-year postoperative evaluations to assess the patients' progress and collect follow-up images and outcomes data.

At all mission sites, standardized high-quality digital images are collected by trained volunteers before surgery

(during screening and once under anesthesia before surgery begins), immediately after surgery (while still under anesthesia), and at the 1-week, 6-month, and 1-year postoperative visits. The images, as well as postoperative examination forms for each patient, were sent back to the Outcomes Coordinator at Operation Smile headquarters in Norfolk, VA (USA). The 6-month pictures and postoperative forms were matched with the original mission pictures and medical charts to create an outcome evaluation for each patient.

Frontal and basal view images, as well as pictures of the hard and soft palate, were cropped to protect the patient's identity, eliminate any reviewer bias, and allow the evaluator to focus on only the surgical area [12].

Cropped images were then inserted into a FileMaker database that is used as an evaluation template containing fields for scoring outcomes and noting complications (Figs. 1, 2). Presurgery and 6-month postoperative pictures were placed next to each other so the before and after conditions can clearly be seen. All complications and physician notes, as well as drawings of fistula locations, were included in each patient evaluation. Additional pages contained postsurgery images and speech sample evaluation forms. The patients' chart numbers were removed, and the evaluation was given an identifying letter to maintain patient confidentiality. Compiled evaluations, including presurgery, postsurgery, and 6-month postoperative pictures, were then sent to an unbiased member of the International Outcomes Council, comprised of plastic surgeons with great experience working with clefts. The evaluator then scored the outcomes using a standardized evaluation system previously developed and tested for reliability.

The qualitative assessment of the nasolabial appearance has been used as a reliable system of evaluation of the surgical outcomes, allowing outcomes comparisons among centers [13]. Facial symmetry is a proven way to measure surgical outcomes [14–16], and it is a key factor when measuring attractiveness and patient satisfaction. Symmetrical outcomes of unilateral and bilateral cleft lip repairs, stigmata for bilateral repairs, secondary repair outcomes, and palate repair outcomes were evaluated using the criteria in Fig. 3. To evaluate outcomes of soft palate repair, a perceptual speech evaluation system has been created and tested in Latin America using digitally compressed speech samples [17].

Once the outcomes evaluations were returned, they were stored in the outcomes database; and a feedback report was created with scores, comments, and recommendations for each patient. Final feedback reports were sent to respective surgical teams, in-country executive and medical directors, and the region medical officer to encourage discussion about outcomes and best surgical practices (Fig. 4).

Separate emails were sent directly to each surgeon listing which patients they operated on, so only they can identify their own patients. Records kept at the headquarters can be analyzed by site, surgeon, or type of surgery for auditing purposes.

Results

One year after the WJOS, on-site postoperative evaluations were completed for 24 of the 40 sites, with 812 of 4086 patients returning for a return rate of 19.87% (Fig. 5). Of those sites, 19 sent back postoperative images; and most returned postoperative examination forms. At those 19 sites, 703 of 1917 patients returned for a 6- to 9-month postoperative visit, for a 36.67% return rate. After matching before and after pictures, 562 patients were able to be entered into the database, thereby allowing 580 procedures to be evaluated.

Figure 6 shows the proportion of the required 3346 patient images that were usable, unusable, or missing. Figure 7 shows the proportions of the required 703 postoperative forms that were complete, incomplete, or missing. Upon completion of scoring the outcomes for all 19 sites, 134 feedback reports have been sent to volunteer surgeons around the world, allowing them to see their results and facilitate discussion on best surgical practices and trends.

Discussion

The current outcomes auditing and evaluation system has proven beneficial for tracking patient outcomes, auditing surgical performance, and providing feedback to surgeons and other team members. Many surgeons have responded favorably to the feedback reports, whether they received a positive or negative score, and enjoy seeing their patients' outcomes. Country executive and medical directors appreciate the ability to track the overall outcomes of the children in their country and thus address any concerns that may arise in a timely manner. Overall, the system has succeeded in fulfilling its intended purpose.

The system, however, is not without challenges and limitations, as seen in the number of patients who were not followed up and the amount of missing data. Conveying the importance of postoperative visits for patients has been a major challenge. There is a general belief that following up patients who undergo surgery from humanitarian organizations is extremely difficult if not impossible. The most common obstacles encountered are the impact of the patients' socioeconomic status on their ability to leave work and travel to the postoperative follow-up site due to the fact that most live in inaccessible geographic areas.

Fig. 1 Sample outcome evaluation of a bilateral cleft lip. This was a good outcome, with a final score of 18/20. The scar is evaluated as an independent outcome because there are several factors in addition to the surgical technique that influence its quality

Operation Smile Outcomes Evaluation. MISSION:

Outcome Evaluation | Immediate POP and Other Pictures | Speech Evaluation

Verified Surgery Primary Lip Repair Furlow for VPI Other...
 Primary Palate Repair Skin Graft
 Lip Revision Flap
 Palate Revision Z-plasty
 Fistula Closure Injection
 Orticochea Scar Excision
 Pharyngeal Flap Tumor Excision

Patient Evaluation Letter F

Severity of Cleft
 Mild

Unilateral Cleft Lip Repair
 Symmetry Cupid's Bow
 Symmetry Lateral Lip
 Nose Symmetry
 Symmetry Free Vermilion
 Symmetry Dry/Wet
 UCL Outcome / 10

Bilateral Lip Repair 1
 Symm. of Cupid's Bow 2-Good
 Nasal Symmetry 1-Satisfactory
 Vert Symm of Lat Lip 2-Good
 Horz. Symm of Lat Lip 2-Good
 Symm of Free Vermilion 2-Good

Wide Philtrum 1-Avoided
 Undimpled Philtrum 1-Avoided
 Long Lip 1-Avoided
 Malpositioned Premaxila 1-Avoided
 Lack of Muscle Integrity
 Vermilion Color Mismatch 1-Avoided
 Absence of White Roll 1-Avoided
 Flat Nose/Oblique Nostrils/Short Columella 1-Avoided
 Whistle Deformity 1-Avoided
 Absence of Upper Labial Sulcus 1-Avoided
 BCL Outcome 18 / 20

Scar
 Hypertrophy Discoloration 2-Absent
 Spreading Suture Marks 1-Moderate
 Outcome Scar 3 / 4

Improvement Scale

Pre-Op. Image- Frontal/Hard Palate
 Post-Op. Image- Frontal/Hard Palate

Pre-Op. Image- Basal/Soft Palate
 Post-Op. Image- Basal/Soft Palate

Early Comp. No complication Late Comp. No complication

Pre-aly Post-aly
 Junc. Prim/Secondary Hard Palate
 Junc. Hard/Soft Soft Palate

Fistula
 Length (mm)
 Width (mm)
 Symptomatic Yes No

Comments
 Granuloma (nose) noted on post op form.

Both conditions contribute to the low percentage of WJOS patients (19.87%) returning for follow-up despite efforts by local foundations to get them to return. Additionally, many parents do not think it is necessary to bring their child back for a follow-up visit if they do not see a complication or the need for additional surgery.





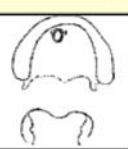
However, because most oral cleft patients need a sequence of surgical and nonsurgical treatments, postoperative follow-up also serves as a recruitment process for future care. Patients should not be asked to return for just an evaluation of the surgical site; a system to provide continuous care must be developed, and time and resources must be committed. It was a big accomplishment to hold

6-month to 1-year follow-up evaluations in 24 of the 40 sites; and through work with in-country foundations, we hope to increase the number of countries holding postoperative visits as well as the postoperative return rate.

In developing countries, there is a big problem with the quality of long-established health indicators, such as mortality rates. In the 2008 report of basic health indicators from the Pan-American Health Organization, the quality of the mortality data was good in 40% of the 48 countries in the region [18]. A major factor contributing to this situation is that the burden of collecting excessive amounts of data falls on health care workers who do not see any benefit from that effort [19]. Similar problems can be expected

Fig. 2 Sample hard palate evaluation template. Fistula size and position are recorded on site, on the evaluation form, and with pictures

Operation Smile Outcomes Evaluation. MISSION:

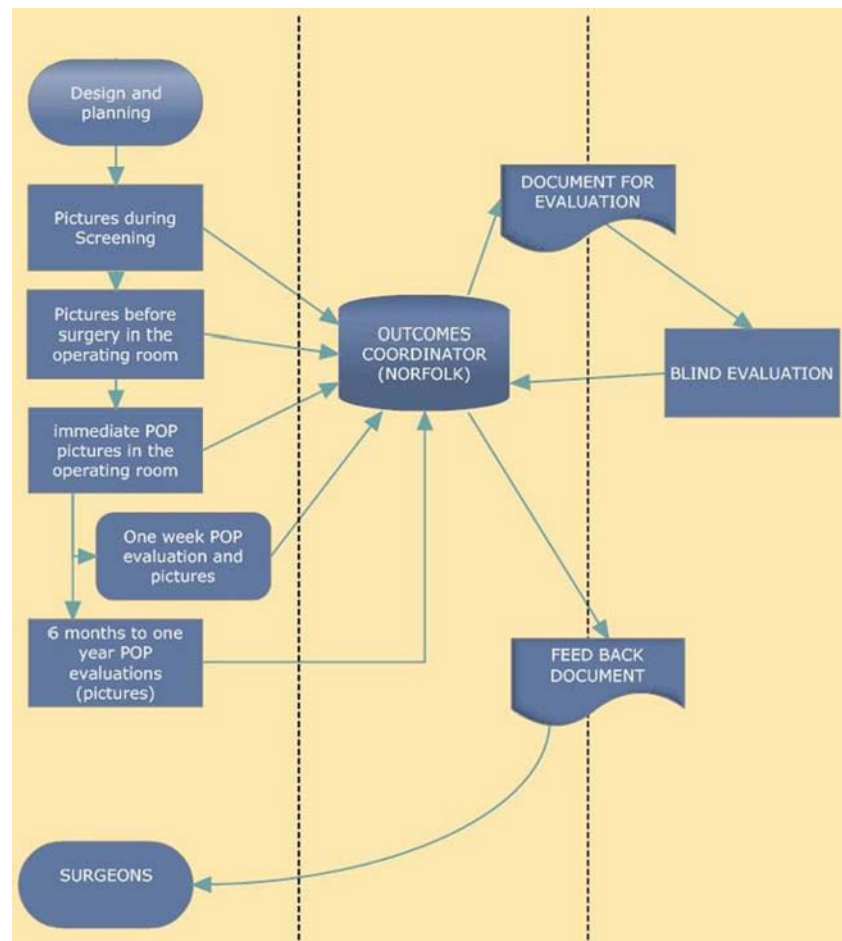
Outcome Evaluation	Immediate POP and Other Pictures	Speech Evaluation
Verified Surgery <input type="checkbox"/> Primary Lip Repair <input checked="" type="checkbox"/> Primary Palate Repair <input type="checkbox"/> Lip Revision <input type="checkbox"/> Palate Revision <input type="checkbox"/> Fistula Closure <input type="checkbox"/> Pharyngeal Flap <input type="checkbox"/> Furlow for VPI <input type="checkbox"/> Skin Graft <input type="checkbox"/> Flap <input type="checkbox"/> Z-plasty <input type="checkbox"/> Injection <input type="checkbox"/> Scar Excision <input type="checkbox"/> Tumor Excision <input type="checkbox"/> Other...	Pre-Op. Image- Frontal/Hard Palate  Post-Op. Image- Frontal/Hard Palate  Pre-Op. Image- Basal/Soft Palate  Post-Op. Image- Basal/Soft Palate 	Patient Evaluation Letter: E1 Severity of Cleft Moderate Unilateral Cleft Lip Repair Symmetry Cupid's Bow Symmetry Lateral Lip Nose Symmetry Symmetry Free Vermilion Symmetry Dry/Wet UCL Outcome: <input type="text"/> / 10 Bilateral Lip Repair 1 Symm. of Cupid's Bow Nasal Symmetry Vert Symm of Lat Lip Horz. Symm of Lat Lip Symm of Free Vermilion Wide Philtrum Undimpled Philtrum Long Lip Malpositioned Premaxila Lack of Muscle Integrity Vermilion Color Mismatch Absence of White Roll Flat Nose/Oblique Nostrils/Short Columella Whistle Deformity Absence of Upper Labial Sulcus BCL Outcome: <input type="text"/> / 20 Scar Hypertrophy Discoloration Spreading Suture Marks Outcome Scar: <input type="text"/> / 4 Improvement Scale
Early Comp. No complication Late Comp. No complication	Fistula Length (mm) <input type="text"/> Width (mm) <input type="text"/> Symptomatic: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 	
Comments Symptomatic anterior palate fistula. Additional surgery is needed to fix the fistula. should be scheduled for surgery in six month if possible		

when trying to collect other less well known indicators, such as surgical outcomes. The lack of commitment to completing the simplified postoperative data form was one of the main reasons for the missing or incomplete data. The other reason was lack of knowledge and experience with the new form. A goal of the outcomes evaluation process is to show the value of, and uses for, good quality data to encourage better collection and recording processes internationally. The pilot project during the WJOS was a step in the right direction.

The current system acknowledges the limitations (static, two-dimensional) of using only still pictures to evaluate surgical outcomes of cleft lip surgery, but they have been

utilized for a long time to conduct clinical studies [20–29]. We have found that digital photography provides the most feasible way to collect, store, and share objective information for evaluative purposes. Along with the time it takes to ensure proper conditions and patient positions for quality pictures taking, images risk losing definition when they are cropped, thus affecting the evaluation. Additionally, although symmetry and aesthetics can be evaluated using quality images, function cannot. Speech samples are taken for separate evaluation in many countries; however, outcome involving feeding, breathing, hearing, or other processes that may be affected by the surgery are not taken into account with the current system.

Fig. 3 Outcomes evaluation process flow. POP postoperative picture



Limitations

Ensuring picture quality and standardization became one of the major challenges of this process. As seen in the number of missing pictures, collecting full image sets is a challenge, as is collecting quality standardized images that allow before and after comparisons. For these reasons, the outcomes data Fellows position was created to collect images at each mission. The Fellows are trained by Operation Smile and work with in-country volunteers at each mission in the hope that with the same people collecting images consistently the image quality will improve. To accompany the sets of images, significant efforts have been made to promote completion of postoperative forms so a more thorough outcomes review can be conducted.

Having a strong, reliable outcome evaluation system allows a quicker, more streamlined patient evaluation process. With patient objectives increasing from year to year, more and more patients are returning for follow-up visits, providing more outcomes for evaluation. The current system allows the organization to adapt to the increase in

patients and accommodate the additional data being sent from mission sites. The feedback process will help keep surgeons engaged and interested in volunteering, provide high quality surgery, and motivate in-country teams to encourage patients to return for follow-up visits. Finally, the vast amount of data, both surgical and postoperative, contained in the evaluation database provides a resource for clinical audit, quality improvement systems, and future research projects. Subsequent articles on outcomes, techniques, and best practices will be published as sufficient data become available.

Conclusions

This system is an example of how work done in the field by humanitarian organizations, particularly those utilizing volunteers, can be audited. Similar systems using an unbiased third party for the evaluation could be replicated by other organizations, both medical and nonmedical, to examine outcomes as part of their quality monitoring and process improvement. To maintain true transparency,

Unilateral Cleft Lip Repair	Bilateral Cleft Lip Repair		Cleft Palate Repair	Secondary Repairs
Symmetry 0= unsatisfactory 1= satisfactory 2= good	Symmetry 0=unsatisfactory 1=satisfactory 2=good	Avoidance of Stigmata 0= present 1= absent	Fistula occurrence, position and size	Improvement Scale Improved Slight/No Improvement Worse
Symmetry of the cupid's bow	Symmetry of the cupid's bow	Wide philtrum Undimpled philtrum	Location and size of palate fistulas are noted and draw on evaluation forms.	
Symmetry of the lateral lip	Symmetry of the nose	Long lip Malpositioned premaxila	Dehiscence and other surgical site complication are also noted on each evaluation.	
Symmetry of the nose	Symmetry of the free vermillion	Lack of muscle integrity Vermillion color mismatch		
Symmetry of the free vermillion	Vertical symmetry of the lateral lip	Absence of the white roll Nose/oblique nostrils		
Symmetry of the wet/dry vermillion	Horizontal symmetry of the lateral lip	Whistle deformity Absence of an upper labial sulcus		
Outcome Score: Good 8-10; Fair 5-7; Bad 0-4	Outcome Score: Good 16-20; Fair 11-15; Bad 0-10			

Fig. 4 Outcome evaluation criteria

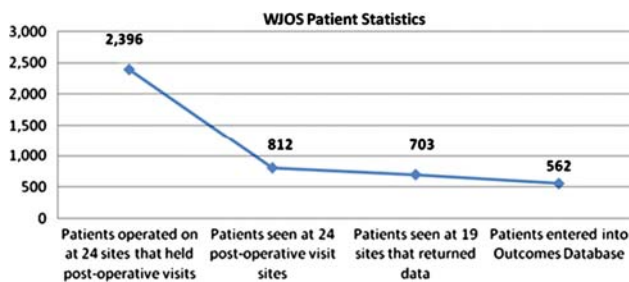


Fig. 5 Total patient, postoperative return, and database entry statistics

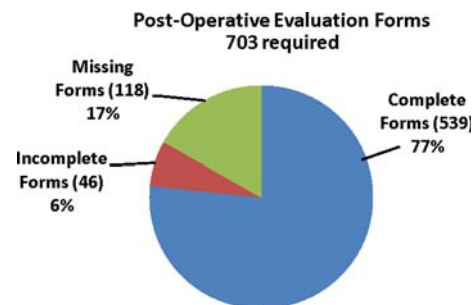


Fig. 7 Percentages of the 703 required postoperative evaluation forms that were complete, incomplete, or missing

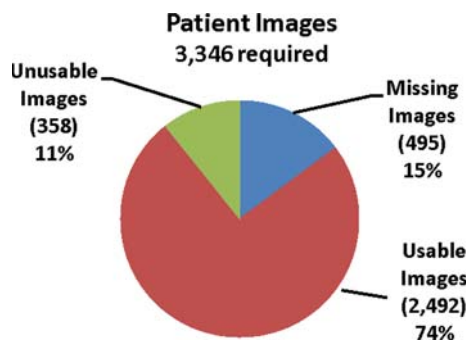


Fig. 6 Percentages of the 3346 patient images required for full evaluation that were usable, unusable, or missing

surgical and mission activities should be reported not only based on the number of procedures performed or people reached but also on the outcomes.

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