

# Are Patients With Longer Emergency Department Wait Times Less Likely to Consent to Research?

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## Abstract

**Objectives:** There are unique challenges to enrolling patients in emergency department (ED) clinical research studies, including the time-sensitive nature of emergency conditions, the acute care environment, and the lack of an established relationship with patients. Prolonged ED wait times have been associated with a variety of adverse effects on patient care. The objective of this study was to assess the effect of ED wait times on patient participation in ED clinical research. The hypothesis was that increased ED wait times would be associated with reduced ED clinical research consent rates.

**Methods:** This was a retrospective cohort study of all patients eligible for two diagnostic clinical research studies from January 1, 2008, through December 31, 2008, in an urban academic ED. Sex, age, race, study eligibility, and research consent decisions were recorded by trained study personnel. The wait times to registration and to be seen by a physician were obtained from administrative databases and compared between consenters and nonconsenters. An analysis of association between patient wait times for the outcome of consent to participate was performed using a multivariate logistic regression model.

**Results:** A total of 903 patients were eligible for enrollment and were asked for consent. Overall, 589 eligible patients (65%) gave consent to research participation. The consent rates did not change when patients were stratified by the highest and lowest quartile wait times for both time from arrival to registration (68% vs. 65%,  $p = 0.35$ ) and time to be seen by a physician (65% vs. 66%,  $p = 0.58$ ). After adjusting for patient demographics (age, race, and sex) and study, there was still no relationship between wait times and consent ( $p > 0.4$  for both wait times). Furthermore, median time from arrival to registration did not differ between those who consented to participate (15 minutes; interquartile range [IQR] = 9 to 36 minutes) versus those who did not (15.5 minutes; IQR = 10 to 39 minutes;  $p = 0.80$ ; odds ratio [OR] = 1.00, 95% confidence interval [CI] = 0.99 to 1.01). Similarly, there was no difference in the median time to be seen by a physician between those who consented (25 minutes; IQR = 15 to 55 minutes) versus those who did not (25 minutes; IQR = 15 to 56 minutes;  $p = 0.70$ ; OR = 1.00, 95% CI = 0.99 to 1.01).

**Conclusions:** Regardless of wait times, nearly two-thirds of eligible patients were willing to consent to diagnostic research studies in the ED. These findings suggest that effective enrollment in clinical research is possible in the ED, despite challenges with prolonged wait times.

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The 2006 Institute of Medicine report on emergency care called for increased research efforts to enhance emergency medical care.<sup>1</sup> One challenging aspect of emergency medicine (EM) research is the informed consent process. Participation in EM research studies is influenced by a wide variety of

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factors, including characteristics of the patients, the study specifics, and the setting.<sup>2,3</sup> Identifying and addressing barriers to informed consent is critical, as populations frequently seen in emergency departments (EDs) are underrepresented in other research settings.

Although many studies have investigated which patient features are associated with willingness to participate in research, most of these have been in fields other than EM.<sup>4-10</sup> Those in the field of EM have examined features of the patient or informed consent document associated with research participation.<sup>2,3,11-15</sup> It is not clear how the clinical care provided to the patient affects his or her decision to participate in research. It has been demonstrated that wait times can affect a patient's overall satisfaction with an ED visit.<sup>16,17</sup> It has also been shown in a hypothetical research setting that patients value convenience when deciding on research participation.<sup>18</sup> Additionally, many subjects participate in research out of a sense of altruism,<sup>19</sup> which might be reduced if a patient is dissatisfied with his or her overall ED visit. Therefore, prolonged ED wait times might adversely affect EM research participation. To the best of our knowledge, this possibility has not been examined.

The objective of this study was to determine the effect of ED wait times on patient participation in EM research. We hypothesized that increased ED wait times would be associated with reduced research consent rates for two diagnostic "parent" research studies.

## METHODS

### Study Design

This was a retrospective observational study of the relationship between ED wait times and research participation. This study was submitted to and exempted from full review and informed consent requirements by our institutional review board (IRB).

### Study Setting and Population

Subjects included patients screened for enrollment into two EM minimal-risk diagnostic research studies that were funded by the National Institutes of Health from the period of January 2008 through December 2008 at an urban academic medical center ED with an average annual census of approximately 65,000 visits. During the time period of the current study, the median wait times to be registered, to be seen by a physician, and overall length of stay were 18, 27, and 301 minutes, respectively, for patients seen in this ED.

Both parent studies were approved by our institutional review board. Trained study coordinators screened for eligible patients with infection from 8 AM to 10 PM during weekdays, with intermittent sampling on weekends. Eligible patients were approached for the parent studies as soon as possible after being evaluated by an attending emergency physician in a treatment room. Patients were eligible for either of the two parent research studies if they had a suspected infection and two or more systemic inflammatory response signs (Study 1) or had signs and symptoms of pneumonia as determined by emergency physician evaluation (Study 2). They were excluded from the parent studies if they

could not speak English or were not competent to consent. After patient consent was obtained, research coordinators obtained blood samples, using existing intravenous lines whenever possible. The only other intervention for either parent study was data collection and follow-up. Neither study required a time-sensitive window for enrollment.

### Study Protocol

For each eligible patient, pertinent wait times were obtained from administrative databases. Trained study personnel recorded patient sex, age, race, study eligibility, and consent. Study personnel kept prospective screening logs, including demographics and reasons for nonenrollment for all eligible patients. All study personnel completed both local IRB-mandated general training and parent study protocol-specific research training.

We collected the following wait times: 1) time from patient arrival (when a patient is first entered into the electronic tracking board) to full registration and triage (as defined as the time of first nursing triage note) and 2) time from arrival to being seen by a physician (as noted by a physician "signing up" for the patient on electronic tracking board). Consent to participate was considered our binary outcome. Overall ED length of stay times were recorded for descriptive purposes.

### Data Analysis

Demographic data are reported as proportions. All patient wait time data are presented in minutes and as medians with interquartile ranges (IQR). We performed a chi-square test comparing the underlying characteristics of consenting and nonconsenting patients to determine if consent rates were associated with age, race, or sex. As wait times were not normally distributed, the Wilcoxon rank sum test was used. Additionally, a Cochran-Armitage test for trend to compare participation rates across wait time quartiles was performed.

We then analyzed the association between consent rates and patient wait times using a multivariate logistic regression model. Because our sample was derived from two parent studies, we knew a priori how many subjects had consented and were thus confident of having enough events to power our analysis. However, we used 1 year's worth of data to account for any seasonal variation. Two separate models were built. Time to registration and time to see a physician were entered into separate models to avoid colinearity. Both models contained patient demographics (age, race, sex) and parent study for which the patient was approached as main effect predictor variables. These predictor variables were selected based on prior research performed at this site and the general literature on this topic.<sup>3-6,9,20-29</sup> In both models, we identified consent to participate as our outcome variable. Overall robustness of the models was determined by  $-2 \log$  likelihood statistic. A  $p$ -value  $\leq 0.05$  was considered statistically significant, with no adjustment for multiple comparisons. All analyses were performed using SAS (Version 9.2, SAS Institute, Cary, NC).

Table 1  
Total Demographics and Wait Times and Univariate Comparison by Consent Outcome

Characteristics	Total (N = 903)	Consenters (n = 589)	Nonconsenters (n = 314)	p-value
Age (yr)				
Younger than 18	44 (4.8%)	28 (4.8%)	16 (5.1%)	0.2
18–40	235 (26.0%)	156 (26.5%)	79 (25.2%)	
41–65	384 (42.5%)	261 (44.3%)	123 (39.2%)	
Older than 65	240 (26.6%)	144 (24.4%)	96 (30.6%)	
Race				
Black or African American	394 (43.6%)	256 (43.5%)	138 (43.9%)	1.0
White	470 (52.0%)	307 (52.1%)	163 (51.9%)	
Other	39 (4.3%)	26 (4.4%)	13 (4.1%)	
Sex				
Male	426 (47.2%)	282 (47.9%)	144 (45.9%)	0.6
Time to registration, minutes (IQR)	15 (9–37)	15 (9–36)	15.5 (10–39)	0.8
Time to be seen by physician, minutes (IQR)	26 (15–57)	25 (15–55)	25 (15–56)	0.7

Time to registration = time from patient arrival (when a patient presented to the front desk or arrived by ambulance) to full registration and triage; time to be seen by a physician = time from arrival to being seen (as noted by a physician "signing up" for the patient on electronic tracking board).  
Univariate comparisons were made between consenters versus nonconsenters with the chi-square test with p-values as reported. No adjustments were made for multiple comparisons.  
IQR = interquartile range.

## RESULTS

Overall, 1403 patients were approached for these research studies, of whom 36% were ineligible, leaving 903 patients eligible for participation. Of these patients, 589 patients (65%) consented to participate and were enrolled. Patient demographics are listed in Table 1. In univariate analysis, demographics were not significantly different between those consenting to participate and those not consenting (Table 1).

Overall, the median time from arrival to registration was 15 minutes (IQR = 9 to 37 minutes), arrival to being seen by a physician was 26 minutes (IQR = 15 to 57 minutes), and length of stay was 505 minutes (IQR = 351 to 705.5 minutes). The median time from arrival to registration was similar ( $p = 0.8$ ) between the consent group (15 minutes; IQR = 9 to 36 minutes) and nonconsent group (15.5 minutes; IQR = 10 to 39 minutes). Furthermore, median times from arrival to being seen by a physician were similar ( $p = 0.7$ ) between the consent group (25 minutes; IQR = 15 to 55 minutes) and nonconsent group (25 minutes; IQR = 15 to 56 minutes).

Likewise, the percentage of patients consenting to participation was compared across wait time quartiles for arrival to registration and arrival to being seen by a physician (Figure 1). Percent consented was not different between the highest and lowest wait time quartiles ( $p = 0.35$  for time to registration,  $p = 0.58$  for time to be seen).

After adjustment for potential confounders, consent was not associated with time to registration or time to be seen. Only the parent study for which patients were approached showed any significant association with consent (Tables 2 and 3).

## DISCUSSION

In this study, we analyzed the relationship between ED wait times and EM research participation. After adjusting for patient demographics, we found that the

majority of eligible patients consented to the two diagnostic research studies regardless of wait times. To our knowledge, this is the first study examining the effects of wait times on ED clinical research participation. Previous work has examined various factors that influence research participation including age, sex, education, geographical residence, race/ethnicity, income, familiarity with clinical trials, trust of the medical system, disease severity, availability of surrogate decision-makers, health beliefs, readability of consent documents, and qualifications of the research staff approaching subjects.<sup>3–6,13,14,20,22,23,25–27,29–35</sup>

This study's findings highlight the complex nature of EM research consent. Altruism has been identified as a key factor in research participation.<sup>19</sup> Inconvenienced patients may feel less altruistic.<sup>18</sup> We therefore hypothesized that patients who are forced to wait longer to register or to see a physician would be less willing to enroll in a research study, especially for studies that do not provide financial compensation or direct clinical benefit. Our findings indicate that other factors play a more important role in the decision to participate in research. Patients demonstrated a high rate of willingness to participate in research studies. Although it is not clear whether these observations will hold for non-ED settings, our findings are encouraging for ED research sites with prolonged wait times.

Also of note, in the current study we found no difference in enrollment in different racial or age groups. This is in contrast to prior work performed at this same site.<sup>3</sup> Although the reasons for this are unclear, possible reasons include staff awareness of the prior publication and increased sensitivity to enrolling patients who were previously underrepresented. Other possibilities are turnover in research staff and differences in the parent research studies from which this sample was drawn. Although not the focus of the current study, this finding is encouraging, suggesting that racial and age disparities in research participation can be ameliorated.

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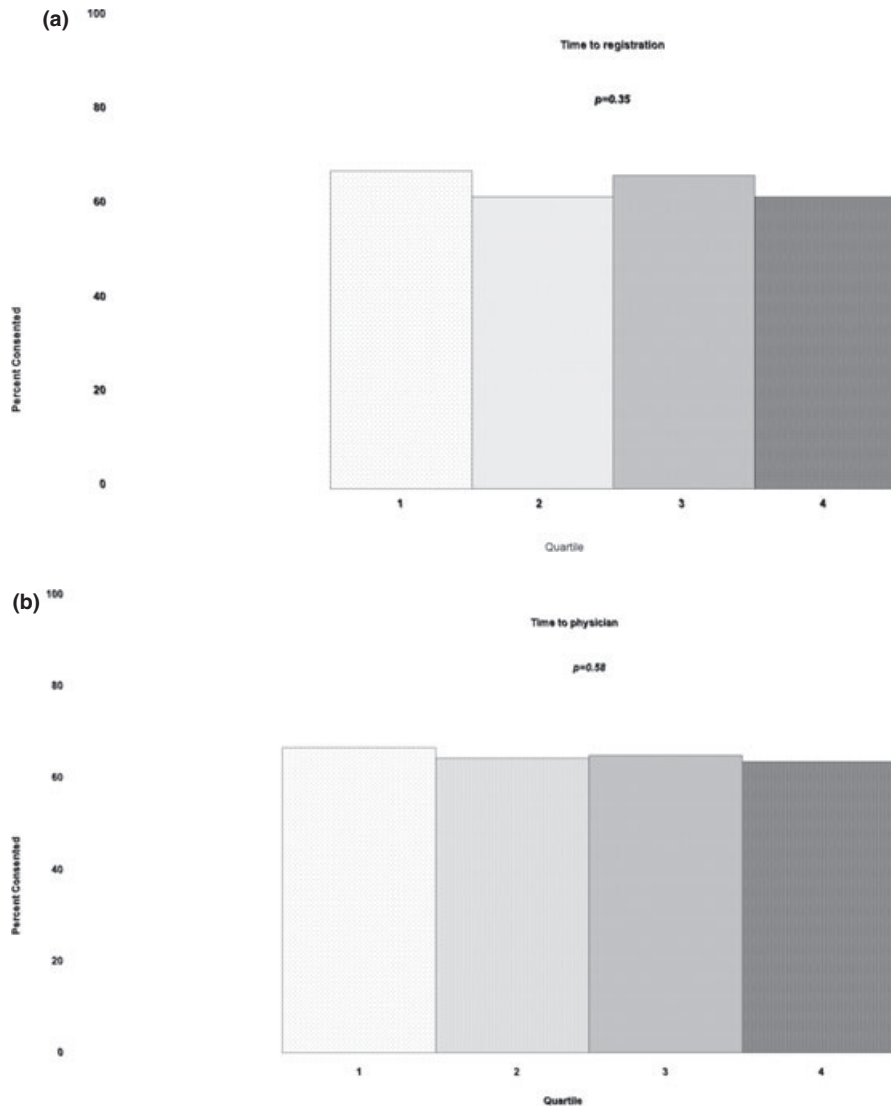


Figure 1. XXXXXXXXXXXXXXXXXXXX.

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Table 2  
Multivariate Logistic Regression Analysis for Time to Registration

Variables	Coefficient	OR	95% CI	p-value
Age	-0.005	0.99	(0.99-1.00)	0.14
Sex (male)	0.076	1.08	(0.81-1.43)	0.60
Race (white)	0.081	1.09	(0.80-1.47)	0.59
Parent study (pneumonia)	0.408	1.50	(1.07-2.12)	0.02
Time to registration (minutes)	-0.0001	1.00	(0.998-1.001)	0.89

Parent study = the parent study for which patient was approached; time to registration = time from patient arrival (when a patient presented to the front desk or arrived by ambulance) to full registration and triage. Robustness of model was assessed by  $-2 \log L = 1109.8$ .

Table 3  
Multivariate Logistic Regression Analysis for Time to Physician

Variables	Coefficient	OR	95% CI	p-value
Age	-0.005	1.00	(0.99-1.00)	0.17
Sex (male)	0.068	1.07	(0.80-1.43)	0.64
Race (white)	0.026	1.03	(0.76-1.39)	0.86
Parent study (pneumonia)	0.347	1.41	(1.004-1.992)	0.04
Time to physician (minutes)	-0.0002	1.00	(0.998-1.001)	0.78

Parent study = the parent study for which patient was approached; time to physician = time from arrival to being seen (as noted by a physician "signing up" for the patient on electronic tracking board). Robustness of model was assessed by  $-2 \log L = 1081.3$ .

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**LIMITATIONS**

This study is limited by use of administrative data for measures of ED crowding. These are created on the

basis of time stamps created by our electronic charting system, and as such are subject to inaccuracies caused by idiosyncratic use of the charting system by providers. Overall, however, because our subjects were

randomly distributed across providers, this should not produce a systematic bias to this study. Our study does not address the time from arrival until patients are approached for consent. The patients in this study were approached as soon as possible after physician evaluation. Although we did not systematically record the time of approach, this time was usually within 2 hours of physician evaluation. We hypothesized that patients' participation decisions would be affected by their wait for medical care, not how long they had been in the ED prior to being approached for consent. Whether the latter is more important is a separate research question worthy of further study.

There are multiple other potential confounders that we were not able to control. This study also does not control for patient perceptions and attitudes toward research. It is possible that patients with longer waits were either more or less inclined toward research at baseline. Patients with longer wait times will also be systematically biased toward having lower acuity of illness by nature of triage protocols. It is possible that severity of illness affects patient willingness to participate in research trials. Another possible confounder not controlled for was the characteristics of the research staff approaching patients. Our findings are restricted to research studies without time-sensitive windows to enrollment. Such studies may affect non-participation by increasing time pressures on research staff. There is no literature to support any of these as confounders in EM research, but future study could evaluate their effect on participation.

## CONCLUSIONS

We found that patient wait times did not adversely affect ED research participation. We believe that our results show that patients can be recruited for research even in clinical environments where patients are required to wait for care. Future efforts should focus on elucidating factors associated with research participation and refusal and the effect of crowding on time-sensitive research and on vulnerable populations such as those who are unable to consent, critically ill patients, and populations underrepresented in other research settings.

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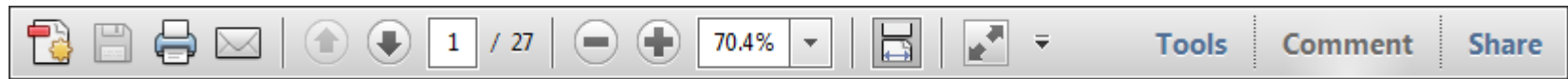
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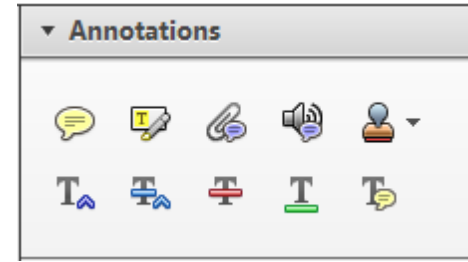
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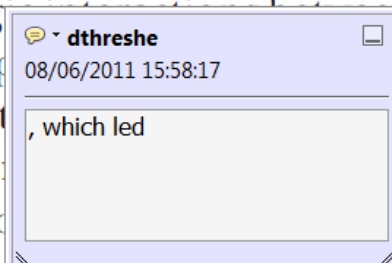


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**4. Add sticky note Tool – for making notes at specific points in the text.**

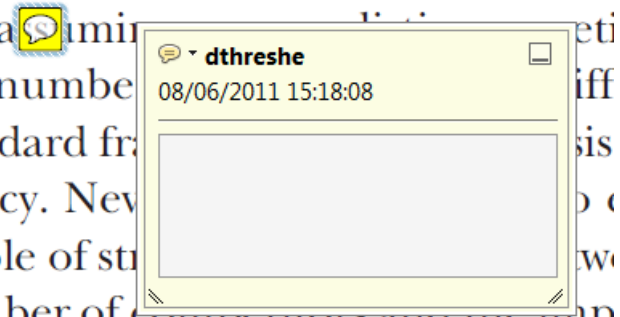


Marks a point in the proof where a comment needs to be highlighted.

**How to use it**

- Click on the [Add sticky note](#) icon in the Annotations section.
- Click at the point in the proof where the comment should be inserted.
- Type the comment into the yellow box that appears.

and supply shocks. Most of the... number... standard fr... cy. Nev... ple of str... ber of competitors and the imp... is that the structure of the secto





USING e-ANNOTATION TOOLS FOR ELECTRONIC PROOF CORRECTION

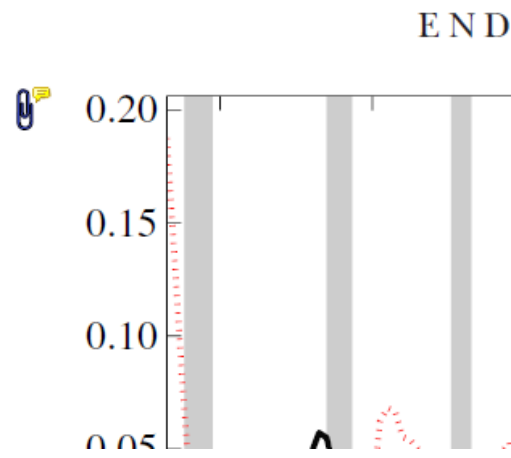
**5. Attach File Tool – for inserting large amounts of text or replacement figures.**



Inserts an icon linking to the attached file in the appropriate place in the text.

**How to use it**

- Click on the [Attach File](#) icon in the Annotations section.
- Click on the proof to where you'd like the attached file to be linked.
- Select the file to be attached from your computer or network.
- Select the colour and type of icon that will appear in the proof. Click OK.



**6. Add stamp Tool – for approving a proof if no corrections are required.**

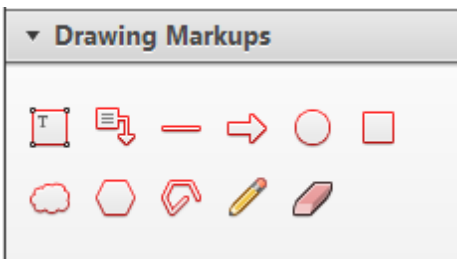


Inserts a selected stamp onto an appropriate place in the proof.

**How to use it**

- Click on the [Add stamp](#) icon in the Annotations section.
- Select the stamp you want to use. (The [Approved](#) stamp is usually available directly in the menu that appears).
- Click on the proof where you'd like the stamp to appear. (Where a proof is to be approved as it is, this would normally be on the first page).

of the business cycle, starting with the  
 on perfect competition, constant ret  
 production. In this environment goods  
 extra profits and the market for marke  
 he market for goods is determined by the model. The New-Key  
 otaki (1987), has introduced produc  
 general equilibrium models with nomin  
 and... Most of this literature

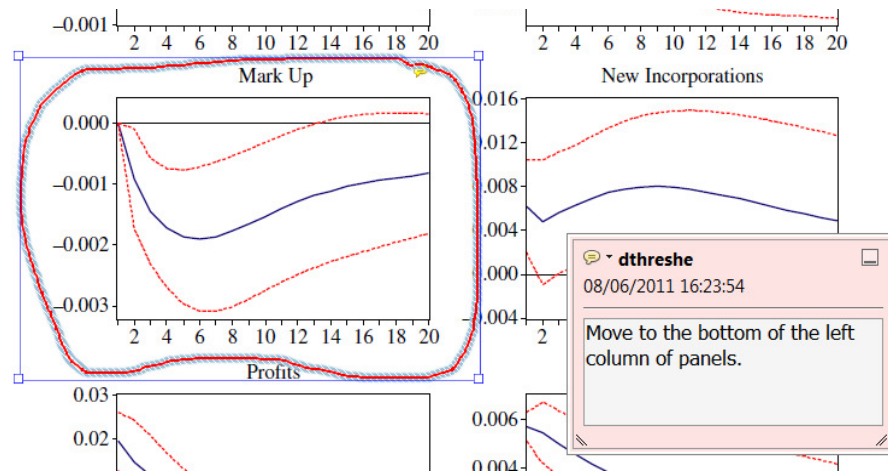


**7. Drawing Markups Tools – for drawing shapes, lines and freeform annotations on proofs and commenting on these marks.**

Allows shapes, lines and freeform annotations to be drawn on proofs and for comment to be made on these marks..

**How to use it**

- Click on one of the shapes in the [Drawing Markups](#) section.
- Click on the proof at the relevant point and draw the selected shape with the cursor.
- To add a comment to the drawn shape, move the cursor over the shape until an arrowhead appears.
- Double click on the shape and type any text in the red box that appears.



For further information on how to annotate proofs, click on the [Help](#) menu to reveal a list of further options:

