

Reporting Observational Studies of the Use of Information Technology in the Clinical Consultation

A Position Statement from the IMIA Primary Health Care Informatics Working Group (IMIA PCI WG)

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Summary

Objectives: To develop a classification system to improve the reporting of observational studies of the use of information technology (IT) in clinical consultations.

Methods: Literature review, workshops, and development of a position statement. We grouped the important aspects for consistent reporting into a “faceted classification”; the components relevant to a particular study to be used independently.

Results: The eight facets of our classification are: (1) Theoretical and methodological approach: e.g. dramaturgical, cognitive; (2) Data collection: Type and method of observation; (3) Room layout and environment: How this affects interaction between clinician, patient and computer. (4) Initiation and Interaction: Who starts the consultation, and how the participants interact; (5) Information and knowledge utilisation: What sources of information or decision support are used or provided; (6) Timing and type of consultation variables: Standard descriptors that can be used to allow comparison of duration and description of continuous activities (e.g. speech, eye contact) and episodic ones, such as prescribing; (7) Post-consultation impact measures: Satisfaction surveys and health economic assessment based on the perceived quality of the clinician-patient interaction; and (8) Data capture, storage, and export formats: How to archive and curate data to facilitate further analysis.

Conclusions: Adoption of this classification should make it easier to interpret research findings and facilitate the synthesis of evidence across studies. Those engaged in IT-consultation research should consider adopting this reporting guide.

Keywords

Healthcare research; observation; information science; medical informatics; medical records systems, computerized

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1. Introduction

The use of computers during the clinical consultation is increasing; video and other direct observation methods in particular are being used to research this interaction. Information technology (IT) is becoming a routine element of healthcare delivery in many countries, [1, 2, 3, 4] this being used by a range of health professionals and also now by patients [5]. Despite their ubiquity, patients [6] and clinicians [7] have reservations about their use [8], and the scientific evidence on the benefits associated with IT use still needs to be better established [9]. Despite the many new tools to facilitate remote communication, it is now appreciated that these are an adjunct to, rather than a replacement of, the face-to-face consultation [10, 11, 12].

Video and direct observations have been widely used to evaluate the impact of IT on the clinical consultation. Observational methods have been used to evaluate the effects of IT (principally the electronic health record) on the clinical consultation. Furthermore, it is possible to identify specific effects of systems on clinical decision making, reasoning, as well as clinical workflows and communication including clinician-patient dialogue and interaction [13]. It is increasingly recognised that this type

of research can provide valuable input to inform customisation, ergonomic redesign of systems and office layouts, and system improvement, as well as providing improved training to clinicians in optimising the benefits of IT [14].

Consensus statements are now widely used in the medical literature aiming to improve the clarity of reporting of studies [15]. The CONSORT statement for standardising reporting of clinical trials is probably the best known [16]. Similar statements are beginning to be used in medical informatics, for example the European Federation for Medical Informatics (EFMI) Evaluation group have developed guidance for reporting evaluation studies [17]. To date, no consensus tools or guidance has been produced to describe research into the impact of IT on the clinical consultation. Whilst a variety of studies describe and analyse the clinician-computer-patient interaction, the terms and descriptions used often vary markedly between studies. Furthermore, typically little is reported on about the context of the research, which makes comparisons between and across studies unnecessarily difficult [18].

This paper describes the development of and proposes the use of a new classification to improve the reporting of observational studies of the use of

IT in the clinical consultation in primary care. It is written by researchers in this field with a view to promoting the use of a common terminology and descriptors, which should in turn facilitate greater comparability between research reports, without forcing undue conformity to any specific method.

2. Methods

Two international primary care informatics working groups came together to develop this position statement. This area is a research theme of the European Federation of Medical Informatics Primary Care Informatics Working Group (EFMI PCI WG) [19]. The International Medical Informatics (IMIA) PCI WG has focussed more on a complementary area: how to promote uptake of IT in primary care [20] and the barriers to IT implementation [21].

We carried out a critique and synthesis of the literature, and ran workshops at three international informatics meetings to explore common lessons and issues in conducting research about the clinical consultation. These workshops explored common barriers and solutions to conducting research on the use of computers at the point of care.

We explored how we could best group together the key elements that should be used when reporting observational studies of the use of IT in the consultation. We developed a “faceted classification” to bring together the components that we concluded were an important part of reporting these studies. The main advantage of a faceted classification is that it offers considerable flexibility; this is because facets can be ordered in different ways rather than requiring a single taxonomic order [22]. A faceted classification can thus include: 1. Using categories which express various aspects of the knowledge; 2. Classifications which are iterative and evolving that may be applied flexibly by different users; and 3. “A movement away from a flat pro-

liferation of particular (phenomenological) aspects of a field of knowledge, toward a synthetic representation that includes basic (both abstract and concrete) categories” [23]. The classification described in this paper meets these criteria.

3. Results

We have identified eight facets, which we propose should be considered when reporting observational studies of IT use in the consultation. It should be noted that this classification is not intended to be comprehensively applied to all studies as it is inevitable that only some of these items will be of relevance to some studies, with perhaps very few needing to report on all of these. Rather, this classification provides a reference point for researchers when designing and reporting on related research.

The items we propose encompass both fundamental issues such as the theoretical approaches employed, to the more descriptive considerations of, for example, issues to do with room layout.

(1) Theoretical and methodological approach to observation: Observers should state the theoretical or methodological background from which they are making observations. For example, a software engineer may design a use-case associated with a clinical system and define an “Actor” as a person, with a specific purpose, interacting with a certain aspect of that system [24]; whereas an “Actor” may mean something completely different to a social scientist using a dramaturgical framework to describe the “Actors” on this particular stage.

(2) Data collection: There should be a clear statement of the type (e.g. direct observation, video recording) and method (e.g. participant observation, multi-channel video recording) of observation(s) and any other types of data collection methods used.

(3) Room layout/clinical setting: The layout of the clinician’s office is

critical in physically allowing or preventing the patient from viewing the screen and offering the potential to interact with it.

(4) Initiation and interaction: We considered the following to be critical components of any consultation description: Who initiated the consultation; how the participants interacted; and the nature of the clinician-patient-IT relationship. Interactions can be complex: patients are often accompanied and the clinician can be interrupted.

(5) Information and knowledge utilisation: The information managed in the consultation is a combination of what the patient says and communicates; what information is contained within the medical record and information sources; and the clinicians own knowledge and experience. Studies should report the use of information retrieval (IR) and decision support, whether passive or reminders that need to cancel should be recorded; especially issues around prescribing. We recommend the use of standard definitions of prescribing software support (e-Prescribing), IR, and clinical decision support software (CDSS) [25].

(6) Timing and type of consultation variables: There are currently no standard descriptive terms used to describe the consultation and to allow comparison of duration and description of continuous activities (e.g. speech, eye contact) and episodic ones, such as prescribing. Whilst what is meant by recording “free text” or “narrative” and “coded” appears consistent there are differences in how the term “structured” is used. Some use this as synonymous with coded whereas our preference is that it relates to data entered into a specific data field (e.g. a risk assessment) which might be coded or narrative or a combination of both; for example, data entry forms, check-boxes etc.

(7) Post-consultation impact measures: There are a wide range of tools

which can be used for post-consultation assessment, including satisfaction surveys, interviews, focus groups and health economic assessments based on the perceived quality of the clinician-patient interaction. Studies should report the type of tool used; their sampling frame, if a questionnaire whether it is validated for use in the context of the study, what quality control measures have been used to ensure the quality and validity of the findings.

(8) Data capture, storage, and export formats:

Researchers have a duty to see that maximum output is gained from research data; and data should be available to be used to check results or for further research; subject to the approval of research ethics committees. Multiple files in proprietary or legacy format makes this difficult and we recommend the creation of data in open source or readily accessible formats. Facilities for merge and analyse data from multiple research project in anonymised or pseudo-anonymised form should also exist. It would therefore be helpful if information on data types and the extent to which these can be shared was reported on.

1. Theoretical and epistemological approach to observation

The theoretical approach and background of the researchers should be clearly stated; technical, quantitative and qualitative studies, or combinations of these, are all potentially appropriate. The approaches used should be clearly stated.

When using qualitative approaches, the depth of enquiry is the key to generating potentially transferable findings [26]. Whilst there is a place for macro e-health theories [27] the study of micro-interaction is used more often, sometimes utilising an ethnographic approach [28]. Early work usually involved conversation analysis [29, 30] though this may limit the analytical frame [31]. The nature of video analy-

sis also lends itself to a hermeneutic methodology [32], using frequent analytical cycles occur relating the micro interactions to the context of the consultation. The formalised 'theatrical' setting of Goffman's dramaturgy [33] is an alternative [34]. Other analytical approaches, such as grounded theory, have also been successfully used in consultation research [35].

Early studies used tended to use simple observational techniques [36, 37, 38, 39]. The cognitive sciences have much to offer [40, 49], with its emphasis on perception, attention [33], and the cognitive load that occurs in the consultation [41]. Quantitative methods may be derived from social exchange theories, such as the Roter Interaction Analysis System (RIAS) [42], or communication task approaches such as SEGUE (Set the stage, Elicit and Give information, Understand the patients perspective and End [43]) and apply standard communication assessment tools to rate various aspects of the interaction; others have followed models for effective consulting in primary care [44,45]. Finally, several studies have used computer programs to aid in the analysis - with the programs becoming part of the analytical framework [46].

2. Data collection

Digital video appears to be the preferred recording technique; though other techniques have a role either alone or to triangulate the findings from video or direct observation. There are a number of general approaches to the video recording or the direct observation of the consultation, these including: the observation is either not captured by video (e.g., direct, non-participant observation); it is collected with a single or multiple cameras; uses a webcam or camera that produces high definition video; includes screen capture of the clinician's computer; and uses one or more views of the consultation [47, 48]. Our classification seeks to capture these; and also to include any special techniques used such as pattern

recognition and the use of action lines to capture movement [49]. We emphasise the importance of listing the number and types of cameras and if screen capture took place. We also suggest that a reference image is published showing a consultation in progress. Ideally, this should be a simulated consultation so that the picture can be published and allow readers of any study to appreciate the data available to the investigator and its resolution. An example is shown in Figure 1.

3. Room layout/clinical setting

Room layout should be described in terms of the screen orientation relative to the patient; and a visual study should usually be an appendix to most studies of the consultation [50]. We recommend using four terms: (i) Exclusive: when the clinician effectively has exclusive use of the computer screen and the patient is excluded from simultaneous viewing [51]; (ii) Semi-inclusive clinician controlled: when the patient can only see the screen by actively turning away from the clinician's usual direction of gaze (which is the commonest room layout in the UK) [52]; (iii) Semi-inclusive patient controlled: when the patient can easily move their direction of gaze and see what is typed into the computer; and (iv) Inclusive: when the patient sits almost alongside the clinician and simultaneous "triadic" [53] consulting is possible (Figure 2).

4. Initiation and interaction

Either the clinician, the patient or the computer can initiate an agenda, and independent studies in the UK and Australia showed these to be of similar proportions [54]. This represents a change in that computers can generate their own agenda now. This is likely to change over time and may be an index of patient empowerment as well as reflecting the increasing role of the computer.

Interaction in the consultation is complex, but there are useful frameworks for describing this from the perspective of clinician, patient and computer. The classic and still useful overview of

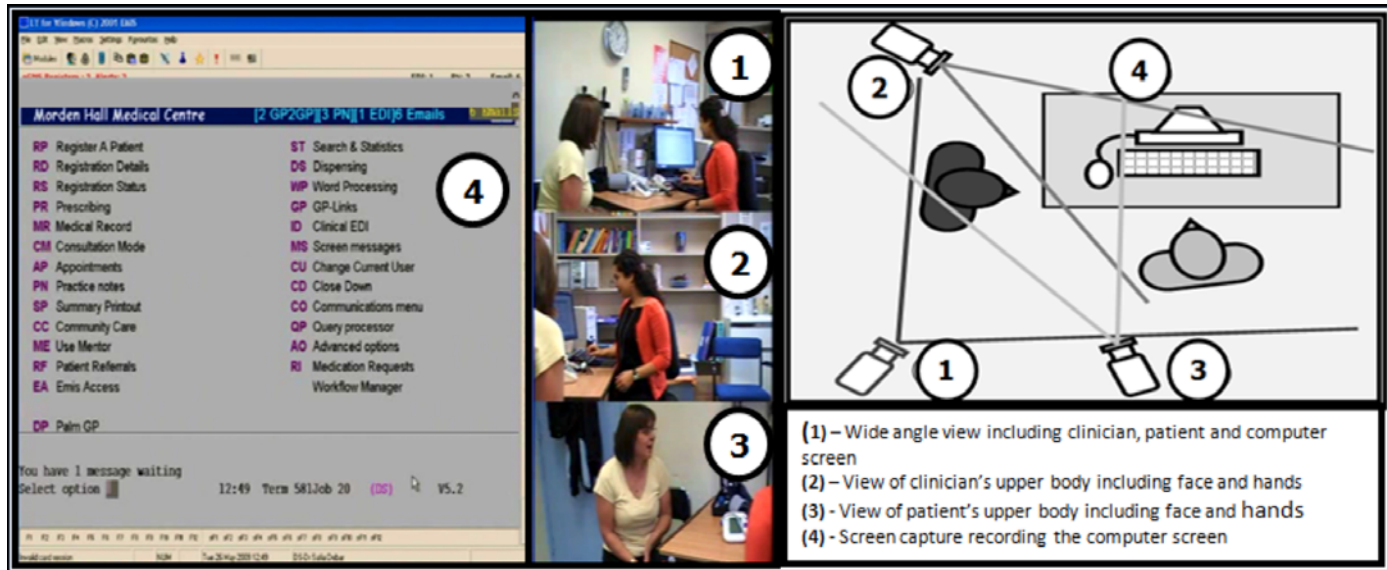


Fig. 1 Types of images which can be produced through a combination of use of three cameras and screen capture

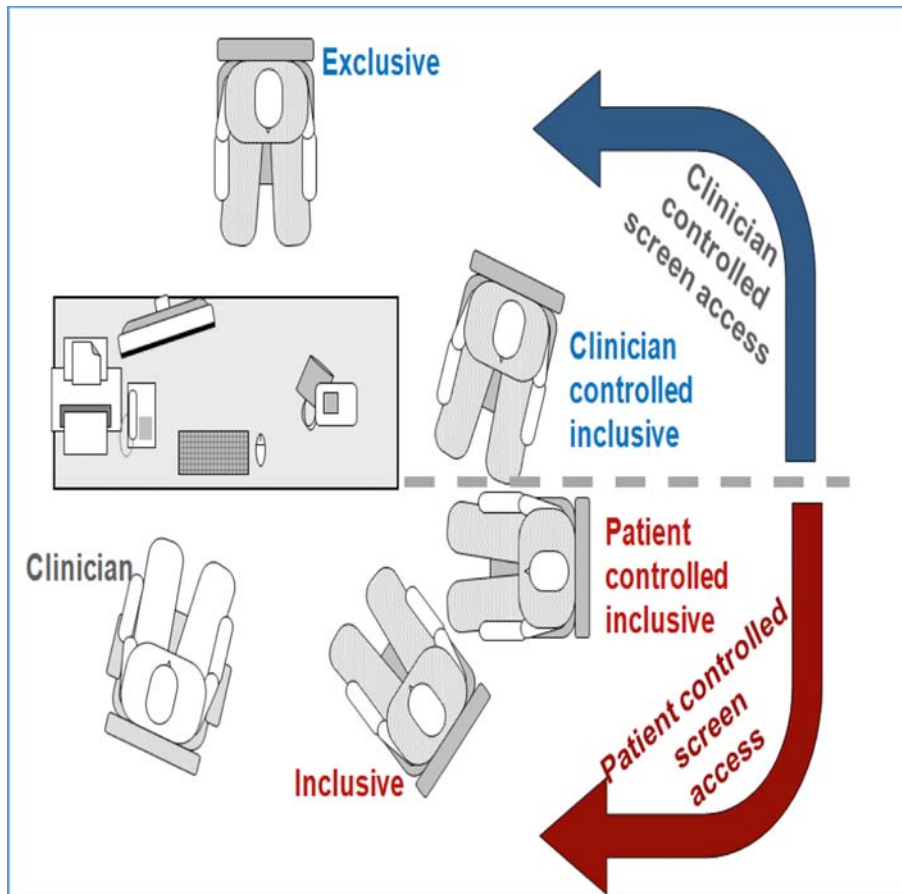


Fig. 2 Describing the room layout

clinicians' use of IT describes it as: minimal (completed after the consultation, but least accurate); block (where the clinician stops to use the IT as if answering the phone); or conversational (on-and-off use) [55].

It is important that the usual orientation of the participants and interaction style in the consultation are described separately (Table 1). Clinicians tend to have a physical orientation preference that is either unipolar (i.e. body orientated in only one direction just moving their head to patient or computer) or bipolar alternating between two definite orientations facing either patient or computer. The clinician's interaction style is either engaging and explaining or responsive [36]; or acting as information manager (also termed cogitating) [26]; or disengaging to take control or time out to think or take control of the consultation [35]. The patient interaction style tends to be dyadic (just focussed on one other actor) or triadic (sharing attention between clinician and screen). The dyadic interaction style tends to be screen ignoring, watching (also called lookers) or controlling. The computers roles are that of informant, prompter or distracter.

Table 1 Classification of styles and interactions in the consultation

Actor	Preferred term from classification		Similar or related concepts
	Orientation	Interaction style	
Doctor	Unipolar	Engaging	Explaining [18] Responsive [20] Minimal IT user [25] Magic box [18] Time out [18] Ignoring [20] Controlling [20] Managerial [10]
		Disengaging	Block or conversational IT user [25] Informational [10]
	Bipolar	Cogitating	Lookers [18]
Patient	Dyadic	Screen controlling Screen watching Screen ignoring	
	Triadic	Screen sharing	
Computer	Excluded Controlled Shared	Informative Prompting Distracting	Divided attention [19], Cognitive dissonance [30]

5. Information and knowledge utilisation

The clinical consultation can be a busy and stressful environment. It appears that information retrieval has a useful role [56], as can prompts and guidance [57] in promoting evidence-based practice [58]. Most consultations include accessing information about medication or being prompted about therapy or interactions. There is scope for technology to improve computerised prescribing/physician order entry (CPOE) [59, 60, 61, 62].

However, full decision support can cause unexpected courses of action caused “cognitive dissonance” among users and result in them not using a system [63]. Providing feedback of aggregated data in a context where there is time for reflection may be superior [64].

Information can be introduced from all three actors at different times in the consultation (Fig 2).

Our classification specifically includes use of medication, guidelines and evidence-based medicine information; whether this information is primary (research); secondary (systematic reviews) or tertiary; and if country, health system or local organisation specific. This information may be provided via the computer or from paper documents; more occasionally by telephone request for guidance in the consultation.

6. Timing and type of consultation variables

Study findings should be reported using clearly defined measures of time and for describing interaction and workflows during the consultation. We suggest the greater consultation duration is defined from the first to the last interaction relevant to that patient (Fig. 3). During the consultation there can be interactions between any two of the actors or between all three. We term the time when all three (doctor, computer and patient) are interacting as ‘Uninterrupted three-actor time (UTAT).’ Interaction between any pair (e.g. doctor reviewing the computer pre-consultation or the doctor examining the patient) as ‘Bilateral actor time (BAT).’

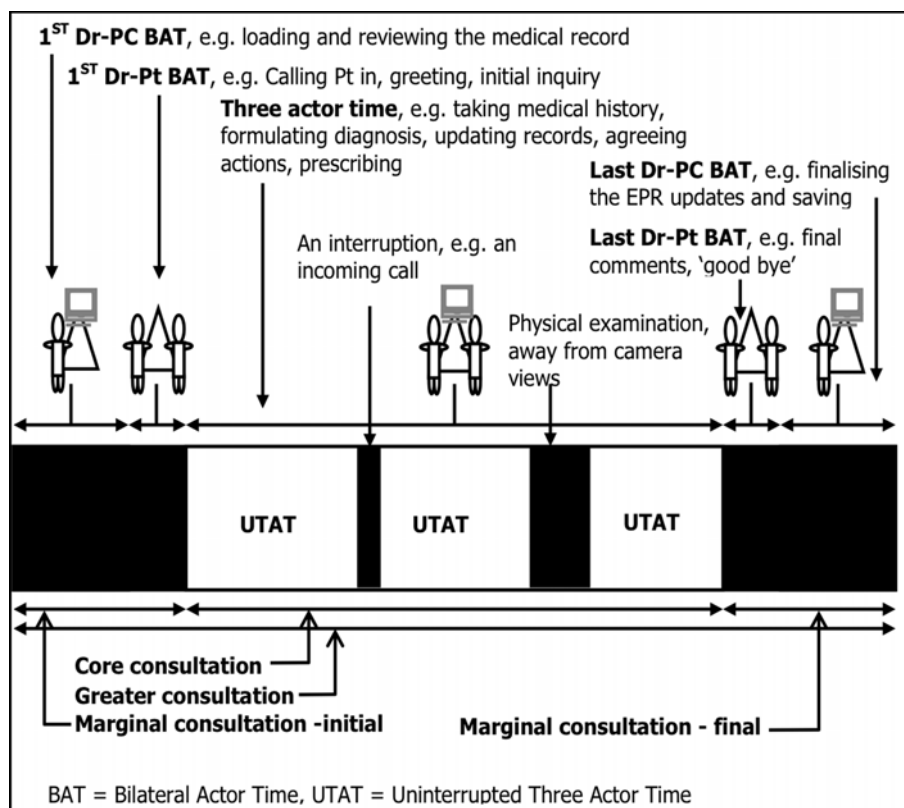
**Fig. 3** Naming the parts of the consultation

Table 2 Continuous and episodic variables in the consultation

Variable type	Properties	Examples
Continuous	Distributed throughout the consultation Occurs frequently Unpredictable durations or difficult to define	Gaze Speech Computer use – key board, mouse Looking at computer screen
Episodic	Separate sections of interactions Less frequent Durations more predictable or relatively easy to observe	Coded data entry Free text data entry Navigation Prompts and alerts Interruptions Screen sharing
Singleton	Generally occurs once	Blood pressure measurement Prescribing Referral Physical examination

We advocate the reporting of studies using interaction identifiers, based on their pattern of occurrence: (i) ‘Continuous’ are distributed throughout the duration (e.g. eye-contact, speech); (ii) ‘Episodic’ includes all the types of computer data entry (e.g. coding data, entering narrative text, navigation time); and (iii) ‘Singletons’ generally occur once (e.g. physical examination, blood pressure recording etc.). These interactions often utilise standard workflows (e.g. measuring BP), which can be observed and compared between different EHR systems [65].

7. Post-consultation impact measures

Studies which conduct qualitative or quantitative data collection post consultation should report this systematically wherever possible using validated methods and tools. The clinician-patient relationship remains the cornerstone of medical practice and has a great impact on a number of post-consultation outcomes, such as patient satisfaction and adherence to recommendations. Indeed, it has been shown that a good consultation improves not only satisfaction with the consultation, but also satisfaction with the wider health system [66] as it is seen as the first stop of the patient’s journey in the system. A good

clinician-patient communication also impacts significantly on the patient’s decision to follow recommendations. There is increasing evidence that the clinician can help the patient improve adherence to medical recommendations, by improving aspects of trust and involvement in the decision making process [67]. This can then be linked to post-consultation outcomes using validated tools to measure adherence [68], patient satisfaction [46], and general health outcomes [69]. There is also scope to conduct post-consultation interviews and immediately replaying the video using techniques like “Think aloud protocol” to gain further insights into the consultation process [70].

8. Data capture, storage, and export formats

Data capture and storage techniques will change rapidly, however using standard file formats and industry standard formats will facilitate later utilisation of data. Technology has progressed rapidly from a time when professional equipment was needed to make multichannel observation to an age where multimedia observations tools are readily available; and the main issue becomes the management of multiple observation files. Early observation

work relied on a single video channel [71, 72] or using professional studios to mix multiple film channels. The ALFA open source toolkit was developed to overcome the practical management issues files containing a large volume of observational data; all the data from multiple observations can be stored as a single multichannel video and all other data as an extensible markup language (XML) file [73]. Different observation tools may have different time stamps so are not readily combined; there was no existing method of providing an overview of the consultation using standardise variables; or to readily navigate between comparable events (e.g. display of prescribing alerts) in these multiple files. The ALFA toolkit overcomes these problems and also enables precise observations to be converted to a format readily usable by a software engineer, the unified modelling language (UML) sequence diagrams [61]. We recommend that those undertaking observational research store their data in using open formats using methods (like UML and XML used in this example) that facilitated them being re-used in subsequent studies.

Classification for describing observational study of the consultation

This consensus classification describes the key elements of clinical consultation (Table 3).

4. Discussion

Principal Findings

We have identified important aspects of reporting observational studies of the impact of IT on the clinical consultation. These facets tend to be reported poorly in the literature, and we have, on the basis of our consensus-building work, proposed a guide for the reporting of these items in future research studies. Our intention is that drawing on this reporting guide will facilitate the improved reporting and interpreta-

Table 3 Final classification

Facet	Detail This is not an exhaustive list other element may need to be considered for each facet taking into account the study design and context
1. Theoretical and epistemological approach to observation	(1) Qualitative, quantitative, technical (2) Social theory at a macro or micro level (3) Cognitive theory (4) Cognitive load (5) Communications skills and consultation models
2. Data collection	(1) Audio only/Audio-visual/ Non-video/Other (2) Number of channels and observation devices (3) Coverage of each channel – wide or targeted (4) Type and physical profile of intrusive devices (5) Automated measurement techniques used (6) Steps for setting up (7) Steps for analysable data extraction
3. Room layout	(1) Inclusive (2) Semi inclusive – clinician controlled, (3) semi inclusive – patient controlled (4) Exclusive (5) Other considerations relating to the physical environment
4. Initiation and interaction	(1) Consultation Initiation- clinician, patient or computer (2) Use of computer – minimal, block, conversational (3) Clinician usual orientation – unipolar, bipolar (4) Clinician behaviour style – engaging, disengaging, cogitating (5) Interaction: Triadic or Dyadic: patient-clinician or clinician-computer (6) Use of computer: excluded, controlled, shared (7) Direction: synchronous, asynchronous (8) Nature of patients-computer interaction: screen controlling, watching, sharing (9) Influence of computer: informative, prompting, distracting, engaging
5. Information and knowledge utilisation	(1) Information: Source, usefulness, outcome (2) Computer: information, facilitation, agenda (3) Clinician: Knowledge, facilitation, training, agenda (4) Patient: Problem, knowledge, agenda
6. Timing and type of consultation variable	(1) Greater consultation: First to last interactions (2) Marginal – before and after patient present; and Core - patient present (3) Bilateral actor times - three actor time and Uninterrupted three actor time (4) Consultation interaction variables - continuous, episodic and singleton (5) Capturing and modelling workflows
7. Post consultation impact measures	(1) Measurement of adherence, (2) Satisfaction with consultation, (3) Clinical indicators and health outcomes, (4) Think-aloud protocol explanation of interaction (replaying video) (5) Post-consultation interviews
8. Data capture, storage, and export formats	(1) Process – automated, semi-automated, subjective manual, (2) Tools and applications used – (a) Direct: installed, plugged-in, external or (b) indirect observation (3) Raw data format – including log file (i.e. time log) or not, (4) Data representation – quantitative, graphical, (5) Computer use – screen, mouse (coordinates), key board use (navigation & active key use (6) Description of IT use - navigation, transition (between functions within EPR), operational use: data values and descriptors (7) Data storage format and mechanism for navigation and linking research output to source data (8) Export formats: Extensible mark-up language (XML); or standard modelling

tion of research findings, and also facilitate more meaningful comparisons both between and across studies. We have released this as a consensus position statement because it is based on over a decade of learning and researchers from an international group who wish to see more generaliseable lessons drawn from this important body of work.

Implications of the Findings

The purpose of the classification is to improve consistency and facilitate the synthesis of evidence from different studies. Our classification should help researchers plan and describe their studies as well as journal editors and readers make comparisons between studies easier. This classification and accompanying checklist should make it easier for data from studies to be combined and learn common lessons and create generaliseable theory within health informatics.

Limitations

We have described the work presented in this paper as a position statement as it is the presentation of one side of an argument, and therefore sets out to make a case; this is a legitimate part of the development of research methods and of the activities of an international working group.

Video observation possibly has a minimal Hawthorne effect on the process of delivering health care [10, 74]. Whilst this effect may occur, the impact on research is impossible to quantify. Refusal rates are uniformly low [10], and usually fall into specific categories. Experience with researchers who are themselves clinicians suggests that there is little Hawthorne effect. Over time, the video recording methods used are becoming more unobtrusive, lessening the impact of observation itself, while still adhering to ethical review and institutional review boards [69].

Need for Further Research

How the clinician-patient-computer relationship evolves during the consultation remains a 'black box' for many researchers; with a lack of understanding as to what elements of use of IT change or modify health behaviours. More evidence is needed to shed light on this important area and video and other observational studies provide important insights. This report was written by a self selected group, is not the result of a systematic review and therefore needs to be tested for its utility in future prospective studies.

This classification, which representing the current state of the art, is still in its infancy in terms of development. Whilst many studies describe what they see, few have moved beyond to the implications of what is being observed. This work can be used to explore more advanced concepts such as the changes in power and authority in the consultation, the implications of different clinical systems and usability design. Practical feedback from such studies can include system redesign and customisation to facilitate usability, design of more effective clinical workflow involving technology, improved ergonomic layouts, and improved IT training. As the role of electronic information expands, so too must the research. Additionally, it is hoped that the classification can be used at a much higher level of analysis on larger samples, facilitating the generaliseability of the findings.

5. Conclusions

Using the IMIA Primary Care Informatics Working Group classification should provide improved clarity on reporting and comparing observational research on the use of IT within the clinical consultation. Authors and editors should consider using it to help ensure consistency of reporting and facilitating combining study data.

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Conflicts of Interest:

The authors have no conflicts of interest to declare.

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