Manuscript title

A qualitative study exploring factors influencing clinical decision-making for influenza-like illness in Solapur city, Maharashtra, India

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ABSTRACT

The co-existence of different types of medical systems (medical pluralism) is a typical feature of India's healthcare system. For conditions such as influenza-like illness (ILI), where non- specific disease signs/symptoms exist, clinical reasoning in the context of medical pluralism becomes crucial. Recognising this need, we undertook a qualitative study, which explored factors underpinning clinical decisions on diagnosis and management of ILI. The study involved semi-structured interviews including clinical vignettes with 20 healthcare practitioners (working within allopathy, homeopathy and ayurveda) working in the private healthcare sector in Solapur city, India. An inquiry was conducted into criteria influencing the diagnosis, treatment, referral to specialist care and role of treatment guidelines for ILI. Thematic analysis was used to identify aspects relating to ILI diagnosis, treatment and referral. The diagnosis of influenza was based largely on clinical symptoms suggestive of influenza in the absence of other diagnoses. Referral for laboratory tests was only initiated if illness did not resolve, generally after 2-3 consultations. Antibiotics were often prescribed for persistent illness, with antivirals rarely considered. Some differences between practitioners from different medical systems were observed in relation to treatment and referral in case of persistent illness. A combination of analytical and intuitive clinical reasoning was used by the participants and clinical decisions were based on both social and clinical factors. Clinical decision making was rarely a linear process and respondents felt that broad guidelines on influenza that allowed doctors to account for the sociocultural context within which they practised medicine would be helpful.

Keywords
India, Influenza-like illness, Clinical reasoning, Decision-making.

INTRODUCTION

Influenza-like illness (ILI) is a particularly interesting condition to explore clinical reasoning as it can present as a host of non-disease specific signs and symptoms (WHO, 2014) and is difficult to differentiate from other respiratory (tract) infections (RTIs) (WHO, 2014; Carrat *et al.* 1999; Reina *et al.* 2004; Denny Jr, 1995). The uncertainty in diagnosis and prognosis is further augmented by the emergence of novel influenza virus strains such as influenza A(H1N1)pdm09 (swine flu) and its successive evolutions which may be clinically indistinguishable from seasonal influenza strains at the outset, while being more lethal over the course of the illness (Purakayastha *et al.*, 2013). A(H1N1)pdm09 caused the influenza pandemic in 2009, and has already become a seasonal virus (WHO, 2011). It has continued circulating with other seasonal viruses since August 2010 (WHO, 2011), and has reportedly spilled over from humans back to swine (Perera *et al.*, 2014). In the lead-in to the 2009 influenza A pandemic, experts predicted that the next pandemic would have possible lethal consequences on a global scale; however, its occurrence could not be precisely estimated. This uncertainty persists even today (WHO, 2004; RCP, 2009; Fineberg, 2014; Holloway *et al.*, 2014) and the complexity and constant evolution of respiratory viruses mean that clinical decisions relating to ILI are made under extreme uncertainty, with limited information to allow for calculative decision(s).

In a typical clinical encounter, the physician needs to evaluate the trade-offs between different diagnostic and treatment options based on their clinical expertise, available evidence and patient preference (Butler *et al.*, 2001). However, over the past few decades, Evidence-based medicine (EBM) has become central to medical practice and education (Hartzband & Groopman, 2009). EBM emphasises applying the ‘best evidence’ to remove ‘ineffective’ or ‘dangerous’ treatments from clinical practice (Miles & Loughlin, 2011). EBM has been described as an attempt to replace clinical judgement with the arguably ‘objective’ scientific evidence that gives pre-eminence to evidence from randomised

controlled clinical trials (RCTs) (Worrall, 2010). Ironically, while EBM mission statements are often couched in anti-authoritarian terms and advocated as an improvement over 'ego-based' medicine practiced by individual clinicians (p.S81) (Ecks 2008), it is seen by many as stripping 'patients of their stories' and responsible for the 'fragmentation and reification of the subject' (p.1062) (Mykhalovskiy and Weir, 2004). Berger (1967) describes the experience of a country doctor in 1960s UK, where over the course of his clinical practice he realises that he must see his patients in relation to their past, their family history and their community. Therefore, it could be argued that 'clinical reasoning encompasses the gamut of thinking about medical practice' (p.173) (Stempsey, 2009) and not just EBM. As the EBM movement gains momentum in developing countries like India, this study responds to Nichter's call for studies into whether EBM is feasible or even relevant in different contexts as well as what kinds of evidence clinicians consider in their decision making (Nichter, 2013). Therefore, the work reported in this paper, aimed to understand the role of clinical judgement, cognitive elements and socio-cultural factors influencing clinical reasoning in relation to influenza-like illness (ILI) in a small city in western India.We chose clinicians working in private sector primary healthcare (PHC) settings in Solapur city to be the focus of a qualitative study which aimed to explore factors influencing their decision making in relation to ILI. Based on the study findings we then sought to link these to a theory of clinical reasoning, in other words, a theory of how clinicians know that the patient presenting to them has a particular diagnosis (in this instance, influenza). The reported findings have implications for (1) strengthening preparedness and responsiveness to the foreseeable threat to global public health from an influenza pandemic, (2) understanding routine medical practice, and (3) avoiding inappropriate use of healthcare.

METHODOLOGY AND METHODS

Study Setting, Design and Participants

This qualitative study was designed in keeping with the ethnographic decision tree modelling approach (Gladwin, 1989) which could be broadly situated within a constructivist paradigm (Guba, 1990). The sampling frame was clinicians working in primary care settings in Solapur city, Maharashtra, India. We chose Solapur as our study setting as one of our research partners, the Halo Medical Foundation (HMF) has over twenty years of experience working with healthcare partners in this setting.

Indian medical practice exhibits medical pluralism, as multiple systems co-exist simultaneously (the main systems in the study setting being Allopathy, Ayurveda and Homeopathy) (Minocha, 1980) and therefore, we used a purposive sampling approach (Lunsford & Lunsford, 1995) to include maximum participants from Allopathy, and at least one each from the other two outlined medical systems. This inclusion of practitioners from other systems was important because while the general assumption in international health is that traditional forms of medicine are a barrier to use of 'modern' biomedicine (or allopathic medicine), previous work by Lambert (1996) has shown that traditional medicine is 'dynamic and very receptive to innovations that are readiliy available and clearly efficacious' (p. 1709) (Lambert, 1996) and practitioners 'combine and fuse different therapeutic approaches' (p. 277) (Quack, 2012). Nevertheless, our sample predominantly comprised allopathic practitioners as we were primarily interested in contextual influences on clinical reasoning within the same medical system with a secondary interest in the interactions between traditional Indian and modern medicine practitioners. It is important to note that our study did not include folk medicine (i.e. local, faith, ritual healing practices as defined by Quack, 2012) practitioners and this is a potential limitation.

Participants working in primary care settings and with the following qualifications were eligible for inclusion: Bachelor in Medicine and Surgery (MBBS), Doctor of Medicine (MD), Post-graduate diploma in Medicine, Bachelor of Ayurveda Medicine and Surgery (BAMS) and Bachelor of Homeopathy Medicine and Surgery (BHMS). The sampling also took into account different geographical areas of the city including old and new urban developments as well as socioeconomically diverse areas. Potential respondents were selected based on a contact list supplied by the Halo Medical Foundation (HMF), which had access to a network of clinicians working within Solapur.

Ethical approvals

Participation in the study was voluntary and no monetary reimbursement was provided. The research project was approved by the Institutional Ethics Committee of MAAS (reference number: MAAS-IEC/2013/001), and the University of Nottingham Medical School Research Ethics Committee (reference number: OVS08102013 SoM EPH).

Data Collection and analysis

A semi-structured interview guide comprising open-ended questions was used to explore how health professionals diagnosed, managed and treated influenza, factors influencing referral to secondary care or specialists, whether management altered during a known epidemic/pandemic, and ways in which the diagnosis and subsequent management of influenza could be improved. The interview also explored the potential benefit of clinical guidelines on diagnosing and managing seasonal and pandemic influenza in primary heath care settings (see Appendix 1 for the interview guide).

The interview guide was developed through series of discussions between research team members representing the disciplines of anthropology and public health. The interview guide was piloted, finalised and then translated into Marathi and Hindi (the local languages) with two trilingual authors verifying the accuracy of the translation.

Written consent was obtained from each participant prior to the interview. All interviews were conducted in Marathi. Participants could also respond in Hindi and English (particularly in relation to medical terminology) to ensure that the responses accurately reflected their opinions. Ideally, ethnographic decision tree modelling (EDTM) should combine interviews with participant observation (Gladwin, 1989), but this was not possible due to concerns around acceptability and resource constraints. Therefore, to simulate the findings that may emerge from the direct observation of clinical encounters, two clinical vignettes were developed based on the responses provided by the first ten respondents (Round 1 interviews) to gain an insight into how clinical reasoning was enacted. In the second round of interviews ten more healthcare practitioners (similar in profile to respondents in round 1) were asked how they would arrive at a diagnosis, what their most probable diagnosis would be, and how they would manage the patients described in the clinical vignettes; this was in addition to the interview guide used for the Round 1 interviews. All interviews were conducted by the same staff members appointed by HMF India [one interviewer and one note-taker who was also responsible for the audio-recording; one quality controller was present at 5 (25 percent) interviews]. Each interview was audio-recorded. All interviews were conducted in participants' usual work environment and by appointment. The interviews took place between May and September of 2014.

Interviews were transcribed verbatim (with Marathi and Hindi responses translated into English). A unique study code was assigned to identify each interviewee by job role, which did not identify participants. Data were analysed using thematic analysis due to its potential for providing 'a rich and detailed, yet complex, account of [qualitative] data', and its applicability across a range of theoretical and epistemological approaches (Braun & Clarke, 2006). NVivo 10 (QSR, 2015) was used to manage and organise the data according to the themes identified.

RESULTS

Twenty-three physicians were invited to participate, and 20 were interviewed successfully. The sample comprised general physicians (GPs) /specialists in Allopathy (n=16), and Ayurveda (n=3) and Homeopathy (n=1) practitioners. The 16 Allopathy physicians included 11 GPs, three paediatricians, one anaesthetist and one practitioner in gynaecology and obstetrics. Only one respondent worked in a public sector clinic. There were four female respondents and the average clinical experience was 25 years (range: 3-42 years) (see Appendix 2, for further details). The mean duration of interviews was 27 minutes (range: 11–43 minutes). The five themes identified following the thematic analysis are summarised in Figure 1, and detailed in the subsequent subsections.

Insert Figure 1 here

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a. Presentation of ILI and process of diagnosis

Irrespective of health professional type, participants routinely referred to a similar set of symptoms seen in patients with suspected influenza. Patients commonly presented with symptoms such as a cold, rhinorrhoea, sore throat, cough, headache, fatigue, fever (measured or subjective), loss of appetite, body ache and weakness, and watery eyes.

A few participants acknowledged several additional symptoms including vomiting, gastrointestinal symptoms and red eyes, which were reportedly seen in more severe cases of suspected influenza. On the whole, the presence of a combination of these symptoms and the absence of another likely diagnosis such as pneumonia or dengue fever resulted in a clinical diagnosis of influenza. Most participants went on to state that confirmatory

tests for influenza or additional laboratory tests were not utilised because they were deemed unnecessary for ‘simple’ influenza, especially when patients presented for the first time. However, one also mentioned that they lacked the facilities to conduct specific tests for Influenza. Some participants stated that blood tests were conducted to check white blood cell counts or platelets, with a decreased count being indicative of influenza.

Diagnosis is primarily based on symptoms. Body ache, fever, cold, cough are the important symptoms. After that, sometimes after conducting a blood test, the number of WBC or platelets is decreased. These are symptoms in flu and sometimes found in blood. (Interview 11, general practitioner)

Whilst many participants felt that influenza could afflict people of all ages and both genders, some participants mentioned that it was more common among children, pregnant women, those with HIV and the elderly, who were also perceived as being at greater risk of infection due to a weakened immune state.

It can especially happen in small children. If likewise it is divided, then it can happen in youth, adult, HIV patients and high risk in old age because the immunity level is changing every time. So, as per my opinion age limit is not criteria. (Interview 12, general practitioner)

Some participants added that those aged between 22 and 40 years were more at risk because they worked outside and were exposed to infection, or that young girls attending college were at risk because of high chances of infection due to intake of street food . The underlying view in these cases seemed to be that exposure to contaminants outside the home increased the risk of ILI. Some felt that women were less likely to seek medical help for ILI because of greater tolerance.

For women less so, because they have patience and they tolerate it. Most of the time, in work, it subsides, so they might not visit clinic. College going girls eat outside food and get contaminated, they are more susceptible. Small children play outside so chances are greater. So I think these groups are likely to have flu. (Interview 19, gynaecologist and obstetrician)

From onset of symptoms to presentation at a clinic, it was suggested that children were brought in by their parents almost immediately or within a day; though others stated those living farther away took longer.

Nowadays a single child or two children are there in most of families and they are precious kids. So they directly come to the paediatrician. That's why patients from Solapur city come within a few hours or within 24 hours. But patients from outside of Solapur are come after two days. (Interview 1, paediatrician)

In contrast, participants stated that adults often tended to self-medicate for several days and only sought medical help if symptoms worsened. However, a few participants felt that more educated adults, those living in better-off urban areas, or those experiencing a high fever, presented sooner.

Patients here are from a poor socioeconomic groups. They try self-medication first and come here after two or three days. Those who are educated, they come on the first day. (Interview 3, ayurvedic practitioner).

Delayed presentation among adults was also attributed to lack of time and concerns about the anticipated treatment costs.

Sometimes they take medication or go to another doctor. Some others, also they just wait and watch. Why spend money to visit doctor? [Interviewer: What are the possible reasons, why some patients wait and watch before coming to you?] There is no specific

reason I think. They feel that, "I will be all right," so they prefer to wait and watch. "If I will not be alright I will see what to do". Sometimes, they are busy and they don't have time to consult with doctor. They don't have time even to go to a medical shop and buy some medicines. Because, in this area the economic condition is poor. They say "there is pain, but okay I will wait for 2-3 days" and sometimes they become alright. (Interview 5, general practitioner)

b. Treatment and monitoring of patients

Although a few participants expressed some caution around treating children, the elderly and pregnant women, most participants stated that patients with suspected influenza were managed and treated in the same way; this approach remained the same during epidemics/pandemics. The only difference between children and adults was in the form and dose of medication prescribed. Furthermore, a couple of participants suggested that they did not wish to burden patients with unnecessary costs and as a result, tended to prescribe only what was necessary. Symptomatic treatment was advised initially, prior to any tests being conducted. If tests were conducted, treatment was given prior to the result of the tests being available.

We start the treatment. If we don't start the treatment, symptoms increase, so we start the treatment. Along with that, we conduct investigations and give treatment side-by-side, and treatment does not affect the investigation. (Interview 10, anaesthetist)

Typically, antipyretics (paracetamol, ibuprofen and aspirin to reduce temperature), analgesics, antihistamines, a good diet with plenty of fluids and rest were advised by Allopathic practitioners. Respondents typically expected resolution of symptoms in a handful of days for uncomplicated illness.

*Most important, we advise rest first, sufficient intake of food, secondly intake of water, tea, and coffee (plenty of fluids). For fever, we give paracetamol and for a cold, we give antihistaminic. Usually, antibiotics are not required. (*Interview 11, general practitioner)

In flu, body ache, cold, sneezing, headache are present. We treat that part. We give symptomatic treatment. The patient doesn't require any antibiotics. The patient doesn't require any other special medicines. By just giving symptomatic treatment, it will subside in 5 or 6 days. (Interview 5, general practitioner)

Ayurvedic and Homeopathic practitioners also preferred this symptomatic approach to treatment but prescribed treatments specific to their own systems of medicine with the aim of boosting general immunity. These practitioners viewed allopathic medicines with some scepticism.

Patients take medicine from medical store like analgesics and wait and observe. If they are not relieved, then they come to us. For viral fever, there is actually no treatment, but in Ayurveda, medicines are given to increase the immunity of the patient. We have many patients, for example, with respiratory tract infection, regular cold, and cough. If modern medicine is given, relief may be there but it will recur soon. To increase immunity power, for example, iron/folic acid is given. In Ayurveda therapy, there are medicines to increase the immunity. If such medication is taken, then there will not be any problem. (Interview 6, ayurvedic practitioner)

Amongst Allopathic practitioners, influenza-specific antiviral medications were generally not prescribed because they were perceived to be ineffective.

*Antivirals do not work and are not used routinely.(*Interview 7, general practitioner)

Whilst a few participants asserted that they avoided prescribing antibiotics, there seemed to be a clearer protocol for their administration among other health professionals. Antibiotics were usually dispensed after patients returned for a second consultation, because symptoms had not subsided or had worsened, or because a bacterial infection was suspected. Even one of the Ayurvedic practitioners prescribed antibiotics in more severely ill patients if symptoms failed to resolve.

*For the first 3 days, only symptomatic treatment is given. After a second visit, if required, we investigate for WBC, typhoid, CBC (complete blood count), Vidal tests etc. First, 3 days for symptomatic relief antibiotics, antihistamine, paracetamol is given. If the patient feels no relief after 3 days, we investigate further. 90% of viral infections are relieved in 3 to 5 days. We generally investigate during the third visit. If there is relief of symptoms after the second visit, we continue the treatment of antibiotics Otherwise, we change the antibiotic. The patient is called after 2 days. If the fever is not reduced after 5 days, then again we investigate. (*Interview 2, general practitioner)

With the confirmation of flu, the treatment is started. If with symptomatic treatment the patient has no relief, and the immunity is low or depending on the condition of the patient and severity, if required we give antibiotics.(Interview 8, ayurvedic practitioner)

Several other participants reported that they routinely prescribed antibiotics in the first appointment itself as it was difficult to differentiate between viral and bacterial infections; this was especially so in instances of high fever, children, immunocompromised patients, diabetics, or smokers with asthma or coronary obstructive pulmonary disorder.

*If there is asthma with flu, and also present with fever, cold and cough, then for general practitioner, it is very difficult to diagnose whether it is a viral infection or bacterial. Thus routinely antibiotics are given immediately. (*Interview 7, general practitioner)

Antibiotics such as amoxicillin, erythromycin, tetracycline, ampicillin, cefuroxime and azithromycin which were described as being ‘simple’ antibiotics were prescribed in the first instance, including for pregnant women. Some participants went on to state that stronger antibiotics or intravenous fluids were initiated if there was no improvement. However, one participant reported that in some instances antibiotics were prescribed against their clinical judgement in response to patients’ insistence.

The patient is insisting to recover earlier or his psychology is that situation. Sometimes patient feels that without medicine "I am not going to recover earlier". Then for patient’s satisfaction we give simple antibiotics. Normally, we don’t recommend this. If symptoms increased then, if needed, we give antibiotic. Otherwise only paracetamol is sufficient. (Interview 15, general practitioner)

Finally, most respondents were interested in the outcomes of their patients but the degree to which active follow-up was initiated differed between respondents.

“We communicate on phone. Most of the time, in flu like illnesses, the patient is cured in two or three days. In such situations, the patient doesn’t come back. But if the patient is not completely recovered, they visit come back. After all, to report relief or to consult for second visit is the personal decision of the patient. As flu is self-limiting and it is not a serious condition so it will be cured.” (Interview 5, general practitioner*)”*

“Usually we don’t visit. Doctors or the relatives of the patient communicate on the phone and tell us the patient is admitted and he is doing well.” (Interview 7, general practitioner*)*

c. Referral practices

Several participants specified that referring patients with simple influenza to hospital or specialists was either rare or unnecessary, and that simple measures, such as advising symptomatic treatment would lead to relief. Patients with complications such as pneumonia and bronchitis (see complications theme), other existing conditions (e.g. chronic obstructive pulmonary disease, asthma, cancer, systemic diseases), those who were unresponsive to treatment (after 2-3 consultations), such as antibiotics or treatment initiated following blood test results, or with worsening symptoms such as breathlessness, a body rash (in children) or vomiting were referred to hospitals that had the appropriate testing and treatment facilities that their clinics lacked.

There is no need to refer in regular patients. If the patient has a high grade fever and is not responding to regular treatment, there is vomiting, then generally we don't wait to refer. We have very limited tools here and no tests are available at our clinic. The patient becomes panic and the doctor also can't do anything. The patient is dehydrated and in major hospital there is a facility for administrating IV, so we refer. (Interview 7, general practitioner)

Additional triggers for referral to hospital/specialist care were patients showing signs of toxaemia and during a known influenza pandemic. These health professionals did not want to risk deterioration in the patient's condition due to delayed referral. Reflecting on their practice during the 2009 influenza pandemic, participants felt more consistent referral processes were in place for patients suspected to have the pandemic influenza strain, with a few participants reporting that these patients were referred immediately, to specialist Government centres that had appropriate treatment facilities.

In swine [flu], if it is proved, then we refer them to Government hospitals (in Solapur). Generally, we don't give treatment in our hospitals because at Government recognised

centres, treatment facilities are available. We refer such patients to ABC Government Hospital [pseudonym] in Solapur. (Interview 9, general practitioner)

Similarly, other participants suggested referral was routinely considered for children and pregnant women; although a few participants felt that their experience enabled them to treat these groups themselves within a primary care setting.

This is not necessary. I will treat them (pregnant women) as far as my scope of knowledge goes, and if I feel it is necessary to refer (to) gynaecologist. Most of the time we treat it. There are not more complications in pregnancy...I am practising for more than 30 years, so why to refer them. During early days of my practice I used to refer to learn for complex cases, but now I have experience so I treat here. (Interview 5, general practitioner)

Those who did refer these patients seemed to do so either as a precautionary measure, or because these cases were beyond their perceived clinical competence. One of the Ayurvedic practitioners interviewed was open to referring patients perceived to be at high risk of complications to Allopathic doctors and hospitals.

In modern medicine, we give analgesics like Calpol or Crocin [proprietary name for paracetamol] (in pregnancy). If the patient is ready to take Ayurveda medication, we have plenty of medicines. Pregnancy and diseases could be life threatening, anything can happen, so there is associated risks. Just after giving birth, death can occur tomorrow due to serious illness. Patient has to be admitted in case of emergency at hospital because at eleventh hour chances of gasping are there. (Interview 6, ayurvedic practitioner)

d. Perspectives on guidelines

Some participants believed that guidelines for the management (treatment and referral) of simple influenza were not required, for reasons such as low mortality rates; and that it was

not perceived as a serious illness. Instead, these participants argued patient education to discourage self-medication with antibiotics for ILI would be sufficient.

A number of participants also claimed that their usual management practices prevailed during epidemics and pandemics, whilst another claimed that clearer definitions of influenza were required prior to developing any guidelines. However, other participants felt that treatment guidelines were necessary during influenza epidemics and pandemics, when risk of spread was high and demands placed on practitioners were increased. One participant however, felt that guidelines were available and sufficient, but clinicians were unaware of them. It was suggested guidelines should cover basic treatment and referral criteria for clinicians, infection control policies (such as the use of face masks) as well as guidance on required infrastructure, capacity and skills for healthcare policy makers to improve preparedness for seasonal epidemics and pandemics.

[…]so such a guideline should be with everyone, so that authorities can make changes on local level such as use mask. Flu is seasonal and it comes in groups with 10-20 patients or 2 to 4 months it will be continued. So such guideline is necessary. [Interviewer: What should be included in such guidelines?] Basic line of treatment, referral points, where to refer the patients, where should be the referral points, the type of referral unit, which centre is referring to higher centre, what capacities should be available, requirements in the hospital, capacity of Hospitals and Doctors, all these should be there in the guideline. (Interview 12, general practitioner)

Several participants highlighted that some clinicians were unaware of outbreaks and guidelines would aid in combatting haphazard management and providing detailed epidemic-specific information to patients.

[…]I feel there must be a perfect protocol for this. In my regular routine I can give more time to patients to give them instructions. But when there is such a load (during

pandemics/epidemics), every patient expects more detail. A doctor is only a human and has some limitations. There are limitations in such situations as every time virulence changes, there should a decided protocol for that time. A protocol will make it easier for all. (Interview 1, paediatrician)

Guidelines would also ensure treatment was timely and uniform, particularly when a virus was at its peak circulation in the population. Furthermore, another participant described how guidelines would ensure timely referral of people in poorly connected rural areas.

It will give benefit to patients. All will receive treatment based on general guideline and doctor can understand until what limit we can work. Considering patients' requirement and available facilities available. Here in city, within 15 minutes to half hour a patient can reach to the hospital but in rural areas there are many problems. In such situations, if there is a guideline available, it will help to refer the patient hospitals in proper time and will be helpful for patient. (Interview 13, paediatrician)

Recent advances in treatment could also be outlined in guidelines, though some participants felt this should form part of a continued professional development programme instead.

At the time of an epidemic, CME [continuing medical education] is required for awareness among doctors. After completion of MBBS, we have learned many diseases, but we do not observe patients with these diseases in medical colleges during education. During an epidemic, CME must be organised for or presentations, diagnosis and treatment which will be helpful. CME to be organised through IMA (Indian Medical Association) or NIMA for BAMS and other (National Integrated Medicine Association) to inform doctors on recent trends in treatment or antibiotics usage. (Interview 2, general practitioner)

Another participant argued that diagnostic kits were needed to differentiate between pandemic influenza and ‘simple’ seasonal influenza, while another stated that diagnostic guidelines were only required if there was a novel viral strain in circulation. Several participants argued that guidelines alone would be of little use unless the appropriate facilities to test and treat influenza were in adequate supply; for example, one participant indicated that timely screening of family members was required, but a current lack of resources would make this difficult.

Screening of relatives and people nearby the patient should be conducted within time. But considering the population and Government health resource availability, it seems difficult. (Interview 9, general practitioner)

Some participants proposed guidelines targeted at patients were also necessary. Such guidelines could advise patients on when they should visit their general practitioner, rather than self-medicate, along with preventive advice for influenza and caring for someone with influenza. Finally, guidelines were welcomed by practitioners working in all three systems of medicine.

Such guidelines will be helpful for these conditions (swine flu), up to a certain limit (health condition) to tell people where to stop and consult the Doctor. Nowadays, still people go to a medical store for self-medication. The Government must stop such practices. Then, there will be some realization of the value of doctors. Otherwise, what is happening is patients are coming to us with higher antibiotics and we are unable to diagnose the level of immunity. If Government gives the guideline for 100% diagnosis and treatment, it will definitely be beneficial. We don’t have any objection. It will be helpful to us. (Interview 8, ayurvedic practitioner)

e. The provision of preventive advice

Although a couple of participants mentioned that they provided leaflets on influenza prevention, most participants delivered advice verbally. The advice seemed to be given in an attempt to prevent further spread rather than general advice on flu prevention. For example, many Allopathic participants stated that they recommended that affected patients were isolated from other family members and that their clothing be washed separately. Homeopathic and Ayurvedic physicians said that they educated patients about healthy eating and lifestyle advice with the aim of boosting or maintaining good levels of immunity.

In air conditioners, the growth of bacteria, viruses is greater. Have natural air. It is required to sleep early, wake up early, go for a morning walk and have a natural diet. Avoid food stored in a freezer, cold drinks, alcohol or this will decrease immunity and there will be invitation to illness. (Interview 4, homeopathic practitioner)

Other participants advised people to maintain a good level of hygiene. However, a few participants acknowledged that avoiding spread within families was difficult, due to crowded living arrangements. The use of face masks as a means of reducing transmission was suggested in the case of an influenza pandemic. Some participants felt that patients did not adhere to preventive advice even if it was given.

We advise them rest, balanced food, cleanliness and also ask to drink boiled water. We say this to every patient but very few follows. Most of the people are using water purification systems but boiled water is the best. Such systems are expensive. We teach them to use medicine drops but to those who don't have money we advise to use traditional purifying agents for water purification. The process is very simple. Some people are very aware but some neglect… (Interview 14, general practitioner).

DISCUSSION

Five key themes (summarised in Fig. 1) were identified from the thematic analysis that shed light on understanding long-standing debates on clinical reasoning in the medical literature. The crucial contributions of this paper include: (1) an understanding of clinical decision-making under uncertainty, and (2) the human factors implicit in clinical reasoning for ILIs.

Our findings contradict the implicit postulate in EBM that clinical decision making is a linear process (Sackett *et al.,* 1997). However, they support the widely recognised dual process theory of decision-making postulated by Kahneman (2003), according to which decision-making involves interactions between intuitive and analytical processes (systems 1 and 2 respectively). Mears & Sweeney (2000) and Woolley & Kostopoulou (2013) observed that clinical decision making is muti-faceted and complex, with clinical practitioners using a combination of analytical and intuitive reasoning to reach decisions. The physicians in our study first looked for salient features in the clinical presentation that would allow them to make a provisional diagnosis of ILI (system 1); interestingly, in keeping with the findings of Balla et al. (2012) who studied UK GPs working out of hours, a key consideration of our participants was ruling out severe disease and looking out for unusual patterns of presentation that may warrant further investigation and analysis (system 2).

The participants in our study generally formulated their judgement primarily based on clinical presentation (signs and symptoms) rather than seeking laboratory confirmation of diagnoses. However, this does not imply that their decisions were irrational; indeed, this diagnostic approach might possibly be more sensible than formulating therapeutic and referral strategies based on expensive laboratory diagnostics given that ILI is usually a self-limiting condition in most cases (Vijayan *et al.*, 2012). Physicians may avoid laboratory testing to save money in resource-poor settings as confirmed by one of the participants,

who was concerned that unnecessary medications would impose a financial burden on patients. This inference is supported by national statistics. In 2003, 85.9% of the spending on health of India was financed through out-of-pocket payments (OOP) (United Nations, 2014). During 2004 to 2005, it was estimated that nearly 5% of the population in Maharashtra was impoverished due to OOP payments (Ghosh, 2011). Therefore, if the physicians did make decisions based on costly diagnostic results (for e.g. influenza virology alone could cost between 15 to 25 percent of the typical household income for Solapur) care could become inaccessible to many and the disease would be likely to spread more widely (Government of Maharashtra, 2015; Ahankari, 2015). Fortin (2010) describes the clinical encounter as a social encounter where social issues and context come into play; she mentions clinicians who acknowledge that making a diagnosis is only secondary to helping their patients and that evidence based medicine is just one of the many chapters in their heads. This social context of medical practice seems extremely important to the clinical practitioners in our study as well, further exposing the problems with an EBM movement that seeks to decontextualise and standardise medicine (Goldenberg, 2006).

In contrast, when our study participants encountered cases with symptoms of severe influenza or those perceived at being high-risk of complications, they stated that they would generally refer them to hospitals/specialists (and sometimes requested for laboratory tests before the referrals). Moreover, they updated their initial judgement based on clinical symptoms over the course of the illness, using an intuitive Bayesian framework (Woolley & Kostopoulou, 2013). This combination of analytical and intuitive strategies for clinical reasoning have also been identified in other studies (Woolley & Kostopoulou, 2013). The physicians in our study used simple clinical reasoning strategies that are reflective of heuristic decision strategies (recognition heuristics) as described by Goldstein and Gigerenzer (1999). According to recognition heuristics, less information based on few

relevant predictors may actually perform better in the area of medical diagnosis than information-greedy algorithms (Marewski and Gigerenzer, 2012).

During epidemics/pandemics, the participants seemed wary of their usual (referral) practice, although not consciously aware of it. The participants claimed applying the same approach to treating and managing suspected cases, but were more ready to refer severe cases or high-risk patients to hospitals/specialists. In general, similar diagnostic principles were applied by Homeopathic and Ayurvedic practitioners but management primarily focused on boosting the patient's immunity. One Ayurvedic physician was quite open to referring patients to Allopathic physicians or hospitals. Across the sample, general physicians felt the limits of their clinical competence when confronted with pregnant patients and children. Some routinely referred high-risk patient sub-groups to hospitals or specialists. The findings suggest that the participants revised their reasoning strategies based on their confidence about the adequacy of current information. They were more likely to employ analytical reasoning when the presentations signalled severe symptomatic conditions. It is not clear whether they did so to minimise the risk of litigation due to medical errors or concerns for patients' well-being. Presumably, they did have a concern for the patients, because they generally emphasised treating or managing the patients' conditions in a timely manner and financial burden on patients was a medication decision factor. To some extent, this phenomenon fits with the precautionary principle which has often been adopted as a strategy by policy makers and clinicians when there is little relevant information. Under this principle, a rational decision-maker would make the decision based on the pessimistic *a priori* probability (Resnik, 2004; ter Meulen, 2005). Participants seemed to make the provision that high-risk patients required secondary or specialist care, especially during pandemics. They highlighted the importance of making the decision quickly and decisively in an emergency situation characterised by considerable scientific uncertainty. That the participants had diverse opinions towards the applications of standardised ILI guidelines was a natural consequence given that they

might have diverse risk averse attitudes. In an extreme case, the participant challenged the relevance of the established definition of influenza; suggesting instead that a clearer definition of 'influenza' was required prior to developing guidelines. These findings illustrate the dichotomy inherent in the translation of EBM into clinical practice, namely, objective facts yielded by clinical epidemiology and tacit knowledge gained through clinical experience in a particular setting (Mykhalovskiy and Weir, 2004); therefore, a similar set of clinical signs and symptoms may indicate a probable diagnosis of influenza in the UK, malaria in Africa and dengue in India. Timmermans and Angell (2001) advocate the term 'evidence based clinical judgement' to allow for a more flexible approach to EBM by emphasising the importance of both epidemiological evidence and clinical experience.

Our findings also provide insights into combating a prominent public health issue – inappropriate use of antimicrobials that leads to emergence of antimicrobial resistance, and consequently, a global health threat (WHO, 2012). Certain participants acknowledged routinely prescribing antibiotics due to uncertainty in the aetiology of the conditions, and to maintain patient satisfaction. The latter is a long standing issue (Macfarlane *et al.*, 1997), and other evidence suggests that if physicians perceive that patients expect medication, they will be ten times more likely to prescribe it (Cockburn & Pit, 1997). Applying a shared decision-making approach (Butler *et al.*, 2001) and delayed prescribing (Little, 2005) seem to mitigate unnecessary antimicrobial prescribing. Shared decision-making requires interacting with the patients to make the decisions based on shared knowledge (Butler *et al.*, 2001). The interview data did not allow us to ascertain whether participants applied this approach to their consultations. This is an area to be studied in further research. Some participants seemed to have been practising delayed prescription (though implemented differently to what Little refers to as 'delayed prescribing', whereby a post-dated prescription would be issued at the first consultation), as they only considered prescribing antibiotics at subsequent visits or after further diagnostic information was available. This approach could effectively reduce overall prescribing of antibiotics (Little, 2005), and is

recommended in UK clinical guidelines (NICE, 2015). Prescribing antibiotics for patients with uncomplicated upper RTIs can sometimes be justified given that we do not yet know who is at risk of subsequently developing rare but serious complications such as secondary bacterial infections (Little, 2005). Some participants routinely prescribed antibiotics to cases presenting with ILI and felt that delayed prescribing was not always a viable option as many patients had already self-medicated themselves with antibiotics (in India antibiotics can be purchased over the counter without a physician prescription). Participants did not comment on antimicrobial resistance or strategies for treating resistant strains; similarly, there did not appear to be a standardised approach for which antibiotic should be prescribed. No participant claimed feeling pressured to prescribe influenza-specific antivirals and some participants suggested feeling uncertain about the effectiveness of antivirals.

Participants had diverse opinions about preventive strategies. They considered their efforts in combating influenza epidemics/pandemics were limited unless the public was educated about the right attitudes towards self-medication with antibiotics and when to seek medical advice. Participants voiced the need for educating physicians and patients to be responsible system users, and granting 'altruistic' physicians autonomy to direct resources based on patients' social circumstances as well as clinical needs ('socio-technical' needs) to improve population health (Tsang, 2015).

Our study has some limitations, most notably that our study findings are based on clinician reports rather than observation of actual clinical practice and thus, reported practice may be quite different from actual practice. While we attempted to use clinical vignettes as a proxy for observation, these only helped us gain a clearer insight into the cognitive processes underlying clinical reasoning but there may still be a mismatch between reported and actual practice. Finally, we were dependent on our local partner organisation

HMF, for identification and recruitment of suitable respondents and it is possible that we have not captured the diversity of views on this subject.

To conclude, our study findings suggest that clinicians use a combination of analytical and intuitive processes in their decision making which draw on evidence, sociocultural context and clinical experience. There were also professional cultural influences associated with the different medical systems though there was recognition for the need to develop shared understandings and ways of working to benefit patients, especially in a crisis situation. Lambert et al. (2006) have previously commented that EBM cannot be a universal, transparent endeavour and evidence needs to be interpreted via a sociocultural lens while De Vries and Lemmens (2006) caution against the 'unchallenged assumptions of the interchangeability of bodies' made by EBM; our study findings supports these views (p.2698). Thus, while our clinicians were open to the idea of clinical guidelines, the implicit message was that EBM principles are best viewed as broad guidelines rather than validated checklists to facilitate 'evidence-based clinical judgment' that insist on blind adherence to a fixed set of rules (Hartzband & Groopman, 2009).

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Endnotes: On the nature of evidence

This paper prompted an extensive debate on the nature of evidence in medical anthropology that is summarised here for readers' benefit and to stimulate further debate. The reviewers of this paper questioned the suitability of this paper for medical anthropology journal despite acknowledging the value of the findings, on the grounds that the evidence was not 'anthropological' in nature. The first criticism was that this was not an ethnographic study and the second, that the discussion was not framed in anthropological terms. The authors recognised the concerns expressed by the reviewer, acknowledging that the work reported in this paper was motivated by challenges faced by public health policy and a sense that the current emphasis on evidence-based practice and guidelines failed to take into account the cultural context within which healthcare was provided. An excerpt from their response making an argument for publication of their paper in this journal is included below.

"Having tried to disentangle the socio-cultural influences on clinical practice in our study setting, we felt constrained by the reporting guidelines of other medical and public health journals and therefore came to the conclusion that 'Anthropology and Medicine' would be a more suitable home for our paper. It is true that we are a multi-disciplinary research team (including medical anthropologists, public health specialists, applied health services researchers and behavioural economists) therefore, our various perspectives have been reflected in the paper; however, in the age of converging disciplines, we feel this discipline-bridging adds value to our paper and hopefully, will be valued by the wider readership of your esteemed journal.

We have also read with interest the papers by Helen Lambert (Evidentiary truths, 2009) and Christopher Colvin (Anthropologies in and of Evidence Making in Global Health Research and Policy, 2015) as well as other work linked to these papers and the messages we have taken on board are as follow: that there is a wider philosophical debate within anthropology of the nature of anthropological evidence in itself; the relational nature of anthropological evidence makes it difficult to use it to inform policies/guidelines as compared to quantitative evidence; that there is nevertheless, a need for anthropological evidence to be considered in public health policy. These broader philosophical debates are beyond the scope our paper though they do prompt the question of whether what we report in our paper can be viewed as 'anthropological evidence'.

The anthropologists in our research team consider our methodological approach and methods 'anthropological' even though we have not used ethnographic observations in our study due to cultural sensitivities; we considered observing actual clinical consultations but decided against these precisely because we were told in our consultations with local stakeholders that such observations could be viewed as being 'judgemental' and 'imperialistic' (in the sense of whether the clinical standards of our study clinicians matched up to international guidelines and best practice). Therefore, in a sense, we were 'doing' anthropology (in the sense described by Christopher Colvin, 2015) by adapting our methods to suit the cultural context. We discovered a compromise in using clinical vignettes through our exploration of ethnographic decision tree modelling as described by Christina Gladwin (Gladwin, 1989). However, we recognise that there are different perspectives in anthropology and therefore, we request the editors to act as arbiters on the matter of whether our paper is anthropological

enough. Perhaps an accompanying endnote commenting on these issues and our paper would be helpful in exploring the nature (and purpose) of anthropological evidence."

Another minor criticism related to the paper including statements that would be obvious to an anthropological readership. One instance of this was the following statement, "This social context of medical practice seems extremely important to the clinical practitioners in our study as well, further exposing the problems with an EBM movement that seeks to decontextualise and standardise medicine (Goldenberg, 2006)." The authors agreed that the statements on the importance of context in the practice of medicine would seem obvious to anthropological readers but ended with the following plea: *"However, we would like to retain this on the grounds that our hope is that this paper will be of interest to readers beyond the traditional readership of Anthropology and Medicine; we hope that this paper will appeal to public health policy makers and clinicians as well and thus, it is important to state what may seem to be 'obvious' to our anthropological colleagues."*

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Authors contribution
The study was initially conceived and designed by PRM, AA, AK, SA, MB and TL. AK sought ethical approval from the MAAS IEC, and PRM sought ethical approval from the Medical School Ethics Committee, University of Nottingham. MB and PRM provided study oversight while AK provided methodological quality oversight for the study conduct in India. AA was responsible for project management during the field research phase including data collection, translation and transcription. AA received support for data collection from Mr Upendra Tannu and Mrs Anita Gaikwad employed by Halo Medical Foundation, India. AA and FK transcribed and translated the data with validation of transcription/translation by AK. MB and PRM analysed the data with validation from AA, FK, AK and ST. ST led on the theory-building with contributions from PRM. All authors contributed to the interpretation of the findings and drafting of the paper.

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Declaration of interests
PRM has received an unrestricted educational grant for research into pandemic influenza from F.Hoffman La Roche previously but this study has been conducted independently of that grant. ST is a Research Associate at the Chinese University of Hong Kong, but conducted this research as an International Senior Postdoctoral Fellow of University of Nottingham during a short-term unpaid sabbatical from her employing institution in Hong Kong. Other authors do not report any potential conflicts of interest relevant to this article.

Appendices

Appendix 1: Semi-structured interview guide

General information

1. When did you graduate from the medical college?
2. Do you have any additional qualifications apart from your primary medical qualification and general practice?
3. How long have you been practicing as a general practitioner (GP)?
4. What is your daily routine like? How many patients on an average, do you see every day?

Diagnosis of Influenza

5. How do you diagnose Influenza? Are there set criteria for diagnosis?
6. What is the age group most commonly affected/ or that you most commonly see presenting at your practice with suspected influenza?
7. What are the most common presenting symptoms?
8. What do you think is the average duration of time between onset of symptoms and presenting at the practice?
9. How do you confirm a suspected case of influenza? (If the answer is via some sort of laboratory test, a possible follow-up question is– How soon do you receive test results?)

(The decision to ask question 10 will depend on answer to question 9. In the interview, if the GP says there is no method of confirming a case of influenza, question 10 may not be necessary).

10. Do you wait for confirmatory results before definitive influenza treatment commences?
11. What are the most common complications?
12. In which groups of patients do you observe complications the most? Have you observed any death due to influenza like illnesses? If yes, what would be the proportion?

Management of Influenza

13. What is the first line management of influenza? (Depending on answer, follow-up with question on the type of treatment – Antibiotics, Antivirals, etc.) What is the approximate cost of treatment of influenza like illnesses?
14. At what point do you decide to administer Antivirals/Antibiotics? What antivirals do you administer to patients?
15. Does management vary for different groups? (For example, children, adults, elderly or immunosuppressed patients?
16. Do you have to refer some patients to hospital? What are the factors that determine which patients you refer and which patients you don't? (Prompts may be needed to investigate the impact of factors like age, gender, pregnancy status, co-morbidities, symptom severity, duration of symptoms, confirmatory test, etc.)
17. Are there any other circumstances in which you refer patients to acute care?
18. In some countries, national clinical guidelines are made available to clinicians to help them in their referral decisions. Is this something that you would find helpful? (Irrespective of whether they think such guides would be useful or not, explore further to gain an understanding of 'why' they think in this way; if they say that they would find guidelines useful, ask what would they ideally like to see in such a guide)
19. What if national guidelines on influenza treatment, management and referral were be introduced? How would you feel about this?
20. How much involvement do you have once you've referred the patient? Is there any follow-up care after the patient has left the hospital?
21. Do you provide any preventive advice to patients and their families? (If preventative advice is provided, ask in what form such as leaflets, verbal advice etc.)

Impact on the practice

22. Does the approach to diagnosis and management of patients presenting with influenza-like illness change during known epidemics/pandemics? If so, how and why?

Clinical Vignette Questions

1. A girl child of 3 years has been brought in by her parents. She has been irritable for the past 2 days and not feeding properly. Her parents report that she felt feverish (they haven't checked her temperature) and she has been crying constantly. They have been giving her Calpol syrup for one day based on a recommendation by the local pharmacy.

    a) *Based on these symptoms, what do you think is the most likely diagnosis?*
    b) *Would you request any laboratory investigations (blood tests, x-rays etc.) for such a case?*
    c) *What treatment would you recommend?*

d) Will you advise a follow-up visit for this patient?

2. A 27 year old male accompanied by his wife consults the doctor. He has been feeling lethargic and weak for the past 3-4 days with body ache, headache and nausea. He has felt feverish and faint but has not checked his temperature. He has been taking ibuprofen and paracetamol for the past 2 days. He does not have a runny nose but his throat feels slightly sore. His eyes have been watery.

a) Based on these symptoms, what do you think is the most likely diagnosis?
b) Would you request any laboratory investigations (blood tests, x-rays etc.) for such a case?
c) What treatment would you recommend?
d) Will you advise a follow-up visit for this patient?
e) The patient's wife rings up 1 day later saying that her husband is too weak to get out of bed and has a productive cough with yellowish phlegm and severe breathlessness. What would you advise?
f) If you encountered such a case during a known influenza pandemic period, would your approach change?
g) If you were told this patient had a history of asthma and had suffered asthma exacerbations requiring hospitalisation in the past, would your approach change?
h) If this was a pregnant woman, would your approach change?

Appendix 2: Characteristics of participants

Type of health professional	Qualified and years practicing	Gender	Nature of daily work environment	Average number of patients seen per day
MBBS MD Paediatrics	1981; 34 years	Female	1 tertiary care department, 1 outpatients clinic	30 low season, 45 high season
MBBS	2003; 8 years	Male	1 morning, 1 afternoon outpatients clinic	100 outpatients
BAMS-Ayurvedic	2000; 13 years	Male	1 morning and 1 evening outpatients clinic	80 low season, >100 high season
BHMS – Homeopathic	2008; 7 years	Male	1 all day clinic	8 outpatients
MBBS	1976; 35 years	Male	1 afternoon, 1 evening clinic	50 outpatients
BAMS – Ayurvedic	1973; 30 years	Male	1 morning and 1 evening clinic	Variable depending on season
MBBS	1973; 30 years	Male	1 morning and 1 evening clinic	40-50 outpatients
BAMS – Ayurvedic	1983; 27 years	Male	4 clinics daily; two each at two different settings	40-50 low season, 100 patients in rainy season
MBBS MD Medicine	1994; 25 years	Male	1 outpatient clinic and Inpatient ward round in morning	25-30 inpatients, 60-80 outpatients
MBBS MD Anaesthesia	1969; 42 years	Male	1 outpatient clinic	25-30 outpatients
MBBS MD Medicine	1987; 22 years	Male	1 all day clinic	60 patients
MBBS DPH	1991; 20 years	Female	2 outpatient clinics	20-25 outpatients
MBBS DCH (Diploma in child health)	1975; 34 years	Male	1 morning and 1 evening outpatient clinic	Variable depending on season
MBBS	1986; 25 years	Male	1 morning and 1 evening outpatient clinic	20 outpatients
MBBS	1974; 37 years		1 morning and 1 evening outpatient clinic	50 outpatients
MBBS DCH (Diploma in child health)	1971; 40 years	Male	1 morning and 1 evening outpatient clinic	40 outpatients
MBBS	1974; 40 years	Male	1 all day outpatients clinic	40-50 outpatients
MBBS	2005; 3 years	Male	1 morning and 1 evening outpatients clinic	50-60 outpatients
MBBS DGO (Diploma in Gynaecology and Obstetrics)	1997; 12 years	Female	1 morning outpatients clinic and evenings in maternity	20 outpatients
MBBS	1993; 17 years	Female	1 morning and 1 evening outpatients clinic	20 outpatients

Figure 1 Summary of thematic analysis